Filed pursuant to Rule 424(b)(4)
Registration No. 333-293204

25,000,000 Shares

Generate : Biomedicines

Common Stock

This is the initial public offering of shares of common stock of Generate Biomedicines, Inc. We are offering 25,000,000 shares of our common stock.

Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is $16.00. Our common stock has been approved for listing on The Nasdaq Global Select Market ("Nasdaq") under the symbol "GENB."

We are an "emerging growth company" and "smaller reporting company" as defined under the United States ("U.S.") federal securities laws and, as such, we have elected to comply with certain reduced reporting requirements.

Investing in shares of our common stock involves a high degree of risk. See the section titled "*Risk Factors*" beginning on page 17 to read about factors that you should consider before deciding to invest in shares of our common stock.

	Per Share	Total
Initial public offering price	$ 16.00	$ 400,000,000
Underwriting discounts and commissions(1)	$ 1.04	$ 26,000,000
Proceeds, before expenses, to us	$ 14.96	$ 374,000,000

(1) See the section titled "*Underwriting*" for additional information regarding compensation payable to the underwriters.

We have granted the underwriters the option to purchase up to an additional 3,750,000 shares of common stock from us, at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares of common stock on or about March 2, 2026.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Goldman Sachs & Co. LLC **Morgan Stanley**

Piper Sandler **Guggenheim Securities** **Cantor**

February 26, 2026


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Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the U.S.: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the U.S. Persons outside of the U.S. who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the U.S.

All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

Market, Industry and Other Data

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled "*Risk Factors*" and elsewhere in this prospectus. Some data are also based on our good faith estimates.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections of this prospectus titled "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless otherwise indicated, all references in this prospectus to "Generate," the "company," "we," "our," "us" or similar terms refer to Generate Biomedicines, Inc. and its wholly owned subsidiary, or either or both of them as the context may require.

Overview

We are a clinical-stage generative biology company pioneering the AI revolution in biotechnology and drug design and development. Our vision is to program biology to generate optimal therapeutics for the greatest impact on human health. Central to our vision is the Generate Platform, designed to be a therapeutic area and protein modality agnostic system integrating computational innovation with scalable biohardware to address therapeutic challenges beyond the reach of traditional technologies. We have built our Generate Platform to be a tight and fully-integrated loop (design–build–test–learn) to create proprietary, therapeutically relevant data and differentiated molecular solutions for the biological challenges we aim to address. In addressing these challenges, the Generate Platform can engineer solutions against therapeutic targets by either starting from existing reference proteins or suggesting completely novel ones without a reference starting point, also known as *de novo* design. The Generate Platform's therapeutic potential has been demonstrated by successfully progressing three computationally engineered proteins into human clinical testing, the most advanced of which is GB-0895, an investigational long-acting anti-thymic stromal lymphopoietin ("TSLP") monoclonal antibody, which is enrolling patients in pivotal Phase 3 clinical trials for severe asthma. The first patient was dosed in one of the Phase 3 clinical trials on January 26, 2026. We also expect to advance two additional computationally generated oncology product candidates into Phase 1 clinical trials in 2026.

Biology is an information science. DNA encodes biological function through the way its sequence determines the structure and activity of the molecules it produces, which, in principle, makes biology programmable. In practice, however, the immense complexity of biology has made programming it very difficult. Historically, drug discovery has emphasized two general approaches to manage this complexity. One approach was an intentional, mechanically guided design approach at low-throughput. The other was a high-throughput experimental exploration approach that was generally less able to encode specific intent. We believe that dramatic reductions in the cost of compute and the cost of making and measuring DNA and proteins enable a new paradigm: intentionality at scale. In this paradigm, our generative models learn generalizable design principles from data to generate hypotheses at scale, and scalable experimental systems verify those hypotheses. The Generate Platform was built to implement this paradigm, generating large numbers of specific molecular and biological hypotheses in response to pre-specified therapeutic objectives and rapidly testing them. We believe intentionality at scale is foundational to achieving programmable biology: enabling systematic generation of medicines across therapeutic areas and protein modalities while producing proprietary data that improves our generative models over time.

The Generate Platform integrates generative and predictive models that learn design principles from proprietary data—*e.g.*, diffusion-based models (such as our Chroma model) and graph neural networks, among other architectures—with advanced experimental biohardware systems for scalable verification. Our biohardware systems include scalable DNA assembly, rapid protein production, and high-throughput, multiplexed assay miniaturization enabling us to measure up to billions of molecules per generation cycle, as well as a cryogenic electron microscopy ("Cryo-EM") core for high-content structural data generation, which has produced more than 500 high-resolution maps in 2025 alone. These capabilities significantly reduce the cost and time per assay data point, tightening the loop between generative models and real-world biological verification.

The Generate Platform establishes modular capabilities that are designed to be deployed individually or in combination to engineer differentiated therapeutic candidates. We have successfully translated these modular capabilities to create programs and product candidates with therapeutic potential. For example, our lead product candidate, GB-0895, utilizes our binding affinity and developability optimization modules, and is currently enrolling patients in Phase 3 clinical trials for severe asthma, and is also being evaluated in a Phase 1b clinical trial for chronic obstructive pulmonary disease ("COPD"). We used binding affinity and developability optimization modules, as well as additional modules, including functional optimization, to engineer our other product candidates, including GB-4362 and GB-5267. Investigational New Drug applications ("INDs") were cleared by the FDA for both GB-4362 and GB-5267 in December 2025, and we expect to dose the first patient for both programs in 2026.

Our lead product candidate, GB-0895, is an investigational long-acting anti-TSLP monoclonal antibody in development for severe asthma that is intended to be dosed every six months ("Q26W"). Severe asthma represents a substantial unmet medical need, with industry sources suggesting that only 15% to 25% of eligible patients receive biologic therapy. There are adherence and persistence challenges with existing shorter-acting biologic agents and GB-0895's potential Q26W dosing regimen is designed to reduce injection frequency to address these challenges. We have engineered GB-0895 to have ultra-high binding affinity, reaching an estimated twenty-fold improvement over tezepelumab (106 femtomolar binding affinity) and a YTE amino acid modification, a clinically-validated half-life extension technology. A YTE amino acid modification is a specific change made to three amino acids (M252Y/S254T/T256E) in an antibody's fragment crystallizable ("Fc") region. Preclinical and Phase 1 clinical data for GB-0895 have demonstrated favorable safety results, long half-life (approximately 98 days), and suppression of key biomarkers, such as blood eosinophils ("EOS"), fractional exhaled nitric oxide ("FeNO"), IL-5, and IL-13, supporting its potential Q26W dosing regimen. We are currently enrolling patients in two parallel global Phase 3 clinical trials for GB-0895 initiated in December 2025 (SOLAIRIA-1 and SOLAIRIA-2) for severe asthma, with full enrollment expected by the first half of 2028. The first patient was dosed in our SOLAIRIA-1 Phase 3 clinical trial on January 26, 2026. We intend to develop GB-0895 as a biologic-device combination product.

In parallel, we are currently conducting a Phase 1b clinical trial for moderate-to-severe COPD with expected data in 2026. COPD is a widespread and often fatal lung condition. Current biologics target patients with higher eosinophil counts, leaving the majority of patients without an approved biologic option. The Phase 1b COPD trial for GB-0895 is evaluating safety, tolerability, pharmacokinetics ("PK"), pharmacodynamics ("PD") and immunogenicity. Preliminary data showed biomarker reductions and a PK profile consistent with our earlier Phase 1 trial for GB-0895 for the treatment of mild-to-moderate asthma, supporting an extended dosing interval in COPD. We plan to evaluate multiple approaches to determine the optimal development path for GB-0895 in COPD, taking into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial.

In addition to progressing GB-0895, we are advancing additional programs and product candidates that leverage the Generate Platform's modular capabilities. These include GB-4362, a systemically administered monoclonal antibody designed to neutralize free monomethyl auristatin E ("MMAE") as an adjunctive therapy to antibody-drug conjugate ("ADC") molecules with an MMAE payload, as well as GB-5267, an armored, MUC16-directed CAR-T cell therapy candidate developed in collaboration with Roswell Park Comprehensive Cancer Center ("Roswell Park"), for solid tumors, initially targeting platinum-resistant ovarian cancer. Beyond these product candidates, we are advancing additional preclinical programs, including a next-generation ADC that is being developed as an internal program, along with other early stage preclinical programs. In addition, the Generate Platform's modular capabilities underpin the confidential programs being developed in collaboration with Amgen Inc. ("Amgen") and Novartis Pharma AG ("Novartis").

We are led by an experienced team of executives with backgrounds in leading pharmaceutical and life sciences companies and academia and deep experience in generative biology and computational sciences, supported by a distinguished board of directors. We were founded in 2018 by Flagship Pioneering, bringing together advancements in generative biology and computational protein science.

The Generate Platform and Our Modular Capabilities

Since inception, the Generate Platform was designed to create differentiated protein therapeutics and unlock the promise of a new method of designing drugs through a concept we call programmable biology. For biology to be programmable, it means that we must be able to design, write, and execute biological functions with pre-specified intent, across therapeutic areas and protein modalities.

Our Generate Platform is designed to implement intentionality at scale by coupling AI models that generate large numbers of design hypotheses with scalable biohardware that verifies them. Each time we engineer, build and then test a set of hypotheses, which we refer to as a generation cycle, we generate experimental data that is intended to improve the Generate Platform. We package certain of these learnings into reusable modules—validated capabilities that can be applied across targets and modalities towards differentiated therapeutics.

Our Generate Platform has enabled us to develop numerous modular capabilities, many of which have already demonstrated the ability to successfully translate computationally engineered proteins into human clinical testing, including our lead product candidate GB-0895, which is currently enrolling patients in Phase 3 clinical trials for the treatment of severe asthma. In addition, we are currently exploiting our modular capabilities for other potential therapeutic applications, including for use in oncology and other historically difficult to treat diseases.

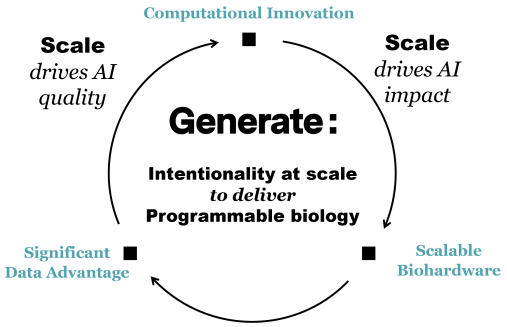
The Generate Platform

We built the Generate Platform on a foundation of integrating computational innovation with scalable biohardware to create a significant data advantage and drive differentiated molecular solutions for the biological and therapeutic challenges we aim to address, as illustrated in the figure below.

The Generate Platform is designed to systematically decode and comprehend biology at speed and magnitude

ML scales hypotheses
- molecules and biological hypotheses generated at scale using models + agents

Data compounds
- each cycle creates proprietary therapeutically-relevant data that improves the next cycle



Modular Capabilities & Potential Therapeutic Impact

To date, we have deployed our Generate Platform to establish numerous modular capabilities, many of which we can now reliably and repeatably direct towards developing future therapeutic candidates. Our initial focus in building modular capabilities was on one of the most fundamental ways proteins mediate biology: binding. We have leveraged this starting point to expand our capabilities to include (i) binding with context, including selective and conditional target binding, and (ii) protein design for a desired function; in parallel, we have invested in a set of capabilities focused on developability. We have already seen the translational impact of our established modules in our first three clinical product candidates, as well as in two additional product candidates that are anticipated to enter clinical trials in 2026. Examples of our current modules and the intended purposes are summarized in the figure below.

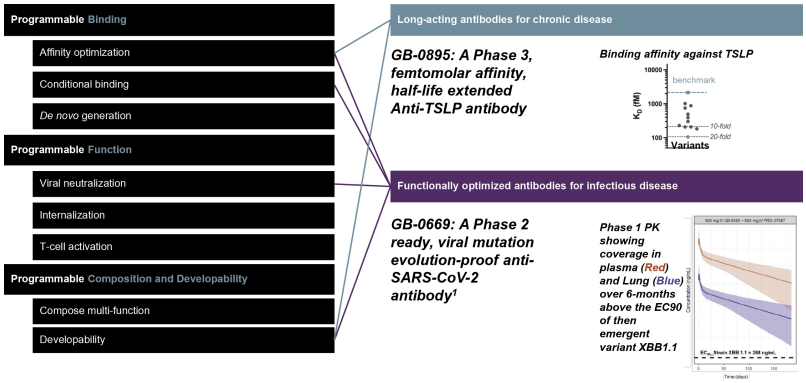
Examples of modular capabilities developed to date

Examples of Modular Capabilities Developed To-date

Programmable Binding	
Affinity optimization	Tune binding affinity, up or down, for desired outcomes
Conditional binding	Bind given condition, e.g., pH, or selectively/cross reactivity
De novo generation	Generate a completely novel binder to a specific epitope
Programmable Function	
Viral neutralization	Therapeutically relevant neutralization across viral strains
Internalization	Receptor internalization and payload delivery
T-cell activation	Antigen specific T-cell activation for selective tumor killing
Programmable Composition and Developability	
Compose multi-function	Graft and fuse protein modules with different functions
Developability	Manufacturability, e.g., aggregation, viscosity

We have built these modular capabilities with the intent to explore and decode biological challenges with a direct link to a therapeutic opportunity. For example, many biologics require a drug developer to "tune" the binding of antibodies to a target, otherwise known as binding affinity. Previously, this would have taken multiple cycles of library generation and screening, often with limited ability to reliably reach a specific affinity window, such as very high affinities in picomolar or femtomolar ranges. In contrast, our generative models propose new proteins with intent to increase, decrease or engage in selective binding depending on what is needed in the given program context. These diverse modules can be used alone, or in combination with one or more other modules, to generate unique proteins that are designed to address important therapeutic challenges. As shown in the figure below, two examples of proteins we designed that utilize our modules include our lead product candidate, GB-0895, and a functionally optimized antibody to neutralize a virus that has otherwise demonstrated meaningful resistance against all other approved antibody therapies. These examples reflect our deep conviction: programmable biology is only possible when therapeutic intent, computational engineering and biological data generation operate as a unified system to enable intentionality at scale and a compounding data advantage over time.

Application of modular capabilities to therapeutic applications



[1] Development paused for commercial reasons.

As we develop our Generate Platform and its modular capabilities, we are focused on translating their potential into meaningfully differentiated therapeutic development programs. Initially, we pursued therapeutic opportunities in which our modular capability or combinations of modular capabilities are likely to solve a molecular challenge in areas of well-understood biology. We believe that this approach allowed us to shift risk to the preclinical setting, where we can quickly identify differentiated proteins with the desired attributes. If we successfully engineer desired proteins, we believe it will unlock our ability to develop therapeutic candidates that can be moved into clinical testing with lower risk and potentially differentiated product profiles, thereby creating the potential for outsized patient impact and value. One or more of these modules can also be deployed to address therapeutic opportunities with potential partners, enabling an additional value generation route for us, as exemplified by our Amgen and Novartis collaborations.

Through deploying our Generate Platform towards therapeutic opportunities, we have seen a significant impact on the speed, cost and probability of success of drug design and development as summarized in the below figure. Our future programs may not be developed within time frames or at costs comparable to our existing programs, and factors such as program reprioritization, funding constraints, and unforeseen technical or scientific challenges may extend drug discovery timelines.

Impact of the Generate Platform relative to traditional drug discovery

	Traditional drug discovery *laborious, high-cost exploration*		**Generate:** **programmatic, at-scale prosecution**
Time to proof of concept	6 - 8 years	❯	**3 - 5 years[1]**
Cost to proof of concept	$380mm	❯	**$25 - 60mm[1]**

Generate demonstrated success in translating our technology to product candidates:
- 8 programs successfully reached candidate nomination
- Created 5 clinical / clinic-ready product candidates
- 2 / 2 product candidates for which we initiated proof of concept trials achieved clinical proof of concept

[1] Referring to our GB-0895 and GB-0669 programs.

Building on these efficiency gains, we are deploying our reusable modular capabilities to tackle increasingly complex biological challenges, such as engineering receptor-mediated internalization or conditional binding, each tightly linked to significant therapeutic opportunities. Capabilities such as these are being deployed in our early-stage pipeline. In parallel, we continue to innovate and invest across the Generate Platform to further lower the time and cost required to design, build and test each new hypothesis, so we can learn faster from real-world biology and build a compounding advantage over time. We believe this will expand the modular capabilities we can deploy, broaden the set of challenges we can reliably address, and ultimately translate into differentiated future product candidates.

Our Pipeline

We leveraged our initial Generate Platform modular capabilities to develop our first product candidates with differentiated features that focused on targets with well validated disease biology. This approach allowed us to significantly decrease the time and, we believe, the risk to advance our first product candidates to late-stage clinical development.

Our current pipeline of product candidates is summarized in the figure below:

	Proposed Indication(s)	Target	Modality	Preclinical	Phase 1	Phase 2	Phase 3	Next Milestone	Collaborations
IMMUNOLOGY & INFLAMMATION									
GB-0895	Severe Asthma	TSLP	Antibody					Fully enrolled Ph 3 studies (2H27/1H28)	
GB-0895	COPD	TSLP	Antibody					Ph1b data (1H26)	
ONCOLOGY									
GB-4362[1]	Various in combo with MMAE ADCs	Free MMAE	Antibody					Ph1 initiation (2026)	
GB-5267[1]	Metastatic Ovarian Cancer	MUC-16	Armored CAR-T					Ph1 initiation (2026)	ROSWELL PARK 50:50

[1] IND "Study May Proceed" notification received in December 2025

Beyond this pipeline, we are also leveraging the Generate Platform and its modular capabilities to:

- Advance multiple innovative preclinical programs, each designed with differentiated characteristics that we believe are beyond the reach of traditional technologies, including a next-generation ADC we are progressing toward product candidate nomination (this preclinical program utilizes one of our modular capabilities to enhance internalization and cytotoxicity against a target with naturally low internalization rates); and
- Establish platform collaborations to help our collaboration partners address therapeutic challenges while maximizing the potential of our technology, including:
  - Six confidential collaboration programs with Amgen, first announced in January 2022; and
  - Multiple confidential collaboration programs with Novartis, first announced in September 2024.

We have not received regulatory approval for any product candidate to date, have incurred significant operating losses since inception and anticipate continuing to incur substantial losses for the foreseeable future.

GB-0895: An Anti-TSLP Monoclonal Antibody

GB-0895 is a long-acting anti-TSLP monoclonal antibody intended to be dosed every six months ("Q26W") designed using our Generate Platform to address unmet needs in respiratory diseases. We are initially developing GB-0895 for the treatment of severe asthma. TSLP is a clinically and commercially validated target in severe asthma and has demonstrated broad potential in Type 2 and Non-Type 2 inflammatory diseases in clinical trials by third-parties. We are currently enrolling patients in two Phase 3 clinical trials of GB-0895 for the treatment of severe asthma (SOLAIRIA-1 and SOLAIRIA-2) following promising data in mild-to-moderate asthma patients in our Phase 1 clinical trial.

In its Phase 1 clinical trial for the treatment of mild-to-moderate asthma patients, GB-0895 demonstrated a favorable safety profile, long half-life and suppression of key biomarkers supportive of a Q26W dosing regimen using a single 300 mg subcutaneous injection:

- Long half-life showed sustained drug concentration for the full six-month period.
- EOS, FeNO, IL-13 and IL-5 biomarkers indicated deep and sustained reductions over six months.
- Total TSLP demonstrated target saturation.
- GB-0895 was generally well tolerated, with low ADA and no impact from ADA observed on PK profile.

Preclinical and clinical data demonstrated ultra-high affinity inhibition of TSLP signaling, with a 106 femtomolar binding affinity for TSLP and a mean terminal half-life of approximately 98 days in adults with mild-to-moderate asthma, which, together with quantitative PK/PD modeling, support evaluation of a subcutaneous Q26W dosing regimen. If approved, this dosing regimen, which is being evaluated in our Phase 3 clinical trials, would represent a potentially significant improvement to approved biologic therapies, which are typically dosed every two to eight weeks.

In parallel, we are also assessing GB-0895 in an ongoing Phase 1b expansion trial in moderate-to-severe COPD patients. As of January 15, 2026, preliminary data for GB-0895 from such trial showed reductions in key biomarkers and a PK profile generally consistent with the Phase 1 mild-to-moderate asthma trial. The results below reflect descriptive least square mean estimates based on emerging data and are expected to be refined as additional subjects complete month 3 and subsequent follow-up:

- Preliminary EOS data showed ~50% reductions from baseline at month 3.
- Preliminary FeNO data showed ~20% reductions from baseline at month 3, though similar reductions are also observed in the placebo cohort.
- Preliminary IL-13 and IL-5 data showed ~50% reductions from baseline at month 3.

We also plan to evaluate multiple approaches to determine the optimal development path for GB-0895 in COPD, taking into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial. As part of such evaluation, we plan to seek engagement with regulatory authorities in 2026 to discuss our development strategy and obtain regulatory feedback on our proposed approach. We will also consider whether to pursue other indications in the future.

GB-4362: An MMAE Payload Neutralizer Monoclonal Antibody

GB-4362 is designed to selectively bind and clear circulating MMAE released from ADCs while preserving intratumoral payload delivery and anti-tumor activity of the ADC. We received the IND "Study May Proceed" notification from the FDA on December 31, 2025 for GB-4362. We subsequently received Fast Track Designation on January 23, 2026 for this program. We expect to initiate a Phase 1 dose-escalation trial in combination with enfortumab vedotin (“EV”) plus pembrolizumab in 2026. This clinical trial is designed to primarily assess GB-4362’s safety and tolerability, characterize the PK/PD effects of GB-4362, including reductions in free MMAE, and identify a recommended Phase 2 dose. In the expansion portion of this clinical trial, we intend to evaluate GB-4362's safety, PK/PD and impact on free MMAE reduction. We are considering using this expansion portion of the clinical trial as an early proof of concept, and if we determine to proceed, we plan to evaluate the impact of GB-4362 on progression from Grade 1 to Grade 2 peripheral neuropathy in patients who develop their first sustained Grade 1 peripheral neuropathy while receiving EV plus pembrolizumab for the treatment of first-line metastatic urothelial cancer ("1L muC"). In preclinical mouse and non-human primate (“NHP”) studies, GB-4362 demonstrated dose-dependent reductions in systemic free MMAE exposure. Preclinical data suggest that a 50% or greater reduction in free MMAE may improve tolerability, reduce dose-limiting toxicities and maintain ADC dose intensity. As development progresses, we may explore the potential of GB-4362 in additional combinations with approved or in development MMAE-ADC regimens. This is intended to allow us to broaden our focus to additional tumor types where MMAE-related toxicities limit therapeutic benefit.

GB-5267: A MUC16 CAR-T Cell Therapy

GB-5267 is an armored, MUC16-directed CAR-T cell therapy engineered using the Generate Platform to address unmet needs in solid tumors, which we are initially developing for the treatment of platinum-resistant ovarian cancer. GB-5267 was designed to have a high-affinity MUC16 binder and cytokine-based armor in order to enhance T-cell activation, proliferation and persistence within the tumor microenvironment ("TME") while maintaining strict MUC16-dependent specificity. We are developing GB-5267 in collaboration with Roswell Park, who submitted an IND to the FDA for GB-5267 in early December 2025. This IND was cleared in December 2025, and they received a "Study May Proceed" notification from the FDA on December 30, 2025. Pursuant to our collaboration, Roswell Park is expected to sponsor and initiate a Phase 1 clinical trial in 2026. This open-label trial will assess safety and tolerability following intravenous dose escalation and could subsequently explore combined intravenous and local intraperitoneal administrations in an expansion cohort. Secondary objectives are expected to include PK/PD assessments, characterization of CAR-T cell persistence and preliminary anti-tumor activity. In preclinical studies, GB-5267 showed proliferation and cytotoxicity across multiple donors and no activity on MUC16-negative cells. As we evaluate GB-5267 clinically, we may investigate its use in earlier-line ovarian cancer settings if it shows benefit in later-line ovarian cancer.

Our Strategy

Since our formation, we have focused on investing in our differentiated Generate Platform to unlock a new way of designing and developing drugs by integrating computational and experimental innovations. We believe these investments move us closer to a paradigm of programmable biology where drug discovery becomes more akin to engineering than traditional methods.

To move the company toward our vision, we focus on the following key strategic initiatives:

- Progress our advanced clinical-stage lead product candidate, GB-0895.
- Advance our next wave of clinical and preclinical product candidates in a broad range of indications, starting with oncology.
- Advance our Generate Platform to scale productivity, unlock new modular capabilities and translate additional differentiated programs and product candidates.
- Establish additional partnerships and collaborations to maximize value from and for our Generate Platform.

Our Team

Our company is led by a team of executives who collectively bring decades of experience from leading pharmaceutical and life sciences companies and academia and deep experience in generative biology and computational sciences. Our Chief Executive Officer, Michael Nally, M.B.A., joined us in 2021 after an 18-year career at Merck & Co., Inc. ("Merck"), where he served as Chief Marketing Officer overseeing global strategy for a $40 billion portfolio and as President of Global Vaccines. Our Co-Founder and Chief Technology Officer, Dr. Gevorg Grigoryan, Ph.D., is a leading protein scientist who drives the development of our Generate Platform and has authored more than 50 peer-reviewed publications in journals including *Nature*, *Science* and *PNAS*. Our President and Chief Financial Officer, Dr. Jason Silvers, M.D., J.D., brings more than 20 years of finance experience, previously serving as a Partner at Goldman Sachs & Co. LLC, where he advised on more than $400 billion in global transactions and where he most recently co-led the EMEA healthcare investment banking group.

Our Chief Scientific Officer, Dr. Aarif Khakoo, M.D., M.B.A., is a physician-scientist with extensive experience in drug discovery and development. Previously the Chief Scientific Officer and Head of Research and Development at Scribe Therapeutics, Inc., he has also held senior R&D leadership roles at Calico Life Sciences LLC and Amgen, where he advanced multiple programs into the clinic and oversaw translational medicine and early clinical development across multiple therapeutic areas. Dr. Laurie Lee, M.D., our Chief Medical Officer for Immunology & Inflammation, leads late-stage clinical development across our immunology portfolio and previously held senior R&D roles at CSL Behring LLC and GSK plc, where she led development of the Trelegy Ellipta asthma program from Phase 2 through global regulatory submissions that led to approval. Dr. Dinesh de Alwis, Ph.D., our Senior Vice President and Head of Clinical Drug Development, is an accomplished drug developer with more than 25 years of industry experience, including a decade at Merck contributing to the development of pembrolizumab.

Beyond our exceptional leadership team, we have assembled a multi-disciplinary team with deep scientific, clinical, technological, and operational expertise across biotechnology, machine learning and drug discovery and development. In this regard, as of December 31, 2025, we employed 138 M.D.s and Ph.D.s with advanced degrees and experience across multiple therapeutic areas and in fields such as biologic engineering, biochemistry, biomedical engineering, biophysics, biostatistics, chemistry, physics, computer science and PK/PD.

Our Beginnings: Generate and Flagship Pioneering

Flagship Pioneering founded Generate in 2018 as Flagship VL56, Inc., working together with Dr. Gevorg Grigoryan, Ph.D., our founding Chief Technology Officer. In 2019, Flagship VL56, Inc. was combined with complementary generative biology explorations from another Flagship company, Flagship VL57, Inc. Flagship Pioneering invents and builds platform companies, each with the potential for multiple products that transform human health, sustainability and beyond. Generate's founding team is the Flagship Pioneering origination team led by co-founders Dr. Noubar B. Afeyan, Ph.D., Founder and Chief Executive Officer of Flagship Pioneering, Dr. Geoffrey von Maltzahn, Ph.D., Dr. Avak Kahvejian, Ph.D., Dr. Molly Gibson, Ph.D., other scientists at Flagship Pioneering, and Dr. Grigoryan.

Generate was based on an exploration of the following question: What if we could generate novel protein therapeutics using generative AI tools, without having to discover them through trial and error? The team set out to explore whether advances in generative AI, large-scale protein sequence and structural data, and high-dimensional modeling could unlock a systematic, AI-first approach to creating new therapeutic proteins.

Recognizing the deep scientific synergy between Flagship Pioneering's data-driven exploration and Dr. Grigoryan's pioneering insights into the learnable, recurring structural patterns that govern how proteins fold and function, Flagship Pioneering brought these efforts together to launch the world's first generative biology platform capable of learning the underlying rules of protein function and generating novel therapeutic candidates on demand. Since our inception, we have continued to build on this foundation, advancing our platform, expanding our discovery and development capabilities, and assembling a leadership team committed to translating this new approach into transformative medicines for patients.

Summary of Material Risks Associated With Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include, but are not limited to, the following:

- We are a clinical-stage biotechnology company with a limited operating history and no products approved by regulators for commercial sale, which may make it difficult to evaluate our current and future business prospects.
- Even if this offering is completed, we will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate programs, product candidates (including clinical trials), investments in our Generate Platform or future commercialization efforts.
- Our management and our independent registered public accounting firm have concluded that there is substantial doubt as to our ability to continue as a going concern. We have incurred recurring losses since inception, including a net loss of $223.0 million and $181.4 million for the years ended December 31, 2025 and December 31, 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $676.3 million. There is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to fund continuing operations, if at all. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate some or all of our programs, product candidates, development of our Generate Platform, or commercialization efforts. In addition, if we cannot continue as a going concern, our stockholders may lose some or all of their investment in our company.
- We are dependent on the success of our product candidates, including GB-0895, GB-4362 and GB-5267, and our ongoing and anticipated trials may not be successful.
- Our approach to the engineering and development of our programs is unproven, and we may not be successful in our efforts to identify and develop any programs and product candidates of commercial value by leveraging our Generate Platform.
- We are substantially dependent on the successful application of our Generate Platform to develop programs and product candidates that can be commercialized by us or our current or future collaboration partners.
- Issues relating to our use of AI in the identification of our programs and the engineering and development of our product candidates could adversely affect our business and operating results.
- Preclinical and clinical development is inherently lengthy and uncertain. Preclinical and clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which would have a material adverse impact on our Generate Platform or our business.
- We are currently enrolling patients in clinical trials for GB-0895 globally and may in the future conduct clinical trials for other product candidates outside the United States, and the Regulatory Authorities (as defined below) may not accept data from such trials.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third-parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.
- Due to the significant resources required for drug development and depending on our ability to access capital, we intend to prioritize the development of GB-0895 for severe asthma. Moreover, we may fail to expend our limited resources on the development of GB-0895 for the treatment of other indications or for the development of other potential future product candidates that may have been more profitable or for which there is a greater likelihood of success.
- The regulatory approval processes of the Regulatory Authorities are lengthy, time-consuming and inherently unpredictable, and if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.
- We rely on third-parties for the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and may do the same for commercial supplies of our products, if approved. As our pipeline increases and matures, the increased demand for

supplies from our manufacturers may increase the risk that we will not have sufficient supply when needed or at an acceptable cost.

- We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our suppliers, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.
- The product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of our CDMOs (as defined below) encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped.
- We have in the past entered into, and in the future may enter into, partnership, collaboration and licensing arrangements with third-parties to support development of programs product candidates. If these partnership, collaboration and licensing arrangements are not successful, our business could be adversely affected.
- Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to adequately protect and/or enforce our intellectual property.
- If we do not obtain sufficient patent term for our product candidates, our business may be materially harmed.
- The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any drugs that we develop.
- An active trading market for our common stock may not develop.
- The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled "*Risk Factors*" and the other information set forth in this prospectus, including our audited consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission (the "SEC"). The risks summarized above or described in full elsewhere in this prospectus are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

Corporate Information

We were incorporated under the laws of the State of Delaware. Flagship Pioneering incorporated our company in August 2018 under the name Flagship VL56, Inc., and we changed our name to Generate Biomedicines, Inc. in February 2020. Our principal executive offices are located at 101 South Street, Suite 900, Somerville, MA 02143, and our telephone number is (888) 469-0055. We have one subsidiary, Generate Biomedicines Securities Corporation, formed in 2021 under the laws of the Commonwealth of Massachusetts. Our website address is *www.generatebiomedicines.com*. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited consolidated financial statements, in addition to any required unaudited interim consolidated financial statements, with correspondingly reduced "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" disclosure in this prospectus;

- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"); and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the consolidated financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We may choose to take advantage of some but not all of these exemptions. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our consolidated financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a "smaller reporting company," meaning that the market value of our shares held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited consolidated financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

THE OFFERING	
Common stock offered by us	25,000,000 shares.
Option to purchase additional shares of common stock	We have granted a 30-day option to the underwriters to purchase up to 3,750,000 additional shares of common stock from us at the public offering price, less underwriting discounts and commissions.
Common stock to be outstanding immediately after this offering	127,450,201 shares (or 131,200,201 shares if the underwriters exercise their option to purchase additional shares of common stock in full).
Use of proceeds	We estimate that the net proceeds from the sale of our common stock in this offering will be approximately $368.8 million (or approximately $424.9 million if the underwriters exercise their option to purchase additional shares of common stock in full), based on the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, primarily to (i) advance GB-0895 through the completion of our two Phase 3 trials in severe asthma, (ii) complete our ongoing Phase 1b clinical trial of GB-0895 for the treatment of COPD and to initiate the next phase of clinical development (pending results from our Phase 1b trial in COPD and regulatory alignment), (iii) fund platform and technology innovation and engineer multiple programs and product candidates through development candidate nomination and into IND-enabling activities and (iv) advance GB-4362 and GB-5267 through topline Phase 1 data; and the remainder for additional research and development efforts for new programs and product candidates, as well as for working capital and other general corporate purposes. See the section titled "*Use of Proceeds*" for additional information.
Risk factors	See the section titled "*Risk Factors*" for a discussion of factors you should carefully consider before deciding whether to invest in our common stock.
Directed share program	At our request, the underwriters have reserved up to 5% of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers, employees and certain other individuals identified by management. The sales will be made at our direction by Morgan Stanley & Co. LLC and its affiliates through a directed share program. The number of shares of our common stock available for sale to the general public in this offering will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of our common stock offered by this prospectus. Except for any shares acquired by our directors and officers, shares

	purchased pursuant to the directed share program will not be subject to lock-up agreements with the underwriters. See the section titled "*Underwriting—Directed Share Program*" for additional information.
Trading symbol on the Nasdaq Global Select Market	"GENB"

The number of shares of our common stock that will be outstanding after this offering is based on 102,450,201 shares of our common stock outstanding as of December 31, 2025 after giving effect to the automatic conversion of all outstanding shares of our Series A convertible preferred stock, par value $0.001 per share (the "Series A preferred stock"), Series B convertible preferred stock, par value $0.001 per share (the "Series B preferred stock"), and Series C convertible preferred stock, par value $0.001 per share (the "Series C preferred stock" and, together with the Series A preferred stock and Series B preferred stock, the "preferred stock"), into an aggregate of 69,333,244 shares of our common stock upon the completion of this offering, and excludes:

- 20,422,301 shares of common stock issuable upon exercise of outstanding stock options as of December 31, 2025 under our 2019 Equity Incentive Plan, as amended (the "2019 Plan"), with a weighted average exercise price of $5.91 per share;
- 441,076 shares of common stock issuable upon exercise of outstanding stock options granted after December 31, 2025 under our 2019 Plan, with a weighted average exercise price of $11.75 per share;
- 3,404,855 shares of common stock reserved for future issuance as of December 31, 2025 under the 2019 Plan, which ceased to be available for issuance at the time that our 2026 Stock Option and Incentive Plan (the "2026 Plan") became effective;
- 98,749 shares of our common stock issuable upon exercise of an outstanding warrant to purchase Series A preferred stock with an aggregate exercise price of $150,000 that will become a warrant to purchase common stock upon the completion of this offering;
- 11,852,719 shares of our common stock reserved for future issuance under our 2026 Plan, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, which number includes options to purchase an aggregate of 4,799,160 shares of our common stock, based upon the initial public offering price of $16.00 per share and the Black-Scholes value of the options, which were granted to certain of our executive officers, directors and employees at the time of effectiveness of the 2026 Plan with an exercise price equal to the initial public offering price per share, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2019 Plan that expire or are repurchased, forfeited, cancelled or withheld; and
- 1,481,589 shares of common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan (the "ESPP"), which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

Unless otherwise indicated, the information in this prospectus reflects or assumes the following:

- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 69,333,244 shares of common stock upon the completion of this offering;
- the automatic adjustment of an outstanding warrant to purchase 150,000 shares of Series A preferred stock into a warrant to purchase 98,749 shares of common stock, which will occur upon the completion of this offering;
- no exercise of the outstanding stock options or warrants described above after December 31, 2025;
- a one-for-1.5190 reverse stock split of our common stock, effected on February 20, 2026;
- no purchases of shares of our common stock by existing stockholders or their affiliates pursuant to the directed share program;

- no exercise of the underwriters' option to purchase up to an additional 3,750,000 shares of common stock in this offering; and
- the filing and effectiveness of our second amended and restated certificate of incorporation (the "amended and restated certificate of incorporation") promptly following the completion of this offering and the effectiveness of our amended and restated bylaws upon the effectiveness of the registration statement of which this prospectus forms a part.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated statements of operations for the years ended December 31, 2024 and 2025. Our audited consolidated financial statements included elsewhere in this prospectus have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Our historical results are not necessarily indicative of the results that may be expected for any period in the future. You should read the following summary financial data together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and the related notes included elsewhere in this prospectus. The summary consolidated financial data included in this section are not intended to replace the audited consolidated financial statements and are qualified in their entirety by our audited consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2024	2025
	(in thousands, except share and per share data)	
Statements of Operations and Comprehensive Loss Data:		
Collaboration revenue	$ 20,459	$ 31,893
Operating expenses:		
Research and development	175,311	224,698
General and administrative	42,087	42,260
Total operating expenses	217,398	266,958
Loss from operations	(196,939)	(235,065)
Other income (expense), net:		
Change in fair value of preferred stock warranty liability	(154)	(113)
Interest Expense	(2,118)	(1,136)
Interest income	18,118	13,661
Foreign currency exchange loss	(79)	(149)
Total other income (expense) net	15,767	12,263
Loss before provision for income tax	(181,172)	(222,802)
Provision for Income taxes	(212)	(163)
Net loss	(181,384)	(222,965)
Net loss attributable to non-controlling interests	(7,613)	(19,811)
Net loss attributable to Generate Biomedicines, Inc. stockholders	$ (173,771)	$ (203,154)
Convertible preferred stock accrued dividends	(40,006)	(46,369)
Net loss attributable to Generate Biomedicines, Inc. common stockholders, basic and diluted(1)	$ (213,777)	$ (249,523)
Net loss per share, basic and diluted(1)	$ (6.66)	$ (7.57)
Weighted average shares of common stock outstanding, basic and diluted(1)	32,084,572	32,974,656
Comprehensive loss:		
Net Loss	$ (181,384)	$ (222,965)
Unrealized gain (loss) on marketable securities	69	(12)
Comprehensive loss	(181,315)	(222,977)
Comprehensive loss attributable to non-controlling interest	(7,613)	(19,811)
Comprehensive loss attributable to Generate Biomedicines, Inc. stockholders	$ (173,702)	$ (203,166)
Pro forma net loss per share, basic and diluted (unaudited)(2)		$ (2.18)
Pro forma weighted average shares of common stock outstanding, basic and diluted (unaudited)(2)		102,307,938

(1) See Note 2 and Note 8 to our audited consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate historical net loss attributable to common stockholders per share, basic and diluted, and the weighted-average number of shares of common stock used in the computation of the per share amounts.

(2) Pro forma basic and diluted net loss per share attributable to common stockholders has been prepared to give effect to adjustments to (i) the acquisition of the non-controlling interest of Pioneering Medicines 02, Inc. ("PMCo") under a stock purchase agreement (the "Stock Purchase Agreement") with Pioneering Medicines 02, LLC ("PM LLC"), the closing of which is contingent upon the execution of the underwriting agreement for this offering, and (ii) our capital structure arising in connection with the completion of this offering and is calculated by dividing the pro forma net loss attributable to Generate Biomedicines, Inc. common stockholders by the pro forma weighted average common shares outstanding for the period. Pro forma net loss attributable to common stockholders is computed by adjusting our net loss to reverse cumulative dividends on the Series B preferred stock and Series C preferred stock and reverse the fair value adjustment recorded on the liability classified warrants. Pro forma weighted average shares of common stock outstanding is computed by adjusting the weighted average shares of common stock outstanding to give pro forma effect to the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock as if such conversion had occurred on January 1, 2025. Pro forma basic and diluted net loss per share attributable to common stockholders does not include the effect of the shares expected to be sold and related proceeds to be received in this offering.

	December 31, 2025		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
	(in thousands, except for share data)		
Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$ 221,498	$ 221,498	$ 590,298
Working capital(3)	152,162	152,162	520,962
Total assets	330,182	330,182	698,982
Total liabilities	141,553	140,348	140,348
Convertible preferred stock	811,826	—	—
Non-controlling interest	(7,232)	—	—
Common stock, par value $0.001 per share; 200,456,735 shares authorized, 33,116,957 shares issued and outstanding, actual; 200,456,735 shares authorized, 102,450,201 shares issued and outstanding, pro forma; 500,000,000 shares authorized, 127,450,201 shares issued and outstanding, pro forma as adjusted	33	102	127
Additional paid-in capital	60,189	865,919	1,234,694
Accumulated deficit	(676,293)	(676,293)	(676,293)
Total stockholders' (deficit) equity	(615,965)	189,834	558,634

(1) Pro forma amounts give effect to the (i) acquisition of the non-controlling interest of PMCo under the Stock Purchase Agreement with PM LLC, the closing of which is contingent upon the execution of the underwriting agreement for this offering, and (ii) automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 69,333,244 shares of our common stock upon the completion of this offering and the automatic adjustment of our preferred stock warrant to purchase 150,000 shares of Series A preferred stock into a common stock warrant immediately to purchase 98,749 shares of common stock prior to the closing of this offering.

(2) Pro forma as adjusted amounts give effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of 25,000,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our audited consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this prospectus, including our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of the money you paid to buy our common stock. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business. Certain statements below are forward-looking statements. See the section titled "Special Note Regarding Forward-Looking Statements" appearing elsewhere in this prospectus.

Risks Related to Our Business, Financial Position and Capital Needs

We are a clinical-stage biotechnology company with a limited operating history and no products approved by regulators for commercial sale, which may make it difficult to evaluate our current and future business prospects.

Since our inception in 2018, we have focused substantially all of our efforts and financial resources on developing our Generate Platform and researching and developing programs and product candidates. All of our programs and product candidates are still in the research, preclinical development or clinical development stages. We have not yet demonstrated our ability to successfully complete Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third-party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have no products approved for commercial sale and we can provide no assurance that we will obtain regulatory approvals to market and sell any products in the future. We therefore have never generated any revenue from product sales, and we do not expect to generate any revenue from product sales in the foreseeable future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. If we do not address these risks and difficulties successfully, our business will suffer.

Even if this offering is completed, we will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate programs, product candidates (including clinical trials), investment in our Generate Platform, or future commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect to spend substantial amounts to (i) continue our research and development activities, perform preclinical studies, and conduct clinical trials of our current and future programs and product candidates, (ii) continue to develop our Generate Platform, (iii) seek regulatory approvals for our product candidates, including GB-0895 and (iv) launch and commercialize any product candidates for which we receive regulatory approval, including potentially building our own commercial sales, marketing and distribution organization.

As of December 31, 2025, we had approximately $221.5 million in cash, cash equivalents, restricted cash and marketable securities. We estimate that the net proceeds from this offering will be approximately $368.8 million, based on the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We believe, based on our current operating plan, that the net proceeds from this offering together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the first half of 2028. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, royalty financings, government or other third-party grants, asset sales, partnership, collaboration or licensing arrangements such as our collaborations with Amgen, Inc. ("Amgen") and Novartis Pharma AG ("Novartis"), or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing research and development and corporate activities. Because the length of time and activities associated with research and development of our programs and product candidates are highly uncertain, we are unable to estimate the actual funds we will require for research, development, marketing and commercialization activities. Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to the:

- number of programs that result in product candidates we chose develop further;
- initiation, progress, timing, costs and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- resources required to further develop Generate Platform;
- clinical development plans we establish for these product candidates;
- terms of any agreements with our current or future collaboration partners;
- outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration (the "FDA"), the Medicines and Healthcare products Regulatory Agency (the "MHRA"), the European Medicines Agency (the "EMA"), Pharmaceuticals and Medical Devices Agency and other comparable foreign regulatory authorities (collectively, the "Regulatory Authorities");
- cost of filing, prosecuting, maintaining, defending and enforcing our patent claims and other intellectual property rights,
- effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future product candidates; and
- cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily through private placements of our convertible preferred stock, the issuance of convertible notes, payments from Amgen and Novartis, and cost-sharing payments from other partnership, collaboration or licensing arrangements. In December 2021, we entered into a collaboration and license agreement with Amgen, as amended (as amended from time to time, the "Amgen Collaboration Agreement"), and, in connection therewith, we received a non-refundable upfront payment of $50.0 million in January 2022, an equity investment of $25.0 million in October 2023 from the sale to Amgen of our Series C preferred stock, an additional upfront payment of $5.0 million in December 2023 in connection with an amendment to the Amgen Collaboration Agreement, and a $5.0 million development milestone payment in August 2024. In September 2024, we entered into a collaboration and license agreement with Novartis (the "Novartis Collaboration Agreement"), and, in connection therewith, we received a non-refundable upfront payment of $50.0 million in October 2024 and an equity investment of $15.0 million from the sale of our Series C preferred stock. In addition, we have benefited from cost-sharing arrangements in our collaboration arrangements with The University of Texas M.D. Anderson Cancer Center ("MD Anderson"), Roswell Park Comprehensive Cancer Center ("Roswell Park") and Pioneering Medicines 02, Inc. ("PMCo"). Upon the execution of the underwriting agreement for this offering, we will acquire PMCo. At that time, our collaboration, including our cost-sharing arrangements, will terminate and we will become obligated to make certain payments to PMCo's parent based on net sales. We cannot be certain that additional funding will be available on favorable terms, or at all. Until we can generate sufficient product, milestone or royalty revenue to finance our operations, which we may never do, we expect to finance our future cash needs through a combination of public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, and partnership, collaboration or licensing arrangements. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop our programs, develop and commercialize our product candidates or develop our Generate Platform. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms or at all. Among other possibilities, negative clinical trial data or setbacks, or perceived setbacks, in our programs or product candidates, or with respect to our Generate Platform, could impair our ability to raise additional financing or grants, or our ability to enter into partnership, collaboration and licensing arrangements, in each case, on favorable terms, or at all. Moreover, the terms of any equity or debt financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, or the possibility of such issuance, may cause the market price of our shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our stockholders' rights.

Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital from third-parties through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches, we may have to relinquish certain valuable rights to our programs or product candidates, technologies or future revenue streams. We also could be required to seek collaboration partners for one or more of our current or future programs and product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to programs and product candidates, or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back or discontinue the development of one or more of our programs, or the development and commercialization of one or more of our product candidates, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations, cause the price of our common stock to decline, and negatively impact our ability to fund operations.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We will continue to incur significant research and development and other expenses related to our programs, product candidates, Generate Platform, and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital. We have incurred net losses in each year since our inception in 2018, including net losses of $223.0 million and $181.4 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $676.3 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities and the development of our Generate Platform. To date, we have financed our operations primarily through private placements of our convertible preferred stock, the issuance of convertible notes, payments from Amgen and Novartis, and cost-sharing payments from other partnership, collaboration or licensing arrangements. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. We have not completed pivotal clinical trials for any of our product candidates, and it will be several years, if ever, before we or our collaboration partners have a product candidate ready for commercialization. Even if we or our collaboration partners obtain regulatory approval to market a product, our future revenues will depend upon the size of any markets in which such product have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- expand the number of our research and development programs;
- continue or expand our scope of research or development of our current programs and product candidates in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical or other studies or trials for our programs and product candidates, including pursuant to some of our partnership, collaboration and licensing arrangements;
- change or add additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our product candidates and products;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license technologies;
- make payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any program or product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biotechnology companies such as ours, should be carefully considered. Any predictions about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

The development of our programs and the development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We have entered into collaboration agreements for certain programs and product candidates and may decide to collaborate for the future development and potential commercialization of other product candidates. For example, we are party to cost-sharing arrangements in our collaboration arrangements with MD Anderson and Roswell Park, pursuant to which we will collaborate to jointly discover and co-develop protein therapeutics. However, we cannot guarantee that either we or our collaboration partners will have the available funds to fund the research and development activities contemplated by such agreements. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our programs and product candidates or bring them to market and generate product revenue.

Additionally, our expenses could increase beyond our expectations if we are required by the Regulatory Authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in the development of GB-0895 and our other product candidates such as delays in establishing appropriate manufacturing arrangements or delays in completing clinical trials.

Our management and our independent registered public accounting firm have concluded that there is substantial doubt as to our ability to continue as a going concern. If we cannot continue as a going concern, our stockholders may lose some or all of their investment in our company.

Our audited consolidated financial statements, included elsewhere in this prospectus, were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and satisfy our liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from our inability to continue as a going concern. As of December 31, 2025 and 2024, we had cash and cash equivalents and marketable securities of $221.5 million and $393.6 million, respectively. We have incurred recurring losses since inception, including a net loss attributable to Generate Biomedicines, Inc. common stockholders of $203.2 million for the year ended December 31, 2025. As of December 31, 2025 and 2024, we had an accumulated deficit of $676.3 million and $473.1 million, respectively. Based on our current capital resources, which consists of cash, cash equivalents and marketable securities on hand at December 31, 2025, we will not have sufficient cash on hand to support current operations for at least twelve months from February 4, 2026, the date of issuance of the financial statements. This condition raises substantial doubt about our ability to continue as a going concern.

Additionally, if we are unable to obtain funding, through equity financings, debt financings or other capital sources, we could be forced to delay, reduce or eliminate some or all of our programs, product candidates, development of our Generate Platform, or commercialization efforts. Any such actions could adversely affect our business prospects, or our ability to continue as a going concern. There is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to fund continuing operations, if at all. Even if we are able to raise additional capital, there is no guarantee the proceeds would be sufficient to support our operating plans for at least the next twelve months from the date of issuance of these financial statements. If we cannot continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our combined financial statements, and it is likely that our stockholders may lose some or all of their investment in us.

We are dependent on the success of our product candidates, including GB-0895, GB-4362 and GB-5267, and our ongoing and anticipated trials may not be successful.

Our future success is dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our product candidates, including GB-0895, GB-4362 and GB-5267. We are investing a majority of our financial resources into the research and development of these product candidates including our clinical trials for GB-0895 and planned clinical trials for GB-4362 and GB-5267, for which Investigational New Drug applications (“INDs”) were cleared by the FDA in December 2025.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote these product candidates, or any other product candidates, before we receive marketing approval from the applicable Regulatory Authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on a variety of factors. We do not have control over many of these factors, including certain aspects of clinical development and the regulatory submission and review process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts of those of any current or future collaborator. In addition, we do not have control over whether products that target the same indications as our product candidates are introduced, which could impact the competitiveness of our product candidates. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these product candidates, even if approved. If we are not successful in commercializing GB-0895, GB-4362 or GB-5267, or any other product candidate, or are significantly delayed in doing so, our business will be materially harmed.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our product candidates may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives, such as the expected timing for the topline data from our Phase 3 clinical trials of GB-0895 for the treatment of severe asthma or Phase 1b clinical trial of GB-0895 in moderate-to-severe chronic obstructive pulmonary disease ("COPD"). From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, in some cases for reasons beyond our control, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our substantial reliance on third-party contract research organizations ("CROs") to engage, qualify and prepare clinical trial sites, complete these trials successfully, in compliance with regulatory requirements, and on schedule;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the Regulatory Authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our substantial reliance on third-party contract development and manufacturing organizations ("CDMOs") to manufacture our product candidates;
- our CDMOs access to sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the manufacturing and commercialization of our product candidates;
- the ability to commercialize our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

Any inability to meet milestones as publicly announced, or at all, may delay the commercialization of our product candidates or commercialization may never be achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones, and may decrease the attractiveness of our product candidates relative to competitive products expected to be approved by the applicable Regulatory Authorities prior to our product candidates.

Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our

stock price to decline and negatively impact our financing or funding ability as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this prospectus:

- inability to develop promising programs;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the feasibility of developing, manufacturing and commercializing our product candidates;
- our ability to manage our growth;
- the outcomes of research programs, clinical trials or other product development or approval processes conducted by us and our collaboration partners;
- our ability to develop or successfully commercialize product candidates;
- the ability of our collaboration partners to develop and successfully commercialize product candidates;
- our relationships, and any associated exclusivity terms, with collaboration partners, including Amgen and Novartis;
- our contractual or other obligations to provide resources to fund our programs and product candidates;
- our operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business, including manufacturing of our product candidates, the conduct of clinical trials in multiple international locations and potential commercialization in such locations; our ability to consistently arrange for manufacture of our product candidates by third-parties;
- our ability to accurately report our financial results in a timely manner; our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain and enforce our intellectual property (“IP”) rights; our ability to prevent the theft or misappropriation of our IP and know-how or proprietary technologies; potential advantages that our competitors and potential competitors may have in securing funding, obtaining and maintaining the rights to critical IP or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business; our collaboration partners’ ability to obtain additional capital that may be necessary to develop programs and develop and commercialize product candidates pursuant to our partnership, collaboration and licensing arrangements;
- the effect of changes in government regulation;
- cybersecurity breaches and other business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- our ability to use our net operating loss ("NOL") carryforwards to offset future taxable income.

Risks Related to Our Generate Platform and Our Use of Artificial Intelligence

Our approach to the engineering and development of our programs is unproven, and we may not be successful in our efforts to identify and develop any programs and product candidates of commercial value by leveraging our Generate Platform.

The Generate Platform and our approach to drug engineering and development utilizes, among other things, our proprietary artificial intelligence and machine learning (“AI”) solutions to create a pipeline of product candidates. Because our approach is both proprietary and pioneering, the cost and time needed to develop our programs and product candidates can be difficult to predict, and our efforts may not result in the engineering and development of commercially viable human therapeutics.

Any drug engineering and development that we are conducting with our Generate Platform may not be successful in identifying programs and product candidates that have commercial value or therapeutic utility. The Generate Platform may initially show promise in identifying potential programs and product candidates, yet fail to yield viable programs and product candidates for clinical development or potential commercialization for a number of reasons, including:

- research programs to identify new programs and product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new programs and product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop programs and product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;
- programs and product candidates engineered with our Generate Platform may not demonstrate efficacy, safety or tolerability, including because they may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies, or otherwise may interact with human biological systems in unforeseen, ineffective or possibly harmful ways;
- programs and product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our programs and product candidates non-competitive or less attractive; or
- a potential product candidate may not be capable of being produced at an acceptable cost.

In addition, we may in the future seek to identify and develop programs and engineer and develop product candidates that are based on novel targets and technologies that are unproven. If our activities fail to identify novel targets or technologies for drug engineering and development, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional programs and product candidates. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the product candidates resulting from our programs prove to be ineffective, unsafe or commercially unviable, our programs and product candidates would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are substantially dependent on the successful application of our Generate Platform to develop programs and product candidates that can be commercialized by us or our current or future collaboration partners.

Since our formation, we have focused on investing in our Generate Platform to unlock a new way of developing programs and product candidates for development and, if approved, potential commercialization by us and our collaboration partners. The biotechnology industry is capital intensive, and our success depends significantly on our ability to apply our Generate Platform to develop programs and engineer and develop product candidates that can be further developed by us or our current or future collaboration partners. Our ability to engineer and develop product candidates and increase revenue depends in large part on our ability to continue to enhance and improve our Generate Platform. We have invested, and expect to continue to invest, in research and development efforts, acquisitions and licensing agreements that further enhance our Generate Platform. These investments may involve significant time, risks and uncertainties, including the risks that any new software or hardware enhancement or the integration of software or hardware from an acquired company or third-party licensor may not be introduced in a timely or cost-effective manner; may not keep pace with technological developments; or may not achieve the functionality necessary to generate significant revenues. The success of any enhancement to our Generate Platform depends on several factors, including (i) the development of more advanced models and algorithms; (ii) the generation of additional high quality and relevant data; (iii) high quality and high-throughput biohardware, including laboratory analysis and structural solutions from our cryogenic electron microscopy (“Cryo-EM”) core; (iv) innovation in other experimental, computational and/or infrastructure technologies; and (v) increased computational storage and processing capacity.

The Generate Platform depends upon the continuous, effective and reliable operation of our biohardware, including our laboratory systems, Cryo-EM core and AI solutions, including software, hardware, databases and related tools and functions, as well as the integrity of our data. We have from time to time found defects, vulnerabilities or other errors in such tools, functions and data, and new errors may be detected in the future. The risk of errors is particularly significant when new software code or hardware is first introduced or when new versions or enhancements of existing software code or hardware are implemented. Errors may also result from the interface of our proprietary software and hardware tools with our data or with third-party systems and data.

Further, the price of new equipment and hardware, including graphics processing units ("GPUs"), is subject to market fluctuations. Such fluctuations are influenced by factors, including supply and demand for such equipment. In the case of GPUs for AI services, current demand for certain types of GPUs and networking equipment far exceeds supply, impacting the price and availability of such hardware. As a result, the cost of new equipment has been and may in the future be unpredictable, and may also be significantly higher than our historical costs.

If we are unable to successfully enhance our Generate Platform, or if there are any defects or disruptions in our Generate Platform that are not timely resolved, our ability to develop new innovations and ultimately gain market acceptance of our products and our Generate Platform, could be materially and adversely impacted, and our reputation, business, operating results and prospects could be materially harmed.

We have limited clinical data on product candidates that were computationally engineered with our Generate Platform demonstrating whether they are safe or effective for long-term treatment in humans. The long-term safety and efficacy of product candidates computationally engineered with our Generate Platform is unknown. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new product candidates as quickly or cost effectively as expected and we therefore may not be able to execute on our strategic approach as originally expected.

Product candidates engineered with our Generate Platform require substantial technical, financial and human resources to develop and potentially commercialize. We may not be able to maintain sufficient resources and expertise to discover additional programs and product candidates. If we are unable to identify successful programs and product candidates for preclinical and clinical development and regulatory approval in a timely matter or at all, we could experience significant delays or an inability to successfully pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our product candidates, which could harm our business.

Issues relating to our use of AI in the identification of our programs and the engineering and development of our product candidates could adversely affect our business and operating results.

We incorporate AI solutions, among other technologies and capabilities, into our Generate Platform. There are risks involved in utilizing AI, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. If our AI systems fail to achieve their intended purposes – such as identifying viable therapeutic candidates or targets, predicting biological outcomes, producing reproducible results, and other similar or related purposes – our product development efforts may be delayed or unsuccessful. If we are unable to successfully integrate and manage AI within our business, or if AI fails to deliver the expected benefits, our ability to develop our programs and product candidates could be materially adversely affected.

Issues relating to the use of new and evolving technologies such as AI may cause us to experience brand or reputational harm, competitive harm, legal liability and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. Known risks of AI generally include inaccuracy, hallucinations, bias, intellectual property infringement or misappropriation, data privacy and cybersecurity issues and data provenance disputes. Perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI in biopharmaceutical development may cause public confidence in AI to be undermined, which could slow market acceptance of product candidates discovered and developed using AI. In addition, litigation or government regulation related to the use of AI may also adversely impact our ability to identify programs and engineer and develop product candidates using AI, as well as increase the cost and complexity of doing so. For example, regulators may limit our ability to develop or implement our proprietary AI models and algorithms and/or may eliminate or restrict the confidentiality of our proprietary technology, or may limit our ability to secure intellectual property rights to technologies created with the assistance of our proprietary AI models and algorithms, which could have an adverse effect on our business, results of operations and financial condition.

We also face increased competition from other companies that claim to use AI and related methods for drug engineering and development, some of which have more resources than we do and may have developed more effective methods than we and any third-party collaborators have, which may reduce our and any third-party collaborators' effectiveness in identifying potential product candidates and attracting additional collaborators to work with us. In particular, biotechnology companies based in China present both known and emerging competitive threats to our business. Many of these companies operate within innovation ecosystems characterized by substantial government investment, access to large and rapidly expanding biological and clinical datasets, and accelerated regulatory or funding pathways. These factors may allow Chinese biotechnology companies to develop, train and deploy advanced computational models, drug discovery platforms or biologic design technologies more rapidly or at lower cost than we can. If our competitors are able to utilize new technologies more effectively (including but not limited to those that may involve AI or be created using AI) to discover, develop and commercialize products that compete with any of our programs and product candidates, such technologies could adversely impact our ability to compete.

Further, AI may have or produce errors or inadequacies that are not easily detectable. The quality of AI outputs depends heavily on the quality and quantity of input data. If the data used to train AI or the content, analyses or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, incomplete, hallucinatory, overbroad or biased, our business, financial condition and results of operations may be adversely affected. Developing, testing and deploying AI systems may also increase the cost profile of our product offerings due to the nature of the computing costs involved in such systems, which could impact our project margin and adversely affect our business and operating results.

The legal landscape and subsequent legal protection for the use of AI remains uncertain, and the increasing use of AI in drug discovery and development introduces new and evolving risks related to ownership, inventorship and protection of intellectual property generated by or with the assistance of AI technologies. For example, generative AI may be used improperly or inappropriately, which could lead to the tainting of our proprietary information and render us unable to qualify for certain patent or trade secret protection. Moreover, if our vendors, employees, suppliers or contractors with access to our proprietary and confidential information and know-how were to disclose such information as inputs to third-party AI tools this could lead to loss of trade secret protection and otherwise impact our ability to realize the benefit of our intellectual property. If we do not have sufficient rights to collect or use the data on which our AI relies or to the outputs produced by our Generate Platform, we may incur liability through the alleged violation of certain laws, third-party privacy rights, online terms of service or other contracts to which we or our data providers are a party. In addition, we rely on third-party software and hardware for our Generate Platform. If the relevant software or hardware, or updates to such software or hardware, were to become unavailable to us in the future on reasonable commercial terms, or if they became the subject of allegations of intellectual property infringement, our ability to continue to use our Generate Platform could be affected. We also rely on public sources of data, such as the Protein Data Bank, which, if they became unavailable to us on reasonable terms, could affect our Generate Platform. Regulatory and legal frameworks governing inventions created with or using AI are still developing and may create uncertainty regarding our ability to secure and enforce rights in such inventions.

AI presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. In addition to our Generate Platform, we have adopted and integrated, and in the future may adopt and integrate additional generative AI tools into our systems for specific use cases reviewed by our legal department and information technology department. Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Our use of AI may also lead to novel and urgent cybersecurity and privacy risks, which may adversely affect our operations and reputation, as well as the operations of any third-party collaborators. Emerging ethical issues surround the use of AI, and we may be subject to reputational and legal risk if our deployment or use of AI becomes controversial. Our use of AI may also, in the future, result in cybersecurity incidents that implicate personal data of customers or patients. Any such cybersecurity incidents related to our use of AI could adversely affect our reputation and results of operations.

A growing number of federal, state, and international legislators, agencies and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU's Artificial Intelligence Act ("AI Act") entered into force on August 1, 2024, with most provisions becoming effective on August 2, 2026. This legislation imposes significant obligations on providers and deployers of AI systems and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The recently enacted United States Department of Justice Data Security Program (also known as the Bulk Data Transfer Rules), effective April 8, 2025, imposes complex additional restrictions on international data transfers, which may affect our ability to do business in manufacturing and clinical research in foreign countries. Likewise, in the U.S., several states, including Colorado and California, passed laws to regulate various AI uses, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued draft guidance on the use of AI in regulatory decision-making for drug and biological products that centers on the context of use while establishing a credibility assessment framework for establishing and evaluating AI model outputs intended to support regulatory decision-making. If we develop or use AI systems governed by these laws or regulations, including as informed by regulatory guidance, we would need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance. We expect other jurisdictions will adopt similar laws. Uncertainty in the legal regulatory regime may require significant resources to modify and maintain business practices to comply with U.S. and non-U.S. laws, the nature of which cannot be determined at this time. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines or significant restrictions on our ability to conduct our business activities.

We utilize third-party open-source software ("OSS"), which presents risks that could adversely affect our business and subject us to possible litigation.

We utilize software that is licensed from third-parties under open-source licenses, and we expect to continue to use such OSS in the future. We cannot ensure that we have effectively monitored our use of OSS, validated the quality or source of such software, or are in compliance with the terms of the applicable open-source licenses or our policies and procedures. Use of OSS may entail greater risks than use of third-party commercial software because open-source licensors generally do not provide support, updates or warranties or other contractual protections regarding infringement claims or the quality of the code. OSS may also be more susceptible to security vulnerabilities. The availability of OSS could be adversely affected by service outages, data loss, privacy breaches, cyber-attacks and other events relating to the availability of these applications and services they provide, which could diminish the utility of these services and harm our business. We also could be subject to lawsuits by third-parties alleging that what we believe to be licensed OSS infringes such parties' intellectual property rights, which could be costly for us to defend and require us to devote additional research and development resources to change our solutions. Some OSS licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of OSS we use. If we combine our proprietary software with OSS in a certain manner, we could, under certain of the OSS licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of OSS, the terms of many OSS licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our product candidates. We could be required to seek licenses from third-parties in order to continue using our software, to re-engineer our software or to discontinue use of our software in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Research, Development, Regulatory Review and Approval of Our Product Candidates

Preclinical and clinical development is inherently lengthy and uncertain. Preclinical and clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which would have a material adverse impact on our Generate Platform or our business.

Preclinical and clinical testing is expensive and complex and can take many years to complete, and its outcome is inherently uncertain. We and our collaboration partners may not be able to initiate, may experience delays in or may have to discontinue preclinical studies and clinical trials for our product candidates.

Before we can initiate clinical trials for a product candidate, we must first complete extensive preclinical studies, including IND-enabling good laboratory practices ("GLP") toxicology testing, which support our planned INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies. For example, while regulators like the FDA have signaled through draft guidance a movement away from animal testing for monoclonal antibodies, we have thus far depended on the availability of non-human primates ("NHPs") to conduct certain preclinical studies that we are required to complete prior to submitting an IND or foreign equivalent prior to initiating clinical development, and prior to submitting a marketing application. During the past several years, there was a global shortage of NHPs available for drug development. If the shortages in NHPs or other laboratory animals occur in the future, this could significantly increase the costs of obtaining, or decrease the availability of, NHPs or other laboratory animals for our future preclinical studies if regulators continue to require NHP data, or we require other laboratory animals, to support our preclinical and clinical development programs. This could also result in delays in our development and approval timelines.

We must also complete extensive work on Chemistry, Manufacturing and Controls ("CMC") activities (including yield, purity and stability data) to be included in the IND filing. CMC activities require extensive manufacturing processes and analytical development, which is uncertain and lengthy. For instance, batch failures as we scale up our manufacturing may occur. In addition, we may have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our preclinical or clinical product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical or clinical trials of such product candidates.

We cannot predict if the Regulatory Authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the Regulatory Authorities allowing clinical trials to begin.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would also significantly harm our business. Our development costs will also increase if we experience delays in testing or regulatory approvals, and we may be required to obtain additional funds to complete clinical trials. There can be no assurance that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Regulatory Authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We and our collaboration partners also may experience numerous unforeseen events during, or as a result of, any clinical trials that we or our collaboration partners conduct that could delay or prevent us or our collaboration partners from successfully developing our product candidates, including:

- the Regulatory Authorities, institutional review boards (“IRBs”) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges in manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience limitations or shortages in our ability to obtain or supply necessary medical equipment to conduct clinical trials; for example, there are current supply constraints on the ability to obtain certain volumes of equipment for testing airway inflammation measures;
- we may continue to optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to potentially significant changes in our clinical trial designs, requiring additional cost and time, and, as a consequence, lead to a delay in plans for progressing one or more product candidates;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies or add additional cohorts to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB, ethics committee and regulatory authorities for re-examination;
- in an effort to optimize product features, we plan to make in the future changes to our product candidates after we commence clinical trials, which may require us to repeat earlier stages of clinical testing or delay later stage testing of the product candidate;

- clinical trials of any product candidates may fail to show safety or efficacy, or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon development programs;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- differences in clinical trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials; preclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of our CDMOs, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- product candidates may have undesirable side effects or degradation products, any of which could lead to serious adverse events ("SAEs") or other unexpected characteristics;
- occurrence of SAEs in trials of the same class of product candidates conducted by other companies that could be considered similar to our product candidates; and
- the potential for approval policies or regulations of the Regulatory Authorities to significantly change in a manner rendering our clinical data insufficient for approval.

For example, we are developing a biologic-device combination for the administration of GB-0895 with an autoinjector and pre-filled syringe ("PFS") for ease of administration. Earlier clinical trials have used a syringe and vial presentation, and we intend to transition to the PFS presentation for our pivotal Phase 3 trials in severe asthma via protocol and regulatory amendments. Regulatory Authorities may require us to conduct, among other things, PK compatibility studies to bridge the vial and syringe presentation to these new planned devices and human factors testing to support self-administration of these devices. There is no assurance that we will be successful in demonstrating the safety of either of these biologic-device combinations in clinical trials, any other studies or at all, and any such failure would impede our development and commercialization strategy for GB-0895. In addition, Regulatory Authorities could require additional preclinical studies or clinical trials to support introduction of a biologic-device combination, which could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase our clinical trial costs, delay marketing approval of GB-0895 and jeopardize our ability to commence product sales and generate revenue from GB-0895, if approved.

We could also encounter delays if a clinical trial is suspended or terminated by us, the Regulatory Authorities, ethics committees or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the Data Safety Monitoring Board ("DSMB") for such trial. We may experience delays in gaining clearance from Regulatory Authorities to initiate clinical trials through the imposition of a clinical hold in order to address comments from such regulators on our clinical trial design or other elements of our clinical trials. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the Regulatory Authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit or adequate benefit risk ratio from using a product candidate, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Further, conducting clinical trials in foreign countries, as we intend to do for GB-0895 and as we may in the future conduct for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to Regulatory Authorities. The Regulatory Authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The Regulatory Authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the Regulatory Authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize GB-0895 or any other product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, financial condition, results of operations and growth prospects. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. Any delays in the development of our product candidates may harm our business, financial condition and prospects significantly.

We are currently enrolling patients in clinical trials for GB-0895 globally and may in the future conduct clinical trials for other product candidates outside the United States, and the Regulatory Authorities may not accept data from such trials.

We are currently enrolling patients in two global Phase 3 clinical trials for GB-0895 in patients with severe asthma across more than 40 countries in North America, Europe, Latin America and Asia Pacific, and we expect to continue to conduct trials for our current and future product candidates internationally in the future. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the Regulatory Authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, regardless of whether such trials were conducted under an IND, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice (“GCP”) regulations, and the FDA can validate the data through on-site inspections or other appropriate means. Many foreign regulatory authorities have similar approval requirements, including in relation to the use of data from clinical trials conducted in foreign jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the Regulatory Authorities will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the Regulatory Authorities do not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in any product candidates that we develop being delayed or not receiving approval for commercialization in the applicable jurisdiction. Additionally, recent policy proposals in the United States may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third-parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of GB-0895 or any other product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, results seen in our Phase 1 clinical trial for GB-0895 in patients with mild-to-moderate asthma may not translate to similar results in our Phase 3 clinical trials in patients with severe asthma. While a dose-ranging trial in the target patient population or studying multiple doses in the Phase 3 clinical trials for GB-0895 in patients with severe asthma was recommended by the FDA and EMA, and proceeding directly to Phase 3 with a single dose carries higher risk of failure and uncertainty, we did not conduct a dose-ranging trial prior to proceeding into Phase 3 clinical trials in severe asthma. Based on the results of our Phase 1 clinical trial and other scientific considerations, we are evaluating GB-0895 at a single 300 mg subcutaneous dose every six months ("Q26W") in our Phase 3 clinical trials in severe asthma. However, there is no guarantee that the positive results generated at such dose in the completed Phase 1 clinical trial in mild-to-moderate asthma will demonstrate similar results in our Phase 3 clinical trials in patients with severe asthma, and we may be required to conduct additional trials before we can submit a marketing application for the approval of GB-0895. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as those observed in earlier studies and trials, and we may not have generated sufficient safety data to support a marketing application by the time of our targeted submission as other third-party products or product candidates that we believe may have similar profiles. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of GB-0895 or any other product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, adverse safety or efficacy observations made in clinical trials.

Additionally, we intend to utilize an "open-label" clinical trial design for certain of our clinical trials, such as our Phase 1 clinical trial of GB-5267 for the treatment of platinum-resistant ovarian cancer. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from the Regulatory Authorities.

Interim, initial, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, the topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participants enrollment continues and more participants' data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between interim data and final data could significantly harm our business prospects.

Further, others, including Regulatory Authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, study population size, safety database size, interpretations of data or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of the particular product candidate and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or trial is based on what is typically extensive information, and investors may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline or preliminary data that we report differ from actual results, or if others, including Regulatory Authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and growth prospects. Further, disclosure of interim, topline or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

If we encounter difficulties identifying and enrolling participants in our clinical trials, including participants with the required or desired characteristics to achieve diversity in a trial, our clinical development activities could be delayed or otherwise adversely affected.

We depend on enrollment of participants in our clinical trials for our product candidates. We may find it difficult to enroll trial participants in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Delays or difficulties in enrollment may result in increased costs or otherwise affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates, or result in termination of the clinical trials altogether. For example, in order to enroll a sufficient number of participants in our Phase 3 clinical trials for GB-0895 in patients with severe asthma, we plan to contract with sites across more than 40 countries in North America, Europe, Latin America and Asia Pacific.

Identifying and qualifying trial participants to participate in clinical trials of our product candidates is critical to our success. Patient and subject enrollment is affected by factors including: severity of the disease under investigation; complexity and design of the trial protocol; size of the targeted patient population; eligibility criteria for the trial in question; proximity and availability of clinical trial for the disease or condition under investigation; available sites for prospective trial participants; availability of competing therapies and clinical trials, including between our own clinical trials; efforts to facilitate timely enrollment in clinical trials; patient referral practices of physicians; ability to monitor trial participants adequately during and after treatment; ability to recruit clinical trial investigators with the appropriate competencies and experience; clinicians' and trial participants' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; our ability to obtain and maintain participant informed consent; and the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

The timing of our clinical trials depends on the speed at which we can recruit trial participants to participate in testing our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific therapeutic area, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting trial participants, conducting studies and obtaining regulatory approval of potential products may be delayed, which could also have significant commercial competitive impacts in the future.

In particular, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of trial participants available to us, because some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a third-party. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Additionally, if new product candidates show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our clinical trials.

Due to the significant resources required for drug development and depending on our ability to access capital, we intend to prioritize the development of GB-0895 for severe asthma. Moreover, we may fail to expend our limited resources on the development of GB-0895 for the treatment of

other indications or for the development of other potential future product candidates that may have been more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for drug development, we must decide which indications to pursue and advance and the amount of resources to allocate to each product candidate. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. For example, our current strategy is to pursue regulatory approval of GB-0895 for the treatment of severe asthma and to evaluate a potential label expansion into COPD and other indications. If we make incorrect determinations regarding the viability or market potential of GB-0895, or misread trends in the biotechnology industry, our business, financial condition, results of operations and growth prospects could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to our product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Our product candidates may face competition from biosimilars approved through an abbreviated regulatory pathway, including biosimilars of competitive products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a Biologics License Application ("BLA") for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing, including the potential for sponsors under FDA draft guidance issued in 2024 to demonstrate interchangeability without conducting so-called "switching" studies and the potential for sponsors under FDA draft guidance issued in 2025 to demonstrate biosimilarity without conducting comparative efficacy studies. Although the FDA has yet to finalize these draft guidance documents, these or similar efforts may increase the risk of competition for our biologic product candidates, if approved.

In the European Union, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for diverse types of biological product.

In addition to the risk associated with biosimilars of our product candidates, the launch of biosimilars to products that compete with our product candidates may intensify competition in the therapeutic areas we target by lowering the overall price point and expanding access to alternative treatments. As these lower-cost biosimilars gain market share, payors may preferentially encourage their use or impose access restrictions that make it more difficult for our product candidates to obtain favorable coverage, reimbursement or formulary placement. These dynamics could materially limit our market opportunity and adversely affect our commercial prospects.

The regulatory approval processes of the Regulatory Authorities are lengthy, time-consuming and inherently unpredictable, and if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain, and may prevent us from obtaining approvals for the commercialization of any product candidates we may develop. Any product candidate we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by Regulatory Authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and our collaboration partners must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and potent or effective in humans, including the target population. Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, a Marketing Authorization Application ("MAA") to the EMA, and similar marketing applications to other Regulatory Authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. The general approach for FDA approval of a new drug is dispositive data from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population. In February 2026, the FDA publicly indicated that a single adequate and well-controlled pivotal clinical trial supported by confirmatory evidence will be the FDA's default standard moving forward for novel products, rather than two such trials, but the scope, implementation and durability of this policy position remain uncertain and the FDA retains broad discretion to require additional clinical data for any product candidate, including a second adequate and well-controlled clinical trial. Regulatory Authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from Regulatory Authorities or those that have been used for the approval of similar drugs, will be acceptable for future approvals. The clinical development of our product candidates is also susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate purity, potency or efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the Regulatory Authorities that a product candidate may not continue development or is not approvable. It is possible that even if our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the Regulatory Authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the Regulatory Authorities that a product candidate is safe and effective for any of its proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the Regulatory Authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the Regulatory Authorities may disagree with our interpretation of data from clinical trials or preclinical studies;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the Regulatory Authorities may not file or accept our BLA or marketing application for substantive review;
- the Regulatory Authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of our CDMOs;
- staffing changes and backlogs at the Regulatory Authorities may create unexpected delays in the review and approval of any applications we may submit; and
- the approval policies or regulations of the Regulatory Authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience as an organization in filing and supporting the applications necessary to gain marketing approvals and will need to rely on CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The Regulatory Authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays or non-approval may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Any such delays may decrease the attractiveness of our product candidates relative to competitive products that are expected to be approved by the applicable Regulatory Authorities prior to our product candidates, and adversely affect our business.

In addition, if our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices ("cGMPs") and GCPs for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third-party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidate's post-approval could adversely affect our business, financial condition, results of operations and growth prospects.

Regulatory Authorities also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials or may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The Regulatory Authorities review the CMC section of regulatory filings. Any aspects found unsatisfactory by Regulatory Authorities may result in delays in clinical trials and commercialization. In addition, the Regulatory Authorities conduct pre-approval inspections ("PAIs") of clinical sites and manufacturing sites at the time of a BLA. Any findings by Regulatory Authorities and failure to comply with requirements may lead to delay in approval and failure to commercialize the product candidate.

Additional time may be required to obtain marketing authorizations for any product candidates that we develop as biologic-device combination products.

We intend to develop GB-0895 as a biologic-device combination product for administration with an autoinjector and PFS for ease of administration. Development of a product candidate as a combination product candidate requires close coordination with the Regulatory Authorities for review of each of the biologic and device components that comprise the product and would typically be reviewed by different centers within the Regulatory Authorities if offered for use as standalone products. For example, the FDA's review of a marketing application for a biologic-device combination that has a primary mode of action as a biologic would likely be subject to a biologics license application with the Center for Biologics Evaluation and Research as the lead center, with coordination with the Center for Devices and Radiological Health for the review of the device component. Although the Regulatory Authorities have or may have systems in place for the review and approval of such combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

For example, we currently plan to begin our pivotal Phase 3 trials of GB-0895 using a syringe and vial presentation, similar to the presentation used in prior trials of GB-0895. We intend to submit the PFS presentation to Regulatory Authorities in our marketing submissions, including our BLA submission to the FDA. During the course of the Phase 3 trials, we also intend to conduct trials of a separate autoinjector pen device using GB-0895; it is our intention to amend our BLA submission at some point in the future include the future autoinjector pen presentation; as a result, we may be required to gather additional data before we are able to submit a marketing application for GB-0895 or any of our other current or future product candidates, if ever. Any delay of clinical trials, the repetition of one or more clinical trials, or any Regulatory Authority's need for additional data to support a combination biologic-device presentation could cause delays in approval of our product candidates, increase our costs, and could jeopardize our ability to commence sales and generate revenue.

If we fail to expand our development of GB-0895 into additional indications, or engineer and subsequently develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although we are initially focused on developing and commercializing GB-0895 for the treatment of severe asthma, we also plan to evaluate developing GB-0895 for the treatment of COPD, such evaluation to take into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial. Expansion into new indications will require additional, time-consuming development efforts and significant additional expense prior to commercial sale, including preclinical studies, clinical trials and approval by the Regulatory Authorities. In addition, we plan to focus on continuing to develop and commercialize GB-4362 and GB-5267. All product candidates are prone to the risks of failure that are inherent in biopharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, there can be no assurance that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, other Regulatory Authorities must also approve the manufacturing and marketing of the product candidate in non-U.S. jurisdictions. In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve product testing and validation and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Our current and future clinical trials or those of our future collaborators may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval, limit commercial potential, or market acceptance of any of our product candidates.

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials. These product candidates may fail to show the desired safety and efficacy or safety, purity and potency profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Undesirable side effects caused by our product candidates, whether used alone or in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the Regulatory Authorities. We may observe unexpected and undesirable safety or tolerability issues with our product candidates in ongoing or future clinical trials. For example, GB-0895 is a biologic developed to be injected subcutaneously. There are risks inherent in subcutaneous injections, such as injection-site reactions (including redness, itching, swelling, pain and tenderness) and other side effects.

If significant adverse events or unacceptable side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting trial participants to any of our clinical trials, trial participants may withdraw from trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the Regulatory Authorities or an IRB, may impose a clinical hold, suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of any of our product candidates could result in harm to patients that are administered any of our product candidates. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, unfavorable benefit risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Any of these developments could materially harm our business, financial condition and prospects.

Moreover, clinical trials are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

In addition, even if we successfully advance our product candidates or any future product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of the foregoing events occur or if one or more of our product candidates prove to be unsafe, our entire pipeline or our Generate Platform could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we obtain regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Even if our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may: issue a warning letter asserting that we are in violation of the law and potentially restricting our ability to sell, manufacture, import or export our products; seek an injunction or impose civil or criminal penalties or monetary fines; suspend or withdraw regulatory approval or revoke a license; suspend any ongoing clinical trials; refuse to approve a pending BLA or supplements to a BLA submitted by us; seize product; or refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

If we are successful in gaining approval for any of our product candidates, we and our CDMOs, which manufacture our products under contract, will continue to face significant regulatory oversight of the manufacturing and distribution of our products. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the Regulatory Authorities for compliance with cGMP and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a Risk Evaluation and Mitigation Strategy ("REMS") as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable requirements may apply in foreign countries. In addition, if the Regulatory Authorities approves any of our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information, reports and registration.

The Regulatory Authorities may impose consent decrees or withdraw or vary approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our CDMOs or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program or a comparable foreign program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by Regulatory Authorities to approve pending applications or supplements to approved applications filed by us or suspension, variation or withdrawal of approvals;
- product seizure, detention or refusal to permit the import or export of our product candidates;
- total or partial suspension of production, distribution, manufacturing or clinical trials;
- operating restrictions;
- suspension of licenses; and
- injunctions, fines or the imposition of civil or criminal penalties.

Additionally, Regulatory Authorities strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The policies of the Regulatory Authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, the U.S. Supreme Court’s July 2024 decision to overturn established case law giving deference to Regulatory Authorities’ interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA’s regulations, policies and decisions may become subject to increasing legal challenges, delays and/or changes. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For more information, see the section titled “*Business—Government Regulation*.”

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may develop certain of our product candidates in combination with other therapies or as add-ons to the standard of care. Developing combination treatments increases complexity and risk, including risks of drug-drug interactions, unforeseen side effects or failures in our clinical trials that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

We plan to initiate a Phase 1 clinical trial of GB-4362 in patients receiving enfortumab vedotin plus pembrolizumab to assess GB-4362's potential as an adjunct therapy for reduction in peripheral neuropathy, while preserving antibody-drug conjugate ("ADC") anti-tumor efficacy. The use of our product candidates in combination with each other and/or in patients already receiving other companies' treatments may subject us to risks that we would not face if our product candidates were to be administered as monotherapies.

For example, either the combination of our product candidates with each other, or when used in patients already receiving other companies' products or product candidates, may result in unexpected adverse side effects or toxicities that the product candidates or other therapy do not produce when used alone. In addition, the product candidates may interact with each other, or with other companies' products or product candidates that patients receiving our product candidates may also be receiving, in undesirable ways that could negatively impact the potency or efficacy and safety of our product candidates, or of the other companies' products or product candidates. Testing product candidates in patients already receiving other treatments may increase the risk of significant adverse effects or failed clinical trials. The timing, outcome and cost of the potential adverse effects of developing products to be used in patients already receiving other therapies is difficult to predict and dependent on a number of factors that are outside our reasonable control. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, or the result of drug-drug interactions between our product candidate and any of the concomitant therapies given to the trial subjects, we, the Regulatory Authorities, or IRBs and other reviewing entities, could interrupt, delay, or halt clinical trials and could result in a more restrictive label or particularly narrow product indication (substantially limiting the product's commercial opportunities), a REMS or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

In addition, to the extent we choose to develop and commercialize a product candidate for use in patients receiving an already approved therapy, as is the case with GB-4362, any safety, efficacy, regulatory, manufacturing or supply issues that could arise with respect to the approved therapy could have an adverse impact on us. Prescribing information for the approved therapy, such as risk information like a boxed warning, or limitations of use, could negatively impact our ability to develop and commercialize a product as an add-on or as further supportive care to the approved therapy. If the approved therapy is replaced as the standard of care, the Regulatory Authorities may require us to conduct additional clinical trials, or we may not be able to obtain adequate reimbursement from third-party payors. Further, the Regulatory Authorities could revoke approval of the therapy patients in our clinical trials are receiving. The occurrence of any of these risks could result in an add-on product candidate being developed as further supportive care, if successfully developed and approved, being removed from the market or being less successful commercially. If the Regulatory Authorities revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with respect to, therapies we choose to evaluate in conjunction with or as background or standard of care therapy for any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies. If we experience safety, tolerability or toxicity issues in any of our ongoing or planned clinical trials that allow patients to remain on other therapies, or if the efficacy data from these trials of our candidates administered to patients on other therapies are not favorable, our clinical development plans could be materially negatively affected or delayed, or we may not receive regulatory approval for our product candidates, which would materially harm our business and likely cause the market price of our common stock to decline.

In addition, because GB-4362 is expected to be administered in combination with other therapies, payors may assess the overall cost of the treatment regimen, not solely the cost or value proposition of our licensed product. Combination regimens are subject to heightened reimbursement risk, as payors may:

- decline to cover the full regimen based on the aggregated cost of the component therapies;
- require step-through use of lower-cost or single-agent treatments before approving the combination;

- assign the combination to a more restrictive formulary tier, resulting in higher patient cost-sharing or reduced utilization;
- impose prior authorization, clinical criteria or other restrictions that limit prescribing; or
- negotiate price concessions with us based on the cost structure or formulary status of the companion therapy.

Even if our product candidate demonstrates clinical benefit as part of a combination regimen, payors may determine that the incremental value is insufficient to justify the overall cost and may refuse to reimburse at levels that are acceptable to us or that support commercial viability. In addition, we do not control the pricing, contracting strategy or reimbursement profile of the companion therapy, which may change over time and adversely impact the attractiveness or economics of the combination. If coverage for the companion therapy is reduced, withdrawn, or made more restrictive, the value proposition for our product candidate could be materially weakened.

While we may in the future seek designations for our product candidates with the Regulatory Authorities that are intended to confer benefits such as a faster development process, a streamlined review or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The Regulatory Authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address serious conditions. These designations may confer benefits such as additional interaction with regulatory authorities, streamlined development pathways and expedited review procedures. However, there can be no assurance that we will successfully obtain such designations for our product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits.

For example, if a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. Fast Track Designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind any Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

Even in the absence of obtaining certain designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate an application for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for acting on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

Where appropriate, we may secure approval from Regulatory Authorities through the use of expedited approval pathways, such as accelerated approval or comparable foreign abbreviated pathways. If we are unable to obtain such approvals, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we

receive accelerated approval from the FDA or approval following comparable foreign abbreviated pathways by foreign Regulatory Authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such Regulatory Authorities may seek to withdraw the accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our potential future product candidates from the Regulatory Authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to act, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

Prior to seeking accelerated approval, or approval following comparable foreign abbreviated pathways, we would seek feedback from the Regulatory Authorities and would otherwise evaluate our ability to seek and receive such accelerated approval or approval following comparable foreign abbreviated pathways. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from Regulatory Authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to apply for accelerated approval, or comparable foreign abbreviated pathways, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The Regulatory Authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway, or comparable foreign abbreviated pathway, and subsequently converted by the Regulatory Authorities to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Disruptions at the FDA and other government agencies caused by, funding shortages, staffing limitations, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed,

review, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and Regulatory Authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign Regulatory Authorities' ability to perform routine functions. Average review times at the FDA and foreign Regulatory Authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain Regulatory Authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations hinder or prevent the FDA or other Regulatory Authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to the Manufacturing of Our Product Candidates and Our Future Pipeline

We rely on third-parties for the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and may do the same for commercial supplies of our products, if approved. As our pipeline increases and matures, the increased demand for supplies from our manufacturers may increase the risk that we will not have sufficient supply when needed or at an acceptable cost.

We currently utilize, and expect to continue to utilize, CDMOs to, among other things, supply and manufacture raw materials, components, parts and consumables, and to perform quality testing for our preclinical and clinical supply for all of our product candidates. For example, we are party to agreements with Lonza AG ("Lonza"), which is currently our sole provider of drug product for GB-0895, and WuXi Biologics (Cayman) Inc. ("WuXi"), which is currently our sole provider of drug product for GB-4362. In addition, given the specialized expertise required to manufacture CAR-T therapies, we intend to rely upon Roswell Park to manufacture GB-5267. In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our CDMOs will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates, as applicable. The transition to larger scale production could prove difficult. If our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality, then we may not be able to meet the demands of clinical trials or market demands, which could adversely impact our ability to timely conduct our clinical trials or commercialize our product candidates, if approved, and have a material adverse impact on our business and results of operations. Furthermore, with the increase of companies developing monoclonal antibodies and other therapeutic proteins, there may be increased competition for the supply of the raw materials that are necessary to make our monoclonal antibodies and therapeutic proteins, which could severely impact the manufacturing of our product candidates.

Even if we are able to maintain arrangements with our CDMOs, reliance on CDMOs entails additional risks, including:

- the failure of the CDMO to comply with applicable regulatory requirements and reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our CDMOs give greater priority to the supply of other products over our product candidates or otherwise do not perform satisfactorily according to the terms of the agreement between us;

- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by our CDMOs because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by our CDMOs, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary technology and IP, including our know-how.

If we are unable to maintain our key manufacturing relationships, we may fail to find replacement CDMOs, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement CDMOs, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the Regulatory Authorities.

We do not currently have long-term supply contracts with all of our suppliers and they are not obligated to supply materials to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our suppliers and manufacturers in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the materials that we are required to purchase.

Additionally, if CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the Regulatory Authorities. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new CDMO could negatively affect our ability to develop or commercialize our product candidates in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidates that such third-party owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another third-party manufacture our product candidates.

If any of our product candidates are approved by any Regulatory Authority, we will likely utilize arrangements with CDMOs for the commercial production of such product. This process is difficult and time-consuming and we may face competition for access to manufacturing facilities as there are a limited number of CDMOs operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with CDMOs on satisfactory terms, which could delay our commercialization.

The operations of our suppliers and CDMOs, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;

- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and CDMOs' compliance with cGMPs or status acceptable to the Regulatory Authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our CDMOs or suppliers are located.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. It is possible further tariffs may be imposed that could affect imports of active pharmaceutical ingredients ("APIs") used in our product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in our product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, contracting matters, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business, financial condition, results of operations and growth prospects. These and other factors beyond our control could interrupt our suppliers and CDMOs' production, influence their ability to export and manufacture our clinical supplies, cost-effectively or at all, and inhibit their ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our suppliers, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We depend on sole source and limited source suppliers for certain raw materials, APIs, drug products, drug substances and other materials used in our product candidates. For example, we are party to agreements with WuXi, which is currently our sole provider of drug product for GB-4362, and Lonza, which is currently our sole provider of drug product for GB-0895. Any change in our relationships with such suppliers or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects. Moreover, there may be difficulties in scaling up the clinical or commercial quantities of our product candidates despite such agreements, and the costs of manufacturing could become prohibitive.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. In addition, geopolitical tensions may impact our suppliers. For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from "biotechnology companies of concern," or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern." Congress has interpreted a "biotechnology company of concern" as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (*e.g.*, collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. This and similar laws could have the potential to restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible some of our contractual counterparties, including WuXi and Lonza, could be impacted by such future legislation or government policies. If WuXi, Lonza or any of the other third-parties that we engage to supply any materials or manufacture products for our preclinical studies and clinical trials should cease to continue to do so, or if we are prevented or restricted from using their services for any reason, we could experience delays in advancing these studies and trials while we identify and qualify replacement suppliers.

Establishing additional or replacement suppliers, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of sole source or limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of our CDMOs encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our product candidates are complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management or shipping. These difficulties could be due to any number of reasons, including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology and product instability. Moreover, we are currently conducting, and will in the future conduct, our clinical trials internationally. For example, we are currently enrolling patients in two global clinical trials for GB-0895 in patients with severe asthma, which are expected to include clinical trials across more than 40 countries. Logistical issues associated with shipping our product candidates and other materials globally from manufacturing sites to clinical sites, such as errors or improper handling by third-party carriers, transportation restrictions, or interruptions caused by natural disasters or force majeure events, could result in loss or destruction of, or damage to, our clinical supply, which may in turn cause delays in initiating or completing clinical trials.

As our product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Our rate of innovation is high, which has caused, and will continue to cause, a high degree of technological change. As we scale the manufacturing output for particular product candidates, we plan to continuously improve yield, purity and the pharmaceutical properties of our product candidates from IND-enabling studies through commercial launch, including shelf-life stability, and solubility properties of product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular product candidate during development. However, after a change in process, additional time is required for pharmaceutical property testing, such as 6- or 12-month stability testing. Such testing may require resupplying clinical material, or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

Such technological changes can negatively impact product comparability during and after clinical development. Furthermore, technological changes may drive the need for changes in, modification to or the sourcing of new manufacturing infrastructure or may adversely affect third-party relationships. Such technological changes also carry the risk that they will not achieve these intended objectives. Any of these technological changes could cause our product candidates to perform differently and affect the results of planned or future clinical trials conducted with the materials manufactured using altered processes, such as impacting the specification and stability of the product. For example, we intend to develop a biologic-device combination for administration of GB-0895 with an autoinjector and PFS for ease of administration. Such changes may also require additional testing, notification or approval by the Regulatory Authorities. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials. Our product candidates may also prove to have a stability profile that leads to a lower than desired shelf life of the final approved product. This poses risk in supply requirements, wasted stock and higher cost of goods.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our product candidates. We may subsequently identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release product candidates until the manufacturing or testing process is rectified.

Moreover, there are risks inherent in biopharmaceutical manufacturing operations that could affect our ability and the ability of the CDMOs or contract manufacturing organizations to meet our delivery requirements or provide adequate amounts of material. The convergence of process and analytical technology, raw materials, consumables, equipment, physical infrastructure, including a clean room environment, and air handling and other utilities, results in complex procedures and systems that must work effectively to manufacture our product candidates. Failure or process defects in any of the interrelated systems at either our manufacturing facilities or those of our third-party providers could adversely impact our ability to manufacture and supply our product candidates.

Certain of our product candidates require specific shipping, storage, handling and administration, which in some cases, may require cold-chain logistics and subject our product candidates to risk of loss or damage if failures occur.

Certain of our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. The handling and administration of our product candidates may need to be performed according to specific instructions and in some steps within specific time periods. Failure to correctly handle our product candidates could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of product candidates. In addition, because it is necessary to ship our product candidates and other materials globally from manufacturing sites to clinical sites, our product candidates will need to be frozen using specialized equipment and maintained following specific procedures in order to be shipped and stored without damage in a cost-efficient manner and without degradation. For administration, the cryopreserved product container must be carefully removed from storage, and rapidly thawed under controlled temperature conditions in an area proximal to the patient's bedside and administered into the patient. The handling, thawing and administration of the cryopreserved therapy product must be performed according to specific instructions, typically using specific disposables, specific bags and in some steps within specific time periods. Failure to correctly handle our product candidates, including the potential breakage of the cryopreservation bags or to follow the instructions for thawing and administration and or failure to administer our product candidates within the specified period post-thaw could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of our clinical supply.

If any of our product candidates are approved, we will need to scale-up a cost-effective and reliable cold-chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale-up our cold-chain supply logistics, by us or third-parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for our commercial supply, if approved. For these and other reasons, we may not be able to manufacture our current or future product candidates at commercial scale or in a cost-effective manner. Even if we or our CDMOs are able to manufacture and distribute the products, if our products require specific procedures to maintain and use them, we may be limited in commercial opportunity.

We are subject to significant regulatory oversight with respect to manufacturing our product candidates. The manufacturing facilities of our CDMOs or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by the Regulatory Authorities could result in significant delays in and costs of our products.

The manufacturing of therapeutics for clinical trials or commercial sale is subject to extensive regulation. Components of a finished product approved for commercial use or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. Poor control of the cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive.

Such production process issues include, but are not limited to: critical deviations in the manufacturing process; facility and equipment failures; contamination of the product due to an ineffective quality control strategy; facility contamination as assessed by the facility and utility environmental monitoring program; ineffective process, equipment or analytical change management, resulting in failed lot release criteria; raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers; ineffective product stability; failed lot release or facility and utility QC testing; ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and failed or defective components or consumables.

We must supply all necessary documentation in support of a BLA or other marketing authorization application on a timely basis and must adhere to the cGMP requirements of the Regulatory Authorities which are enforced, in the case of the FDA, in part through its facilities inspection program.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with cGMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, the product approval to commercialize may not be granted. Inspections by regulatory authorities may occur at any time during the development or commercialization phase of products. The inspections may be product specific or facility specific for broader cGMP inspections or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may influence the ability of our CDMOs or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying product candidates.

The manufacturing process for any products that we may develop is subject to the approval process of the Regulatory Authorities, and we will need to contract with CDMOs who we believe can meet such requirements on an ongoing basis. If we or our CDMOs are unable to reliably produce product candidates to specifications acceptable to the Regulatory Authorities, we or our collaboration partners may not obtain or maintain the approvals we or they need to commercialize such products. Even if we or our collaboration partners obtain regulatory approval for any of our product candidates, there is no assurance that either we or our contract manufacturing organizations will be able to manufacture the approved product to specifications acceptable to the Regulatory Authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMPs. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the Regulatory Authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have limited control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CDMOs are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CDMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CDMOs' facility. Our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaboration partners) and our overall business operations. Our dependence upon others for the manufacture of our product candidates and raw materials may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The Regulatory Authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the Regulatory Authorities may require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls with respect to products produced by either our own facilities or those of our CDMOs could cause us and our collaboration partners to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While we will train and qualify all personnel around the appropriate handling of our products and materials, we may not be able to control or ultimately detect intentional sabotage or negligence by any employee or contractor.

Risks Related to Our Reliance on Third-Parties

We rely on and expect to continue to rely on third-parties to conduct aspects of our research, preclinical studies, clinical protocol development and clinical trials for our programs and product candidates. If these third-parties do not perform satisfactorily, comply with regulatory requirements or meet expected deadlines, we may not be able to develop product candidates in a timely or cost-effective manner, or obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We currently rely and expect to continue to rely on third-parties, such as contract research organizations ("CROs") clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials, including our Phase 3 clinical trials for GB-0895 in patients with severe asthma. We currently rely and expect to continue to rely on third-parties to conduct certain research and preclinical testing activities. In some cases, these third-parties may terminate their engagements with us. If we need to enter into alternative arrangements, it could delay our product development activities or increase our costs.

Our reliance on these third-parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulations, commonly referred to as Good Clinical Practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We are also responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the Regulatory Authorities for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the Regulatory Authorities may require us to perform additional clinical trials before approving our marketing applications. There is no assurance that the FDA or other Regulatory Authorities, upon inspection, will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in cGMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design the clinical trials for certain of our product candidates, our collaboration partners may design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will perform many of the activities required to conduct clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will, in many respects, be outside of our direct control. Our reliance on third-parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead to mistakes as well as difficulties in coordinating activities. Outside parties may: have staffing difficulties; fail to comply with contractual obligations; experience regulatory compliance issues; undergo changes in priorities or become financially distressed; form relationships with other entities, some of which may be our competitors; have human errors or be subject to cyber-attacks.

These factors may materially adversely affect the willingness or ability of third-parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform preclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

We also expect to rely on other third-parties to transport, store and distribute the required materials for our clinical trials. In the past, certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third-parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace.

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third-party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. For example, although we believe there are a number of other CROs we could engage, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, while we believe there may be suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition, results of operations and growth prospects.

We have in the past entered into, and in the future may enter into, partnership, collaboration and licensing arrangements with third-parties to support development of programs and product candidates. If these partnership, collaboration and licensing arrangements are not successful, our business could be adversely affected.

We have entered into or sought to enter into partnership, collaboration and licensing arrangements with third-parties, which we refer to generally as our “collaboration partners” for strategic purposes, including for purposes of collaborating with collaboration partners with distinctive capabilities or experience with different modalities, working with collaboration partners capable of advancing the development and commercialization of our product candidates, and providing access to additional capital.

For example, we are party to collaboration arrangements with Amgen, Novartis, MD Anderson and Roswell Park, pursuant to which we agreed to collaborate to discover and develop protein therapeutics. We expect to enter into additional partnership, collaboration and licensing arrangements to take advantage of our Generate Platform, including for purposes of accessing additional capabilities, expertise and funding in the future. Our existing partnership, collaboration and licensing arrangements, and any future partnership, collaboration and licensing arrangements we may enter into, could pose a number of risks, including the following:

- collaboration partners may not perform their obligations as expected;
- the clinical trials conducted as part of such partnership, collaboration and licensing arrangement may not be successful;
- collaboration partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the strategic collaborators’ focus or available funding, or external factors, such as an acquisition, which divert resources or create competing priorities;
- collaboration partners may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaboration partners could independently develop, or develop with third-parties, products that compete directly or indirectly with our product candidates if the strategic collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in partnership, collaboration and licensing arrangements with us may be viewed by our collaboration partners as competitive with their own candidates or products, which may cause collaboration partners to cease to devote resources to the development of our programs or the development or commercialization of our product candidates;
- a collaboration partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- disagreements with collaboration partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaboration partners may not properly maintain or defend our IP rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the interpretation of key terms regarding control, economic rights, or the ownership of intellectual property developed pursuant to our partnership, collaboration and licensing arrangements;
- collaboration partners may infringe the intellectual property rights of third-parties, which may expose us to litigation and potential liability;
- partnership, collaboration and licensing arrangements may, in certain instances, be terminated for the convenience of the collaboration partner and, if terminated, the development of our programs and product candidates may be delayed, or we may lose rights to IP or expertise related to such programs and products candidates, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, assume indebtedness or contingent liabilities, increase our near- and long-term expenditures, acquire intangible assets, issue securities that dilute our existing stockholders, disrupt our management and business, or otherwise impact our ability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs;
- we could face significant competition in seeking appropriate collaboration partners and the negotiation process and diligence process is time-consuming and complex; and
- our international operations, through any future partnerships, collaborations, acquisitions or joint ventures, may expose us to certain operating, legal, and other risks not encountered in the United States.

Whether we reach a definitive agreement for a partnership, collaboration or licensing arrangement will depend, among other things, on our assessment of the collaboration partner's resources and expertise, the terms and conditions of the proposed partnership, collaboration or licensing arrangement, and the potential collaboration partner's evaluation of a number of factors. Those factors may include, among others: (i) our technologies and capabilities, including our Generate Platform; (ii) our intellectual property position with respect to the subject program or product candidate; (iii) the design or results of clinical trials; (iv) the likelihood of approval by the Regulatory Authorities; (v) the potential market for the subject product candidate; (vi) potential competing products; and (vii) industry and market conditions generally. In addition, the significant number of business combinations among large pharmaceutical and biotechnology companies has reduced the number of potential future collaboration partners with whom we can partner.

Partnership, collaborations and licensing arrangements are complex and time-consuming to negotiate and document. We may have to relinquish valuable rights to our programs and product candidates, intellectual property or future revenue streams, or grant licenses on terms that are not favorable to us or in instances where it would have been more advantageous for us to retain sole development and commercialization rights. For some programs and product candidates, we depend on collaboration partners to design and conduct the clinical trials. As a result, we may not control the manner or time schedule in which these clinical trials are conducted, which may negatively impact our business operations. In addition, if any of our collaboration partners withdraws support for one or more of our programs or product candidates or otherwise impairs their development, our business could be negatively affected. In addition, management of our relationships with collaboration partners requires (i) significant time and effort from our management team; (ii) coordination of our marketing and research and development programs with the marketing and research and development priorities of our collaborators and (iii) effective allocation of our resources across multiple projects.

Partnerships, collaborations and licensing arrangements may never result in the successful development of programs or development and commercialization of product candidates or the generation of sales revenue. The success of these arrangements will depend heavily on the efforts and activities of our collaboration partners. Collaboration partners generally have significant discretion in determining the efforts and resources that they will apply to the development of programs and the development and commercialization of product candidates, and they may not pursue or prioritize the development and commercialization of such programs and product candidates in a manner that is in our best interests. Product revenues arising from partnership, collaboration and licensing arrangements are likely to be lower than if we directly marketed and sold products. Disagreements with collaboration partners regarding clinical development or commercialization matters can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, the termination of the partnership, collaboration or licensing arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Partnership, collaboration and licensing arrangements are often terminable by the collaboration partner, and any such termination or expiration would adversely affect us financially and could harm our business reputation. If we were to become involved in arbitration or litigation with any of our collaboration partners, it would consume time and divert management resources away from operations, damage our reputation, impact our ability to enter into future partnership, collaboration and licensing arrangements and may further result in substantial payments from us to our collaboration partners to settle those disputes.

We may not be able to establish additional partnership, collaboration and licensing arrangements on a timely basis, on acceptable terms, or at all, and to maintain and successfully conclude them. Such arrangements with third-parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return. If we are unable to establish or maintain partnership, collaboration and licensing arrangements on terms favorable to us and realize the intended benefits of those arrangements, our research and development efforts and potential to generate revenue may be limited and our business and operating results could be materially and adversely impacted.

Given the nature of our relationships with our collaboration partners, we often do not fully control the progression, clinical development, regulatory strategy or eventual commercialization, if approved, of our jointly-developed product candidates. As a result, our future success and the potential to receive revenues under these partnership, collaboration and licensing arrangements are significantly dependent on our collaboration partners' efforts, over which we have little control. If our partnership, collaboration and licensing arrangements do not result in the successful development and commercialization of product candidates, a collaboration partner determines not to proceed with the future development of a program or product candidate initially engineered or developed utilizing our Generate Platform, a collaboration partner implements a clinical or regulatory strategy that ultimately does not enable the further development, approval or commercialization of the product candidate, or a collaboration partner terminates its arrangement with us, we may not receive any future research funding or milestone, earnout, royalty or other contingent payments under such arrangement, which may have a material and adverse effect on our business and revenues. In addition, our ability to monitor the achievement of clinical, regulatory and commercial milestones by our collaboration partners and enforce the payment of any corresponding fees is limited. If we do not receive the funding we expect under these agreements, the development of our and our other collaboration partners' product candidates could be delayed and we may need additional resources to develop such product candidates.

In addition, in certain instances, our collaboration partners have the right to terminate their agreement with us for convenience. If one of our collaboration partners terminates its arrangement with us, we may find it more difficult to attract new partnership, collaboration and licensing arrangements and the perception of us in the business and financial communities could be adversely affected. We cannot assure investors that we will be able to maintain or expand our existing collaboration partners or that our Generate Platform will achieve adequate market acceptance among new collaboration partners. Any failure to increase penetration in our existing markets or new markets would adversely affect our ability to improve our operating results from our collaboration, partnership and licensing strategy.

All of the risks relating to product development, regulatory approval and commercialization described in this prospectus apply to the activities of our collaboration partners. If we and our collaboration partners do not receive regulatory approval for a sufficient number of product candidates originating from our Generate Platform, we may not be able sustain our business model.

We may seek to establish additional partnership, collaboration and licensing arrangements and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Certain of our partnership, collaboration and licensing arrangement may restrict our ability to develop certain products.

Our development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaboration partners. Whether we reach a definitive agreement for any additional partnership, collaboration and licensing arrangements will depend, among other things, upon our assessment of the collaboration partner's resources and expertise, the terms and conditions of the proposed partnership, collaboration or licensing arrangement and the proposed collaboration partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the Regulatory Authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to trial participants, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaboration partner may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional partnership, collaboration and licensing arrangements or other arrangements that we may establish may not be favorable to us.

We are also restricted under certain of our existing partnership, collaboration and licensing arrangement from entering into certain future agreements on certain terms with potential collaboration partners to pursue other targets on our own. These restrictions on working with targets could limit our ability to enter into partnership, collaboration and licensing arrangements with future collaboration partners or to pursue certain potentially valuable product candidates.

We may not be able to negotiate additional partnership, collaboration and licensing arrangements on a timely basis, on favorable terms or at all. Strategic alliances are complex and time-consuming to negotiate and document. If we are unable to negotiate and enter into new partnership, collaboration and licensing arrangements, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on favorable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our revenue under our partnership, collaboration and licensing arrangements for any particular period, or on an absolute basis, can be difficult to forecast.

Because of the complexities and long development timelines inherent in the drug development business, it is difficult to predict the timing of payments under our partnership, collaboration and licensing arrangements. In particular, payments under our partnership, collaboration and licensing arrangements are, in some cases, subject to the achievement of milestones and royalties, and our collaboration partner's decisions to initiate or continue the drug creation work, and any future downstream payments with respect to product candidates generated using our Generate Platform will be subject to our collaboration partner's advancement of our programs and product candidates, over which we have no control. As a result, our revenue for any particular period can be difficult to forecast. Our revenue may grow at a slower rate than in past periods or even decline on a year-over-year basis. Because of these factors, our operating results could vary materially from quarter to quarter from our forecasts. Also, due to the limited probability of success for advancement of a program or product candidate by a collaboration partner at any given stage of development and the unpredictability of when a collaboration partner may choose to continue development of a product candidate and whether any payments will be due to us, our revenue may be difficult to forecast on an absolute basis.

Additionally, we recognize revenue either as we perform our development activities, upon completion of performing our development activities or upon achieving certain clinical, regulatory, and commercialization milestones. As a result, much of our revenue is generated from agreements entered into during previous periods. Consequently, a decline in demand for our Generate Platform, a decline in new or renewed business in any one quarter or any delays in the achievement, or any failure to achieve, development, regulatory and commercial milestones by our collaboration partners with respect to product candidates generated using our Generate Platform, may not significantly reduce our revenue for that quarter but could negatively affect our revenue in future quarters. Our revenue recognition model also makes it difficult for us to rapidly increase our revenue through increased operations in any period, as revenue from collaboration partners is recognized over the course of their drug development and commercialization efforts.

Our collaboration partners have significant discretion in determining when and whether to make announcements, if any, about the status of our collaborations, including about preclinical and clinical developments and timelines for advancing collaborations, and the price of our common stock may decline as a result of announcements of unexpected or negative results or developments.

Our collaboration partners have significant discretion in determining when and whether to make announcements about the status of our partnerships, including about preclinical and clinical developments and timelines for advancing product candidates generated using our Generate Platform. We do not generally plan to disclose the development status and progress of individual product candidates of our collaboration partners, unless those collaboration partners have publicly disclosed such information or permit us to make such disclosures. Our collaboration partners may wish to report such information more or less frequently than we expect, or they may not report such information at all, in which case we would not report that information either, unless material to our financial statements. Certain of our collaboration partners may in the future make statements about their goals and expectations for collaborations with us. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or our current and future collaboration partners' drug discovery and development programs, the amount of time, effort, and resources committed by us and our current and future collaboration partners, and the numerous uncertainties inherent in the development of drugs. In addition, if a collaboration partner chooses to announce a collaboration with us, there is no guarantee that we will receive payments related to collaboration revenue in that quarter or even the following quarter, as such payments are only payable to us in accordance with the terms of the agreements governing such collaborations. The price of our common stock may decline as a result of the public announcement of unexpected results or developments in our collaborations, or as a result of our collaboration partners withholding such information.

Risks Related to Our Intellectual Property

Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to adequately protect and/or enforce our intellectual property.

Our success depends, in large part, on our ability to obtain and maintain patents, trademarks, trade secrets, know-how and other intellectual property rights and proprietary technology relating to our Generate Platform and our product candidates, as well as our ability to successfully enforce our rights against third-party infringers and/or defend our intellectual property against third-party challenges or misappropriation. If we (or our licensees or licensors who may have the right to prosecute or enforce certain patents within our portfolio) fail to appropriately prosecute or are unable to obtain and maintain patent protection for our product candidates (or aspects thereof), our ability to develop, license and/or commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using, selling or importing competing products. This failure or inability to properly or adequately protect the intellectual property rights relating to these product candidates could have a material adverse effect on our business, financial condition, results of operations and/or growth prospects.

The use of AI to engineer proteins is a relatively new scientific field, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the field. In general, patents are reserved for human inventors and significant and novel regulatory questions remain in flux about the contributory roles of AI versus the human inventors in securing intellectual property rights. We have obtained grants and issuances of certain patents relating to our Generate Platform and some of our product candidates. The issued patents and pending patent applications that we own or in-license in the United States and in key markets around the world, claim different aspects relating to our product candidates and to the engineering, development, manufacture and commercialization of other potential product candidates including, but not limited to, compositions and methods of use.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining, maintaining, enforcing and defending patents. Patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. These risks and uncertainties include the following:

- patent applications may not result in any patent being issued;
- patents that may be issued may not include claims that cover a broad enough scope to prevent alternative solutions by competitors;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide adequate barriers to entry or any competitive advantage;
- because of the extensive time required for development, testing and regulatory review of a product candidate, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization thereby reducing, or eliminating any advantage of the patent;
- our competitors, many of which have substantially greater resources than we or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with or eliminate our ability to make, use and sell our product candidates;
- there may be significant pressure on the U.S. government and other governmental bodies to limit the scope of patent protection or impose compulsory licensing of patent rights for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have less robust patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products using our technologies and patents; and
- we may be involved in lawsuits and/or proceedings before government agencies, such as patent offices, to defend or enforce our patents or the patents we have rights to enforce, which could be expensive, time-consuming, distracting and/or unsuccessful.

In addition to patents, we also rely on proprietary source code, trade secrets and know-how. Although we have taken steps to protect our unpatented proprietary source code, trade secrets and know-how, including maintaining data security protocols and capabilities and entering into confidentiality agreements with third-parties, and confidential information and assignment agreements with employees, consultants and advisors, there exists the potential that third-parties may still somehow obtain this information or arrive at the same or similar information independently, which could reduce or eliminate our competitive advantages. Moreover, we may become subject to allegations that we directly or indirectly (through our consultants, advisors or independent contractors that we may engage to assist us in developing our product candidates) have wrongfully or inadvertently disclosed, acquired or used trade secrets or other proprietary information of third-parties.

We may be forced to litigate to enforce or defend our intellectual property rights.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets and know-how against unauthorized use, but we may not be able to detect or prevent, alone or with our licensors, infringement, misappropriation or other violation of our intellectual property rights. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable or limited or narrowed in scope such that we may no longer be able to adequately prevent the manufacture, sale or import of competitive product. In an infringement proceeding, a court may decide that a patent we own or a patent we may license in the future is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office (the "USPTO"), may place pending applications at risk of non-issuance or limitations in scope. Further, derivation proceedings, *ex parte* reexamination, inter partes review, post grant review and opposition proceedings provoked by third-parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope or validity of our patents. Additionally, because of the substantial amount of discovery typically required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information, trade secrets or know-how could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the value of the company. Such litigation or proceedings could substantially increase our operating losses. reduce the resources available for development activities or any future sales, marketing or distribution activities and distract our personnel from their normal responsibilities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

The U.S. government and/or government agencies have provided funding or other assistance in connection with the development of the intellectual property rights owned by or licensed to us and if we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh Dole Act of 1980 (the "Bayh Dole Act").

The U.S. government and/or government agencies have provided funding or other assistance in connection with the development of the intellectual property rights owned by or licensed to us, and if we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh Dole Act. To the extent any of our current and future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh Dole Act may similarly apply. If we enter into future arrangements involving government funding, any exercise by the government of certain rights could harm our competitive position, business, financial condition, results of operations and growth prospects.

U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for governmental purposes. In addition, the U.S. government would have the right to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third-party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations, which are referred to as march-in rights. The U.S. government will also have the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that under the circumstances domestic manufacture is not commercially feasible.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts.

Our commercial success depends in part on our ability and the ability of any of our future partners to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing on the intellectual proprietary rights of third-parties. There is a substantial amount of litigation and patent office proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology, biopharmaceutical, pharmaceutical and high-tech industries, including patent infringement lawsuits, oppositions, ex parte reexaminations, post-grant review, inter partes review and interference proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third-parties, exist in the fields in which we are pursuing product candidates.

Third-parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with that purport to claim compositions, formulations, methods of manufacture or methods for treatment relating to our product candidates, their manufacture or use. Because patent applications in most countries remain confidential for a period of time after they are filed (commonly, 18 months), it is possible that there are unpublished patent applications that may later issue with claims that our product candidates may be alleged to infringe. Because patent applications can take many years to issue, there may be pending patent applications which do not currently seem relevant, but may later result in issued patents that our product candidates may be alleged to infringe. In addition, third-parties may obtain patents in the future and then allege that our technologies infringe upon these patents. Additionally, under U.S. patent law, a patent owner may seek a reissue within two years of issuance of a patent to broaden the scope of that patent's claims. As a result, patents that, at the time of issuance, do not appear relevant to our activities may later be broadened in a manner that could impact our business. We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we or our licensors have identified or will identify each and every third-party patent and pending patent application in the U.S. and abroad that is relevant to or necessary for the development, manufacture, and commercialization of our current and future products and product candidates in any jurisdiction. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent application will issue with claims of relevant scope. Alternatively, we may incorrectly determine that the Hatch-Waxman Amendments (as defined below) are a defense for a safe harbor to infringement of a patent we consider relevant to the research or clinical development of our product candidates. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, manufacture and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

If a third-party alleges that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property allegations, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention and financial resources from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees (and, in certain jurisdictions outside of the U.S., we could be ordered to pay the patent owner's attorneys' fees even without such finding);

- a court prohibiting us from developing, manufacturing, importing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to use, which it is not required to do;
- even if a license is available from a third-party, which may not be available, we may have to pay substantial royalties, upfront fees, milestones and other amounts and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot successfully defend against infringement allegations or obtain a license on commercially reasonable terms to relevant third-party patents that cover our product candidates. Even if we have a strong defense and/or believe that third-party intellectual property allegations are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability and/or priority. A court of competent jurisdiction could hold that these third-party patents are valid and enforceable and have been infringed upon, which could materially and adversely affect our ability to commercialize our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is high, which requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the asserted claims of any such U.S. patent.

If we are found to infringe a third-party's intellectual property rights, and we are unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to pay damages and/or an ongoing royalty or obtain a license from such third-party to continue developing, manufacturing, and marketing our product candidates and our technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be non-exclusive, thereby giving our competitors and other third-parties access to the same technologies licensed to it, and it could require us to pay substantial licensing fees and/or make ongoing royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be temporarily or permanently forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed on a patent or other intellectual property right.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have acquired patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others.

We may not be successful in obtaining or maintaining necessary intellectual property rights to product components and manufacturing processes for our development pipeline.

At present, we have rights to certain intellectual property, through licenses from third-parties and under patent filings that we own to develop our product candidates. Because our pipeline may involve additional product candidates that could require the use of proprietary rights held by third-parties, the growth of our business could depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific pharmaceutical formulations to work effectively and efficiently, and these rights may be held by others. We may be unable to acquire or in-license intellectual property rights that may be necessary to permit us to implement our platform technologies or develop, manufacture or use our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Further, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the third-party may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our product candidate and enabling our competitors to compete with our product candidate.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

Our rights to develop and commercialize our product candidates are, and in the future, may be subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third-parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are dependent on patent rights, know-how and proprietary technology licensed or otherwise acquired from third parties, and we may also enter into additional agreements with third-parties in the future. Our current license agreements with third parties impose, and may in the future impose additional diligence, development and commercialization timelines, milestone payments, royalties, indemnification, insurance, non-competes or other obligations on us. If we fail to comply with our obligations to our licensors, collaborators or other third parties, our counterparties may have the right to terminate or take other actions under these agreements. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology that are necessary for our business. In particular, we depend substantially on our license agreement with Flagship Pioneering Inventions VI, LLC ("Flagship"), pursuant to which we in-license patent rights, know-how and other rights that cover, among other things, GB-0895 and certain aspects of our proprietary AI models (the "Flagship License Agreement"). As described elsewhere in this prospectus, Flagship Pioneering may terminate the Flagship License Agreement for cause under specified circumstances. In addition, under the Stock Purchase Agreement with PM LLC, which will replace our current collaboration with PMCo, we are subject to certain new diligence, non-compete and reporting obligations, including with respect to the development of product candidates in various countries. If we breach these obligations, PM LLC may have the right to acquire development and commercialization rights in the applicable country, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. For more information, see the section titled "*Business—License and Collaboration Agreements.*"

Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property. Further, certain patent filings relating to our product candidates may now or in the future be subject to step-in rights of certain of our licensors. We have limited control over certain of our licensors', and may in the future have limited control of our other licensors', prosecution activities or use or licensing of any other intellectual property that may be related to our in-licensed intellectual property. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue from these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. If any of our licensors or licensees having rights to file, prosecute, maintain and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors or other third-parties from making, using or selling competing products. In addition, we may sublicense certain of our rights under various third-party licenses to our collaboration partners. Any impairment of these sublicensed rights could result in reduced revenues under our partnership, collaboration or licensing arrangement or result in termination of an agreement by one or more of our collaboration partners. In addition, intellectual property rights that we may in-license in the future may be sublicensed under intellectual property owned by third-parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with our licensors, such licensors may have the right to control enforcement of our licensed patents or defense of any allegations asserting the invalidity of such patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors or, in some cases, other necessary parties, such as any co-owners of patents or other intellectual property from which we have not yet obtained a license. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such allegations to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of allegations asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after assuming control.

Our current or future license agreements may not provide exclusive or sufficient rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates in the future. Some licenses granted to us may be subject to certain preexisting rights held by the licensors or certain third-parties. As a result, we may not be able to prevent third-parties from developing and commercializing competitive products in certain territories or fields.

In the event that our third-party licensors or other counterparties determine that, in spite of our efforts, we have breached a license agreement or have failed to meet certain obligations thereunder, it may elect to terminate the applicable agreement or, in some cases, one or more licenses under such agreement or otherwise restrict our rights under the agreement. Such termination or restriction of rights could result in us losing the ability to develop and commercialize product candidates and technology covered by the licensed intellectual property. In the event of such termination, or if the underlying patent rights under a third-party in-license or other agreement fail to provide the intended exclusivity, third-parties may be able to seek regulatory approval of, and to market, products identical to ours and we may be required to cease the development and commercialization of our product candidates. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to allegations, regardless of their merit, that we are infringing or otherwise violating a licensor's rights. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, the agreements under which we license or otherwise acquire intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes may also arise between us and our licensors or other counterparties regarding intellectual property subject to a license agreement, including: the scope of rights granted under the agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement; our right to sublicense patent and other rights to third-parties under collaborative development relationships; our diligence obligations with respect to the use of the licensed or otherwise acquired technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaboration partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If we are unable to protect the confidentiality of our proprietary trade secrets or know-how, our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon proprietary source code and know-how protection and data security protocols and capabilities, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors and other third-parties to execute confidentiality agreements upon the commencement of employment, consulting or business relationships with us. These agreements generally provide that all confidential information concerning our business or financial affairs developed by or made known to an individual or entity during the course of that party's relationship with us are to be kept confidential and not disclosed to third-parties, except in certain specified circumstances. In the case of employees, the agreements also provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third-party service providers, the agreements provide us with certain rights to all inventions arising from the services provided to us by those individuals or entities. However, we cannot guarantee that we have entered into agreements with each party that may have or have had access to our proprietary technologies and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or assignment agreements may be breached, and we may be forced to bring claims against third-parties, or defend allegations that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not be able to obtain adequate remedies for any breaches of such agreements. Ultimately, enforcing a claim that a party wrongfully or illegally disclosed or misappropriated trade secrets or know-how can be difficult, expensive and time consuming, and the outcome is unpredictable.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect despite these precautions. Such measures may not, for example, in the case of misappropriation of trade secrets or know-how by an employee, former employee, or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee, former employee, or consultant from misappropriating our trade secrets or know-how and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party wrongfully or illegally disclosed or misappropriated trade secrets or know-how can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets and know-how may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets or know-how, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our competitive position could be harmed.

Certain former employees have obtained employment with companies or academic institutions that could be considered competitive with us and are operating their business in areas that are similar to ours, including in their business model, product design efforts, product development or formulation technology. This competition may be limited by contractual provisions which may or may not be enforceable by us in the Commonwealth of Massachusetts or other jurisdictions. In addition, we may not be aware of such competitive employment arrangements until after our trade secrets or know-how has been disclosed to potentially competitive companies.

If we choose to go to court to stop a third-party from using any of our trade secrets or know-how, we may incur substantial costs. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets or know-how. Even if we are successful, these types of lawsuits may consume, in addition to substantial costs, significant amounts of our time and other resources. We may also need to share our proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may be subject to allegations that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third-parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology industry, we employ individuals, including certain of our key employees, who are or were previously employed at academic institutions or other biotechnology companies, including our competitors or potential competitors. For example, our co-founder, Dr. Gevorg Grigoryan, Ph.D., has held various positions at Dartmouth College since 2017. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to allegations that we, or our employees, consultants or independent contractors, have inadvertently or otherwise used or disclosed intellectual property, including trade secrets, know-how or other proprietary information, of any of our employees' former employers or other third-parties. Litigation may be necessary to defend against these allegations. If we fail in defending any such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such allegations, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to allegations challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to allegations that former employees, collaborators or other third-parties have an ownership interest in our patents or other intellectual property. Ownership disputes may arise, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other allegations challenging inventorship or ownership. If we fail in defending any such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse impact on our business. Even if we are successful in defending against such allegations, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third-parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by

governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid to the USPTO and various non-U.S. patent agencies in several stages over the lifetime of the patents or applications. The USPTO and non-U.S. patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse impact on our business.

In addition, public health pandemics, geopolitical instability, natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our product candidates. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the U.S., China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (*e.g.*, items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our collaboration partners were to initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent subject matter eligibility, novelty, non-obviousness, written description and/or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third-parties may also raise similar allegations before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include ex parte reexamination, inter partes review, post grant review, interference proceedings and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of patent rights covering a product candidate, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1).

If we do not obtain sufficient patent term for our product candidates, our business may be materially harmed.

Patents have a limited term. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from the earliest non provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and also depends upon many factors, including the type of patent, the scope of coverage, the availability of regulatory related extensions, the availability of extensions for patent office delays during the examination process, the availability of legal remedies in a particular country and the validity and enforceability of the patent, and whether a portion of the patent term has been terminally disclaimed based on other patents. These factors may emerge and change over the course of time, and accordingly, a patent's expiration date might change over time in unpredictable ways. Various extensions including patent term extension and patent term adjustment may be available, but the lives of such extensions, and the protections they afford, are limited in the United States and other countries and regions. Additional patent terms may be available through a patent term adjustment process in the United States, resulting from USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generics or biosimilars.

Depending upon the timing, duration and specifics of FDA regulatory approval of our product candidates, one or more patents issued from U.S. patent applications that we or a future licensor file may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A maximum of one patent may be extended per FDA-approved drug as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates.

Despite the possibility of an extension, we may not be granted an extension in the United States or another jurisdiction because of, for example, failure to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than we request.

For biologics, separate non-patent exclusivity under the BPCIA may apply. The FDA cannot make approval of a biosimilar effective until 12 years after the reference product's first licensure, but policy changes could affect the scope or duration of this exclusivity, and competitors may nonetheless pursue full BLAs. As a result, even with patents and any extensions, competition from biosimilars or other biologics could occur earlier than anticipated.

If we are unable to obtain patent term extension or restoration, or the foreign equivalent, or the term of any such extension is less than we request, our competitors or other third-parties may obtain approval of competing drugs following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors or other third-parties may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case. Any of the foregoing could materially harm our business, financial condition, results of operations and growth prospects.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies and innovations in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the U.S. or Europe. These products may compete with our product candidates, and our and our licensors' future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the U.S., but may issue as patents with claims of different scope or may even be refused in other jurisdictions. Furthermore, the requirements for patentability differ in certain jurisdictions and countries. Some countries do not grant claims directed to methods of treatment or have additional restrictions on the scope of method of treatment claims compared to the U.S. Accordingly, depending on the country, the scope of patent protection may vary for the same product candidate.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain protection efforts in all such markets. Additionally, the prosecution of patent applications in other jurisdictions is often a longer process and patents may be granted at a later date than in the U.S., potentially delaying our ability to assert such patents against competitors. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S. and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property rights, which could make it difficult for us to stop the infringement of any patents we obtain or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we obtain at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third-parties to legal claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third-parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third-parties with respect to any patents relevant to our business, our competitive position may be impaired.

In Europe, a new unitary patent system took effect on June 1, 2023, which may significantly impact European patents, including those granted before the introduction of the new system. Under the new system, applicants can, upon grant of a European patent, opt for that patent to become a unitary patent which will be subject to the jurisdiction of a new unitary patent court (“UPC”). During the first seven years of the UPC’s existence, patents granted before the implementation of the new system can be opted out of UPC jurisdiction, and validated as national patents in any one or more of the UPC countries. We may decide to opt out future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. Patents that are under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that, if successful, could invalidate the patent in all countries who are signatories to the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Further, because the UPC is a new court system and there is no precedent for the court’s laws, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market. In addition to changes in patents laws, geopolitical dynamics, such as Russia’s invasion of Ukraine, may also impact our ability to obtain and enforce patents in particular jurisdictions, such as the enforcement of patent rights in Russia. If we are unable to obtain and enforce patents as needed in particular markets, our ability to exclude competitors in those markets may be reduced.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biotechnology industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and in other major jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent rulings from the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of issued patents. Depending on future actions by the U.S. Congress, federal courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the federal courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

The USPTO has issued subject matter eligibility guidance instructing USPTO examiners on the ramifications of the Supreme Court rulings in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, and applied the *Myriad* ruling to natural products and principles including all naturally occurring molecules. In addition, the USPTO continues to provide updates to its guidance that may make it impossible for us to obtain similar patent claims in future patent applications. Currently, our patent portfolio contains claims of various types and scope, including methods of medical treatment. The presence of varying types of claims in our patent portfolio significantly reduces, but may not eliminate, our exposure to potential validity challenges alleging a lack of subject matter eligibility. Furthermore, U.S. Court of Appeals for the Federal Circuit has held that an inventor on a U.S. patent must be a natural person and not a machine or AI. As a result, AI systems, regardless of their sophistication, cannot be named as inventors or joint inventors on a patent application as they are not natural persons. The USPTO has recently issued inventorship guidance for AI-assisted inventions. Given that we use AI in certain aspects of our Generate Platform, certain AI-assisted inventions may be deemed ineligible for patent protection if it is determined that there is not a sufficient level of human inventive contribution.

For our U.S. patent applications, which contain claims entitled to priority date after March 16, 2013, there is a greater level of uncertainty due to the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), which was signed into law on September 16, 2011. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These included provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act did not come into effect until March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either: (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third-parties to challenge any issued patent in the USPTO. These new post grant challenges include post grant review and inter partes review proceedings before the Patent Trial and Appeal Board at the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. However, recent changes at the USPTO have resulted in many fewer inter partes review proceedings being instituted, and the USPTO has proposed modifications to the rules of practice for implementing inter partes review proceedings. The proposed modifications, if adopted, could impact the ability of third-parties, including us, to challenge the validity of granted U.S. patents before the USPTO.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine resulted in Russia issuing Decree No. 299 that effectively nullifies the enforcement of Russian patents owned by entities and individuals in "unfriendly" countries, including the U.S.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated or successfully challenged. If our trademarks and trade names are not adequately protected, or if we are unable to obtain desired trademarks or trade names, then we may not be able to build brand name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from third-party products. Once we select new trademarks and apply to register them, our trademark applications may not be approved. During trademark registration proceedings in the U.S. and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections.

We have also not yet registered trademarks for any of our product candidates in any jurisdiction. Any trademark applications we file may be rejected and registered trademarks may not be obtained, maintained or enforced. If we do not successfully register our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our trademark rights against third-parties, which could adversely affect our business and our ability to effectively compete in the marketplace.

In addition, any proprietary name we propose to use with any of our product candidate in the U.S. will need to be approved by the FDA, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA conducts a review of proposed proprietary names, including an evaluation of potential for confusion with other products' proprietary names, as part of the BLA review process. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary name that would qualify under applicable trademark laws, not infringe the existing rights of third-parties and be acceptable to the FDA.

In addition, our unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, or determined to be infringing on, misappropriating or violating other marks. In the USPTO and in comparable agencies in many foreign jurisdictions, third-parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark registrations may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion.

Our competitors may also infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. We may not be able to protect our rights to our trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. Any of the foregoing events may have a material adverse effect on our business.

Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement allegation asserted by the owner of a senior trademark. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain names or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit it to maintain our competitive advantage. For example:

- our product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms;
- others may be able to make similar molecules to our product candidates that are not covered by the claims of the patents that we license or own now or in the future;
- we, or current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions, potentially resulting in the invalidation of such patents or refusal of such applications;
- we, or current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future.
- we, or current or future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents;
- it is possible that there are unpublished patent applications that may later issue with claims covering our product candidates or technology similar to ours;
- it is possible that our patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or result in a change in ownership;

- issued patents to which we hold rights may be held invalid, unenforceable or narrowed in scope, including as a result of legal challenges;
- the claims of our issued patents or patent applications, if and when issued, may not cover our product candidates or narrowly cover them in such a way that competitors may be able to design around to avoid infringement allegations;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of current or future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that are similar to or alternative to those claimed in our patent filings or become hostile to our patents or patent applications on which they are named as inventors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and we intend to continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the product candidates we develop may be covered by third-party patents or other intellectual property rights;
- the patents of others may prohibit or otherwise harm our ability to conduct our business; or
- we may choose not to file a patent in order to maintain certain know-how, and a third-party may subsequently commercialize the technology and/or file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to the Commercialization of Our Pipeline

We have no sales, distribution or marketing experience, and may invest significant financial and management resources to establish these capabilities. If we are unable to establish such capabilities or enter into agreements with third-parties to market and sell our future products, if approved, we may be unable to generate any revenues.

Given our stage of development as a company, we have no sales, distribution or marketing experience. To successfully commercialize any products that may result from our programs, we will need to develop sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of these product candidates. Any failure or delay in the development of our or third-parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- inadequate funding;
- our inability to recruit and retain an adequate number of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade an adequate number of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We may enter into partnership, collaboration and licensing arrangements with third-parties to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If these third-parties do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product revenue to sustain our business. We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third-parties, we will not be successful in commercializing our product candidates.

The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any drugs that we develop.

The biopharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations, known and unknown, are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the engineering, development, manufacture and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals and in manufacturing, marketing and selling products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Accordingly, our competitors may be more successful than us in obtaining patent protection, regulatory exclusivities or FDA approval and commercialize products or achieve widespread market acceptance more rapidly than we do, which may impact future approvals or sales of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receives regulatory approval but cannot compete effectively in the marketplace.

In addition, our competitors may develop partnership, collaboration and licensing arrangements with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors may also succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates, which could render our product candidates obsolete and noncompetitive. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

We expect to face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop products. We also expect to face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of the conditions for which we are trying, or may in the future try, to develop products. These drugs may be more effective, safer, less expensive or marketed and sold more effectively, than any products we develop. In most cases, we do not currently plan to run head-to-head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

If we successfully develop any product candidates, and obtain approval for them, we expect to face competition based on many different factors, including: the safety and effectiveness of our products relative to alternative therapies, if any; the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration; the timing and scope of regulatory approvals for these product candidates; the availability and cost of manufacturing, marketing and sales capabilities; the price of any approved product; reimbursement coverage; and patent position. See the section titled "*Business—Competition*" included elsewhere in this prospectus for examples of the competition that we face.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third-parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

The commercial success of any current or future product candidate, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients and third-party or governmental payors, and our products in particular, as medically useful, cost-effective and safe. Furthermore, ethical, social and legal concerns about the application of AI to research and development of products could result in additional regulations restricting access to or otherwise limit demand for our products. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: the potential efficacy and potential advantages over alternative treatments; the ability to offer our products, if approved, at competitive prices; the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling; the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered; relative convenience and ease of administration; any restrictions on the use of our products, if approved, together with other medications; the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; the strength of marketing and distribution support and timing of market introduction of competitive products; publicity concerning our products or competing products and treatments; and sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our product candidates.

Even if we are successful in getting marketing approval for any product, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and entry into managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products once approved, whether due to healthcare reform legislation or otherwise, market acceptance and commercial success would be reduced.

In addition, if any of our products are approved for marketing, we or a collaboration partner will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such product, and will need to continue to comply (or ensure that our third-party providers comply) with current cGMP and GCPs for any clinical trials that we or a collaboration partner conduct post-approval. In addition, there is always the risk that we or a collaboration partner or regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third-parties. Recent and ongoing changes in the United States trade policy with foreign countries, including the continued uncertainty surrounding U.S. tariffs and potential retaliatory measures by foreign governments may disrupt the global supply chain for biopharmaceutical products. For example, in September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of APIs and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. Any direct tariffs, if imposed on pharmaceutical products, may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical contract manufacturing organizations, and a delay in our development timelines.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

We are subject to export and import controls, economic sanctions and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

Because we plan to market our products, if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States including, an increase in our expenses, diversion of our management's attention from the acquisition or development of product candidates or forgoing profitable licensing opportunities in these geographies. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: efforts to develop an international sales, marketing and distribution organization; changes in a specific country's or region's political and cultural climate or economic condition; unexpected changes in foreign laws and regulatory requirements; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in foreign countries; trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges; the effects of applicable foreign tax structures and potentially adverse tax consequences; and significant adverse changes in foreign currency exchange rates.

In addition to FDA and related regulatory requirements in the United States and abroad, we are subject to extensive additional federal, state and foreign anti-bribery regulations, which include the U.S. Foreign Corrupt Practices Act, U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the UK Bribery Act 2010 and similar laws in other countries outside of the United States. We are developing and implementing a corporate compliance program based on what we believe are current best practices in the biotechnology industry for companies similar to ours, but we cannot guarantee that we, our employees, our consultants or our third-party contractors are or will be in compliance with all federal, state and foreign regulations regarding bribery and corruption. Moreover, our collaboration partners and third-party contractors located outside the United States may have inadequate compliance programs or may fail to respect the laws and guidance of the territories in which they operate. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations.

The insurance coverage and reimbursement status of newly approved products, in a new category of medicines, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments such as the products that we hope to develop and sell. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment in any of our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational. For example, GB-4362, for which an IND was cleared by the FDA in December 2025, is currently being considered as a potential supportive care treatment to ameliorate important and deleterious side effects of certain cancer treatments, and third-party payors have been known to closely scrutinize the value proposition offered by supportive care treatments.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. The Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"), determines whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for our product candidates that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many biopharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Outside the United States, certain countries, including a number of member states of the European Union (the "Member States"), set prices and reimbursement for pharmaceutical products, or medicinal products, as they are commonly referred to in the European Union, with limited participation from the marketing authorization holders. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaboration partners. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaboration partners, our revenues from sales by us or our collaboration partners and the potential profitability of our products in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world but have been most drastic in the European Union.

Additionally, the requirements governing product pricing vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed, while in others, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

For more information on the laws and regulations that may impact coverage and reimbursement of our product candidates, see the section titled "*Business—Government Regulation—Coverage and Reimbursement*" and "*—Healthcare Reform*" included elsewhere in the prospectus.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See the sections titled "*Business—Government Regulation—Coverage and Reimbursement*" and "*—Healthcare Reform*" included elsewhere in this prospectus.

The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products.

For example, the Inflation Reduction Act of 2022 (the "IRA") includes several provisions that will impact our business to varying degrees, including provisions that allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, among others.

Further, the IRA also imposed rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products.

The One Big Beautiful Bill Act (the "OBBBA") also included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our revenue and commercial prospects.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and became applicable in January 2025, is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit Member States to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual Member States will continue to be responsible for assessing nonclinical (*e.g.*, economic, social, ethical) aspects of health technologies and making decisions on pricing and reimbursement.

These laws, and future supranational, national state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

The estimates of market opportunity and forecasts of market growth included in documents that we file with the Securities and Exchange Commission (the "SEC") may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Although we are initially focused on developing and commercializing GB-0895 for the treatment of severe asthma, we also plan to evaluate developing GB-0895 for the treatment of COPD, such evaluation to take into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial. In addition, an important area of focus of our research and product development activities is the development of treatments for severe rare genetic diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates and independent market research, industry and general publications obtained from third-parties. Market opportunity estimates and growth forecasts included in this prospectus and the other documents that we file with the SEC are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. Additionally, the potentially addressable patient population may not ultimately be amenable to treatment with our product candidate if we cannot achieve our intended dosing interval. Our market opportunity may also be limited by current and future products of our competitors that are already available in the market or may enter the market for such patients. If any of our estimates prove to be inaccurate, the market opportunity for our product candidates could be significantly diminished and have an adverse material impact on our business.

The market opportunities of some of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and for which the market opportunities may be small.

In some therapeutic areas, like oncology, the FDA often approves new therapies initially only for use by patients with relapsed or refractory advanced disease. For example, we are developing GB-5267 in collaboration with Roswell Park and plan to conduct a Phase 1 clinical trial in patients with relapsed or refractory platinum-resistant ovarian cancer in 2026. In the event GB-5267 proves to be sufficiently beneficial we would expect that approval could be sought in earlier lines of treatment and potentially as a first line therapy but there is no guarantee that GB-5267 or any other product candidates targeting relapsed or refractory diseases, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

In addition, our projections of both the number of people who have platinum-resistant ovarian cancer or other cancers we may be targeting, as well as the subset of people with these cancers in a position to receive second- or third-line therapy, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our products, if approved, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Off-label use or misuse of our product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

If our product candidates are approved by the FDA, we will only promote or market them in a manner consistent with their approved labeling. We will train our marketing and sales force to comply with laws and regulations restricting the promotion of our product candidates for uses outside of the indications for use approved by the Regulatory Authorities, known as "off-label uses." Physicians are permitted to prescribe medications for off-label conditions and indications not listed on these approved labels. Furthermore, the use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation. Similar requirements and considerations apply abroad.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, and false claims laws. If we are unable to comply, or have not fully complied with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations that will impact, among other things, our proposed sales, marketing, and educational programs. The laws that will affect our operations include, but are not limited to the following:

- The federal Health Care Program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.
- The federal civil and criminal false claims laws and civil monetary penalty laws prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.
- The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- The U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices.
- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.
- Federal government price reporting laws, which require drug makers to calculate and report complex pricing metrics in an accurate and timely manner to government programs.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- State law equivalents of each of the above federal laws and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures are also applicable to us and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including certain consulting agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options could be subject to challenge under one or more such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, mandatory or discretionary exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization or the regulatory authorities of the individual Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and we may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against allegations that our product candidates caused injuries, or we failed to warn of potential injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, allegations of liability may result in decreased demand for any product candidate that we may develop; loss of revenue; substantial monetary awards to patients, healthy volunteers or their children; significant time and costs to defend the related litigation; withdrawal of clinical trial participants; the inability to commercialize any product candidate(s) that we may develop; and injury to our reputation and significant negative media attention.

We carry product liability insurance which we believe to be sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Risks Related to Our Business Operations and Employee Matters

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology industry depends upon our ability to attract and retain highly qualified managerial, scientific, technical and medical personnel. We are highly dependent upon members of our management, as well as technology and scientific teams, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the development of our Generate Platform and our pipeline. Each of the members of our management team, and all of our employees, including key technical personnel, scientists and clinicians, are employed "at will," meaning we or each officer or employee may terminate the employment relationship at any time. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have "key person" insurance on any of our employees. Many of our key employees, including members of our leadership team, have been with us for an several years, and have a significant amount of fully vested stock options or other long-term equity incentives which may become valuable and will be publicly tradable if we become a public company. We may not be able to retain these employees due to the competitive environment in the biotechnology industry, particularly in the greater Boston, Massachusetts region.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly added capability and capacity through the use of contractors. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel, including in AI, research, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

Our information technology systems or our infrastructure may fail or experience security breaches and incidents that could adversely impact our business and operations and subject us to liability.

Our information technology systems and data are vulnerable to compromise or damage from cybersecurity attacks or accidents. We have experienced significant growth in the complexity of our data and the software tools that our hardware infrastructure supports. We rely significantly upon information technology systems and infrastructure owned and maintained by us or by third-party providers to generate, collect, store and transmit confidential and proprietary information and data (including but not limited to intellectual property, proprietary business information and personal information) and to operate our business. We also outsource elements of our operations to, and obtain products and services from, third-parties and engage in collaborations for drug design with third-parties, each of which has or could have access to our confidential or proprietary information. Our employees on occasion travel to countries which are at elevated risk of cyber-intrusion, data theft and expropriation.

We deploy and operate an array of technical and procedural controls to reduce the risks to our information technology ("IT") systems, infrastructure and data and to work to maintain the availability, confidentiality and integrity of our data, and we expect to continue to incur significant costs on such detection and prevention efforts. While we continue to make investments to improve the protection of data and information technology, including in the hiring of qualified IT personnel, periodic cyber security awareness trainings, improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions or security breaches. Despite these measures, our information technology and other internal infrastructure systems face the risk of failures, interruptions, security breaches and incidents or other harm from various causes or sources, and third-parties with whom we share confidential or proprietary information face similar risks and may experience similar events that materially impact us. These causes or sources include but are not limited to the following:

- service interruptions;
- system malfunctions;
- computer viruses and other malicious code;
- natural disasters and force majeure events;
- global political instability;
- warfare;
- cyber-intrusions by hostile nation-state actors;
- telecommunication and electrical failures;

- inadvertent or intentional actions by our employees or third-party providers; and
- cyber-attacks by malicious third-parties, including the deployment of ransomware and malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

With respect to cyber-attacks, the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups and individuals with a range of motives (including industrial espionage) and expertise, such as organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. These risks may be heightened in connection with geopolitical events such as the conflict between Russia and Ukraine. The costs to investigate and mitigate actual and suspected cybersecurity breaches and incidents could be significant. We may not be able to anticipate all types of security threats and implement preventive measures effective against all such threats. In addition, an increased amount of work is occurring remotely, including through the use of mobile devices. This could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions.

We have experienced, and we may continue to experience, cyber-attacks, security breaches and incidents and other system failures, although to our knowledge we have not experienced any material interruption or incident. The loss, corruption, unavailability of or damage to our data would interfere with and undermine the insights we draw from our Generate Platform and could impair the integrity of our clinical trial data, leading to regulatory delays or the inability to get our product candidates approved. If we do not accurately predict and identify our infrastructure requirements and failures and timely enhance our infrastructure, or if our remediation efforts are not successful, it could result in a material disruption of our business operations and development programs, including the loss or unauthorized disclosure of our know-how, individuals' personal information or other proprietary or sensitive data. A security breach or incident that leads to unauthorized acquisition, disclosure or other processing of our intellectual property or other proprietary information could also affect our intellectual property rights and enable competitors to compete with us more effectively.

Likewise, as we rely on third-parties such as CROs, contractors and consultants, including for the manufacture of our product candidates and for the conduct of our clinical trials, similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in or denials of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed, result in substantial costs and distract management. For more information, see "*—We, our collaboration partners, and our service providers are subject to a variety of stringent and evolving privacy and data security laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.*"

Failures, disruptions, security breaches and incidents, cyber-attacks and other harmful events impacting data processed or maintained in our business, or information technology systems or infrastructure used in our business, including those resulting in a loss of or damage to our information technology systems or infrastructure, or the loss of or inappropriate acquisition, disclosure or other processing of confidential, proprietary or personal information, or the perception any of these has occurred, could expose us to a risk of loss, enforcement measures, regulatory agency investigations, proceedings and other actions, penalties, fines, indemnification allegations, litigation, potential civil or criminal liability, collaborators' loss of confidence, damage to our reputation and other consequences, which could materially adversely affect our business and results of operations. While we maintain insurance coverage for certain expenses and liabilities related to failures or breaches of our information technology systems, it may not be adequate to cover all losses associated with such events. In addition, such insurance may not be available to us in the future on satisfactory terms or at all. Furthermore, if the information technology systems of third-parties with whom we do business become subject to disruptions or security breaches or incidents, we may have insufficient recourse against them.

Interruptions in the availability of server systems or communications with internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.

We rely on third-party data centers and telecommunications solutions, including cloud infrastructure services such as Amazon Web Services, to host substantial portions of our Generate Platform and to support our business operations. We have limited control over these cloud-based service or other third-party providers, although we attempt to reduce risk by minimizing reliance on any single third-party or its operations. We have experienced, and expect we may in the future again experience system interruptions, outages or delays due to a variety of factors, including infrastructure changes, human or software errors, website hosting disruptions and capacity constraints. A prolonged service disruption affecting our cloud-based solutions could damage our reputation or otherwise materially harm our business.

Further, if the security measures of our third-party data center or cloud infrastructure providers are breached by cyber-attacks or other means and unauthorized access to our information technology systems or data occurs, it could result in interruptions to our operations and the loss of proprietary or confidential information, which could damage our reputation, cause us to incur substantial costs, divert our resources from other tasks and subject us to significant legal and financial exposure and liabilities, any one of which could materially adversely affect our business, results of operations, and prospects. Such third-party providers may also be subject to natural disasters, global political instability, warfare, power losses, telecommunications failures or other disruptive events that could negatively affect our business and require us to incur significant costs to secure alternate cloud-based solutions. In addition, any changes in our third-party providers' service levels or features that we utilize or the termination of our agreements could also adversely affect our business.

Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the Regulatory Authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the Regulatory Authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate and plan to operate in a highly regulated industry and we could now or in the future be subject to litigation, government investigation and enforcement actions on a variety of matters in the U.S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other allegations and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources and cause reputational harm.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years there has been an increase in the number of discrimination and harassment allegations generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these allegations have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related allegations, our business could be negatively affected.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage in the future, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. The coverage or coverage limits currently maintained under our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may identify. Additionally, operating as a public company has made it more expensive for us to obtain directors and officers liability insurance. If we do not maintain adequate levels of directors' and officers' liability insurance, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors and in our leadership team.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our current and future CDMOs are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations will involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third-parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort allegations that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future CDMOs, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates. In addition, our supply chain may be adversely impacted if any of our CDMOs become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

We or the third-parties upon whom we depend may be adversely affected by natural disasters or other business interruptions such as cybersecurity attacks and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations, and have a material adverse impact on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, cybersecurity attack or other force majeure event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as the manufacturing facilities of our CDMOs, limited our ability to access or use our Generate Platform or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. Cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach of our computer security protocols or other cybersecurity attack. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse impact on our business.

Risks Related to Ownership of Our Common Stock and This Offering

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters. An active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares, or at all. An inactive market may also impair our ability to raise capital by selling shares, which in turn could materially adversely affect our business.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general, and the market for biotechnology companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including: the commencement, enrollment, completion or results of preclinical and clinical trials of our product candidates or those of our competitors; the success of competitive products or technologies; commencement or termination of partnership, collaboration and licensing arrangements; regulatory or legal developments in the United States and other countries; developments or disputes concerning patent applications, issued patents or other proprietary rights; significant lawsuits, including patent or stockholder litigation; the recruitment or departure of key personnel; the level of expenses related to any of our product candidates or clinical development programs; the results of our efforts to discover, develop, acquire or in-license additional product candidates; actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; variations in our financial results or those of companies that are perceived to be similar to us; changes in the structure of healthcare payment systems; market conditions in the biotechnology and high-tech sectors, including high interest rates and borrowing costs; general economic, industry and market conditions; and the numerous product candidates in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of our stock to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such allegations and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

We may not be able to satisfy listing requirements of Nasdaq or obtain or maintain a listing of our common stock on Nasdaq.

After listing on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. The delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability, as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- the timing and status of enrollment for clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with CDMOs;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our product candidates from regulatory authorities in the United States and internationally;
- exchange rate and interest rate fluctuations;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for our product candidates, if approved, which may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We believe the nature of our pipeline is not suitable to providing forward-looking guidance on the expected timing of individual product candidate milestones, particularly data readout timing. While as a general matter we intend to periodically report on the status of our development programs, including articulating anticipated next steps in the form of development plans or potential data readouts, we do not currently plan to provide forward-looking guidance on the timing of those next steps. In addition, we do not control the timing of disclosure of any such milestones related to certain of our product candidates that are managed by our collaboration partners, including Amgen and Novartis. Any disclosure by our collaboration partners of data that is perceived as negative, whether or not such data is related to other data that we or others release, may have a material adverse impact on our stock price or overall valuation. Not providing forward-looking guidance on the expected timing of product candidate milestones may lead to speculation by investors, shareholders, analysts and other market participants and in the media as to the progress of our individual product candidates, or our product candidates as a whole, which may have a material adverse impact on our stock price or valuation.

A significant portion of our total outstanding shares of our common stock after this offering will be restricted from immediate resale but may be sold into the market in the near future. The substantial number of shares eligible for public sale or subject to rights requiring us to register them for public sale could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Based on shares of our common stock outstanding as of December 31, 2025, we will have 127,450,201 shares of our common stock outstanding after this offering (or 131,200,201 shares of common stock if the underwriters exercise their option to purchase additional shares in full).

In connection with our initial public offering, we, all of our directors and officers and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us under which we and they agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of our initial public offering.

We also intend to file one or more registration statements on Form S-8 under the Securities Act of 1933 ("Securities Act") to register all shares of common stock issued or issuable under our equity plans. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market following the expiration of the applicable lock-up period. See the section titled "*Shares Eligible for Future Sale*" appearing elsewhere in this prospectus for a more detailed description of the restrictions on selling shares of our common stock.

Additionally, after this offering, the holders of an aggregate of 94,349,702 shares of our common stock, or their transferees, will have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be sold freely in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Sales of our shares as restrictions end or pursuant to registration rights may make it more difficult for us to finance our operations through the sale of equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of our common stock to fall and make it more difficult for you to sell shares of our common stock.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

You will suffer immediate and substantial dilution in the net tangible book value of our common stock if you purchase in this offering. Based on the initial public offering price of $16.00 per share, after giving effect to this offering, purchasers of common stock in this offering will experience immediate dilution of $11.63 per share in net tangible book value of our common shares. In addition, after giving effect to this offering, investors purchasing common stock in this offering will contribute 32.9% of the total amount invested by stockholders since inception but will only own 19.6% of the common stock outstanding. In the past, we issued options and other securities to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See the section titled "*Dilution*" appearing elsewhere in this prospectus for a more detailed description of the dilution to new investors in the offering.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. To the extent that we raise additional capital through the sale of stock or convertible or exchangeable debt securities, warrants or other similar equity securities, your ownership interest could be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and alliances and licensing arrangements with third-parties or through asset sales, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of our stock may decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, five percent stockholders and their affiliates beneficially own approximately 64.1% of our common stock and, upon closing of this offering, that same group will beneficially own approximately 55.8% of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options and without giving effect to (i) any potential purchases by such persons in this offering or (ii) issuance of options granted to certain of our employees and non-employee directors upon the pricing of this offering). Therefore, even after this offering, these stockholders will have the ability to influence us through their ownership positions. For example, these stockholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

Participation in this offering by our existing stockholders and their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and principal stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

We have broad discretion in the use of our cash, cash equivalents, restricted cash and marketable securities, including the net proceeds from this offering, and may not use them effectively.

Our management will have broad discretion in the application of our cash, cash equivalents, restricted cash and marketable securities, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse impact on our business, cause the price of our common stock to decline, and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents, restricted cash and marketable securities, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See the section titled "*Use of Proceeds*" appearing elsewhere in this prospectus.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Provisions in our fourth amended and restated certificate of incorporation (the "amended and restated certificate of incorporation"), which will be in effect promptly following the closing of this offering, and amended and restated bylaws (the "amended and restated bylaws"), which became effective upon the effectiveness of this registration statement of which this prospectus forms a part, may significantly reduce the value of our shares to a potential acquiror or make it difficult for a third-party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10,000,000 shares of preferred stock and may fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. The issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our amended and restated certificate of incorporation will contain, and our amended and restated bylaws contain, other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders will not be entitled to remove directors other than by a two-thirds vote and only for cause;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We do not currently intend to declare or pay cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends.

As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the U.S. may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. We will be subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the federal securities laws, including the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including requirements to file annual, quarterly and event driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We may not be able to produce reliable financial statements or file these financial statements as part of

a periodic report in a timely manner with the SEC or comply with the Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company" ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We will remain an EGC until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which the market value of our common stock that is held by non-affiliates exceeds $700 million. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"); not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation; and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive, as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an EGC we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with this offering, we intend to begin the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404, which will require annual management assessment of the effectiveness of our internal control over financial reporting starting with our second filing of an Annual Report on Form 10-K.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis cause investors to lose confidence in the accuracy and completeness of our financial reports and could cause the market price of our common stock to decline significantly.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and

communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our future ability to utilize our NOL carryforwards and certain other tax attributes may be limited.

Since our inception, we have incurred losses and we may never achieve profitability. As of December 31, 2025, we had U.S. federal NOL carryforwards of $331.8 million (which are not subject to expiration) and state NOL carryforwards of $287.6 million (which begin to expire in various amounts in 2045). We also had U.S. federal research and development tax credit carryforwards of $24.9 million available to offset future U.S. federal income taxes, which expire at various times through 2040. As of December 31, 2025, we had state tax credit carryforwards of $13.4 million which expire at various times through 2040. To the extent that we continue to generate taxable losses, under current law, our unused U.S. federal NOLs may be carried forward to offset a portion of future taxable income, if any. Additionally, we continue to generate business tax credits, including research and development tax credits, which generally may be carried forward to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as one or more shareholders or groups of shareholders who own at least five percent of the corporation's equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. Similar rules may apply under state tax laws. Our prior equity offerings and other changes in our stock ownership have resulted in such ownership changes in the past and on December 31, 2025, we have recorded a $207.8 million valuation allowance against deferred tax assets to reflect tax assets which may not be fully realized as a result of such ownership changes. In addition, we may experience ownership changes in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and our financial condition. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

We, our collaboration partners, and our service providers are subject to a variety of stringent and evolving privacy and data security laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.

In the ordinary course of our business, we and the third-parties upon which we rely collect, receive, store or otherwise process personal data, including information we may collect about participants in our clinical trials. Our data processing activities subject us to numerous, evolving privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to privacy and data security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving in a manner that is increasingly stringent and, globally, this legal and regulatory framework is likely to remain uncertain for the foreseeable future. We must devote significant resources to understanding and complying with the changing landscape in this area. Each law is also subject to various interpretations by courts and Regulatory Authorities, creating additional uncertainty, and we may fail to comply with the evolving data protection laws, which may expose us to risk of enforcement actions taken by authorities, private rights of action in some jurisdictions and potential significant penalties if we are found to be non-compliant. Some of these laws and regulations also carry the possibility of criminal sanctions.

In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act), state consumer protection and privacy laws and other similar laws (*e.g.*, wiretapping and communications interception laws) govern the processing of health-related and other personal data. At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While existing state comprehensive privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third-parties upon whom we rely.

Additionally, we may be subject to new laws governing the privacy of consumer health data. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern as implemented by the Department of Justice's final rule issued in December 2024, effective April 8, 2025, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data and biospecimens, to certain countries of concern, including China. The final rule also restricts certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. The final rule does not exempt key-coded or otherwise anonymized, pseudonymized, de-identified or encrypted data. Actual or alleged violations of the final rule may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

Outside the United States, an increasing number of laws, regulations and industry standards may govern privacy, data security and the transfer of personal data between jurisdictions. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's General Data Protection Regulation ("UK GDPR" and, together with the EU GDPR, "GDPR") impose strict requirements for processing personal data including relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required requirements relating to obtaining consent of individuals, disclosures about how personal data is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors. Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines of up to €20 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater, and private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Non-compliance could also result in a material adverse effect on our business, financial position and results of operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to the United States and other countries. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework ("Framework") and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States (or other countries), or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third-parties and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activities activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Although the UK is regarded as a third country under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, a decision recognizing the UK as providing adequate protection under the EU GDPR and enabling data transfers from Member States to the UK without additional safeguards. The UK adequacy decision was renewed in December 2025 and will automatically expire in December 2031. The EU GDPR and the UK GDPR currently impose substantially similar obligations. However, the European Commission retains the authority to monitor developments in UK law, including implementation of the Data (Use and Access) Act 2025, and may amend, suspend or repeal the adequacy decisions if it determines that the UK no longer ensures an essentially equivalent level of protection. Any such action, or a successful legal challenge to the adequacy decisions could lead to additional compliance costs and could increase our overall risk.

Additionally in the EEA, the NIS 2 Directive ("NIS 2") is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant Member State. Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EEA is currently fragmented and uncertain. To the extent we are subject to NIS 2, we will require additional investment of our resources in compliance programs. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

In addition to privacy and data security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to privacy and data security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to privacy and data security are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems and practices and to those of any third-parties that process personal data on our behalf.

We may at times fail in our efforts to comply with our privacy and data security obligations. Moreover, despite our efforts, our personnel or third-parties on whom we rely, including CROs supporting our clinical trials, clinical trial sites with whom we have contracted and other third-parties supporting our clinical trials, may fail to comply with such obligations, which could negatively impact our business operations. If we or the third-parties on which we rely fail, or are perceived to have failed, to address or comply with applicable privacy and data security obligations, we could face significant consequences, including but not limited to: government enforcement actions (*e.g.*, investigations, fines, penalties, audits, inspections and similar); litigation (including class-action claims), and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. The global economy and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, rising inflation, uncertainty from changes in tariff policies, fluctuating interest rates, declines in economic growth, global supply chain disruptions and uncertainty about economic stability. The global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events, including the ongoing war in Ukraine, the Israel-Gaza conflict and the increasingly strained relationship between the U.S. and China. Sanctions imposed by the U.S. and other countries in response to such conflicts may adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates or products we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "*Prospectus Summary*," "*Risk Factors*," "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," and "*Business*," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- the ability of clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results, and the ability of our preclinical studies and earlier clinical trials to predict later clinical trial results;
- the timing, scope and likelihood of regulatory filings and approvals of our product candidates;
- the implementation of our business model, and strategic plans for our business, programs, and current and future product candidates;
- our ability to effectively use AI in our drug discovery and development process, and to maintain and improve our Generate Platform;
- the acceptance of AI in the biotechnology industry, including market acceptance of products and product candidates discovered and developed using AI;
- our ability to obtain additional cash and the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our potential and ability to successfully manufacture and supply our current and future product candidates for clinical trials and for commercial use, if approved;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- existing regulations and regulatory developments in the U.S. and other jurisdictions;
- expectations regarding future events under collaboration and licensing agreements, including potential future payments, as well as our plans and strategies for entering into further collaboration and licensing agreements;
- general economic, industry and market conditions, including fluctuating interest rates and rising inflation;
- our ability to attract and retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing cash, cash equivalents and marketable securities and the proceeds from this offering.

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “*Risk Factors*” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of 25,000,000 shares of our common stock in this offering will be approximately $368.8 million, based on the initial public offering price of $16.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise in full their option to purchase additional shares, our estimated net proceeds will be approximately $424.9 million.

The principal purposes of this offering are to create a public market for our common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities, for the following:

- approximately $300.0 million to advance GB-0895 through the completion of our two Phase 3 trials in severe asthma;
- approximately $100.0 million to complete our ongoing Phase 1b clinical trial of GB-0895 for the treatment of COPD and to initiate the next phase of clinical development (pending results from our Phase 1b trial in COPD and regulatory alignment);
- approximately $75.0 million to fund platform and technology innovation and engineer multiple programs and product candidates through development candidate nomination and into IND-enabling activities;
- approximately $15.0 million to advance GB-4362 and GB-5267 through topline Phase 1 data; and
- and the remainder for additional research and development efforts for new programs and product candidates, as well as for working capital and other general corporate purposes.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above and we expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or technologies to continue to build our pipeline, research and development capabilities and our intellectual property position, although we currently have no agreements, commitments or understandings with respect to any such transaction.

Due to the many inherent uncertainties in the development of our programs and product candidates, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the timing of patient enrollment and evolving regulatory requirements, the timing and success of preclinical studies, our ongoing or future clinical trials, the timing of regulatory submissions, any strategic alliances that we may enter into with third-parties for our investigational medicines or strategic opportunities that become available to us, and other factors described in "*Risk Factors*" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the first half of 2028. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return. Our management will retain broad discretion in the application of the net proceeds we receive from our initial public offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We do not intend to declare or pay cash dividends to our stockholders in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

CAPITALIZATION

The following table sets forth our cash, cash equivalents, restricted cash and marketable securities and total capitalization as of December 31, 2025:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the acquisition of the non-controlling interest of PMCo under the Stock Purchase Agreement with PM LLC, the closing of which is contingent upon the execution of the underwriting agreement for this offering; (ii) the automatic conversion of all outstanding shares of preferred stock into an aggregate of 69,333,244 shares of common stock upon the completion of this offering and the related automatic adjustment of the preferred stock warrant into a common stock warrant upon the completion of this offering and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur promptly following the completion of this offering; and
- on a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) the issuance and sale of 25,000,000 shares of common stock in this offering at the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table should be read together with "*Management's Discussion and Analysis of Financial Condition and Results of Operations,*" "*Description of Capital Stock*," and the consolidated financial statements and related notes appearing elsewhere in this prospectus.

	As of December 31, 2025		
(in thousands, except share and per share data)	**Actual**	**Pro Forma**	**Pro Forma As Adjusted**
Cash, cash equivalents, restricted cash and marketable securities	$ 221,498	$ 221,498	$ 590,298
Convertible preferred stock (Series A, B and C), par value $0.001 per share; 113,956,735 shares authorized, 105,317,255 issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	811,826	—	—
Non-controlling interest	(7,232)	—	—
Stockholders' (deficit) equity:			
Preferred stock, par value $0.001 per share; no shares authorized, issued or outstanding, actual; and 10,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, par value $0.001 per share; 200,456,735 shares authorized, 33,116,957 shares issued and outstanding, actual; 200,456,735 shares authorized, 102,450,201 shares issued and outstanding, pro forma; 500,000,000 shares authorized, 127,450,201 shares issued and outstanding, pro forma as adjusted	33	102	127
Additional paid-in capital	60,189	865,919	1,234,694
Accumulated other comprehensive loss	106	106	106
Accumulated deficit	(676,293)	(676,293)	(676,293)
Total stockholders' (deficit) equity	(615,965)	189,834	558,634
Total capitalization	$ 188,629	$ 189,834	$ 558,634

The number of shares of common stock that will be outstanding after this offering on a pro forma and pro forma as adjusted basis is based on 102,450,201 shares of common stock outstanding as of December 31, 2025 after giving effect to the automatic conversion of all outstanding shares of our preferred stock into the aggregate of 69,333,244 shares of common stock upon the completion of this offering, and excludes:

- 20,422,301 shares of common stock issuable upon exercise of outstanding stock options as of December 31, 2025 under our 2019 Plan, with a weighted average exercise price of $5.91 per share;
- 441,076 shares of common stock issuable upon exercise of outstanding stock options granted after December 31, 2025 under our 2019 Plan, with a weighted average exercise price of $11.75 per share;
- 3,404,855 shares of common stock reserved for future issuance as of December 31, 2025 under the 2019 Plan, which ceased to be available for issuance at the time that our 2026 Plan became effective;
- 98,749 shares of our common stock issuable upon exercise of an outstanding warrant to purchase Series A preferred stock with an aggregate exercise price of $150,000 that will become a warrant to purchase common stock upon the completion of this offering;
- 11,852,719 shares of our common stock reserved for future issuance under our 2026 Plan, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, which number includes an aggregate of 4799,160 shares of our common stock, based upon the initial public offering price of $16.00 per share and the Black-Scholes value of the options, which were granted to certain of our executive officers, directors and employees at the time of effectiveness of the 2026 Plan with an exercise price equal to the initial public offering price per share, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2019 Plan that expire or are repurchased, forfeited, cancelled or withheld; and
- 1,481,589 shares of common stock reserved for future issuance under our ESPP, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value as of December 31, 2025 was a deficit of $625.2 million, or $(18.88) per share of our common stock. Our historical net tangible book value (deficit) represents the amount of our total tangible assets $328.2 million, which excludes deferred offering costs ($2.0 million), less our total liabilities ($141.6 million) and convertible preferred stock which is contingently redeemable ($811.8 million). Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of December 31, 2025.

Our pro forma net tangible book value as of December 31, 2025 was $187.8 million, or $1.83 per share. Pro forma net tangible book value per share represents the amount of our total tangible assets (net of deferred offering costs) less our total liabilities, divided by the number of shares of our common stock outstanding as of December 31, 2025, after giving effect to the automatic conversion of all outstanding shares of preferred stock into 69,333,244 shares of common stock upon the completion of this offering, and the automatic adjustment of our preferred stock warrant to purchase 150,000 shares of Series A preferred stock into a common stock warrant to purchase 98,749 shares of common stock upon the completion of this offering.

After giving further effect to the sale of 25,000,000 shares of common stock that we are offering at the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us our pro forma as adjusted net tangible book value as of December 31, 2025 would have been $556.6 million, or $4.37 per share. This amount represents an immediate increase in pro forma net tangible book value of $2.54 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of $11.63 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Initial public offering price per share		$ 16.00
Historical net tangible book deficit per share as of December 31, 2025	$ (18.88)	
Pro forma increase in net tangible book value per share as of December 31, 2025 attributable to the pro forma adjustment described above	20.71	
Pro forma net tangible book value per share as of December 31, 2025	1.83	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	2.54	
Pro forma as adjusted net tangible book value per share after this offering		4.37
Dilution per share to new investors in this offering		$ 11.63

If the underwriters exercise their option to purchase up to 3,750,000 additional shares of our common stock in full, the pro forma as adjusted net tangible book value after the offering would be $4.67 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be $2.84 per share and the dilution per share to new investors would be $11.33 per share, in each case based on the initial public offering price of $16.00 per share.

The following table summarizes on the pro forma as adjusted basis described above, as of December 31, 2025, the differences between the number of shares of common stock purchased from us by our existing stockholders and common stock by new investors purchasing shares in this offering, the total consideration paid to us in cash and the average price per share paid by existing stockholders for shares of common stock issued prior to this offering and the price to be paid by new investors for shares of common stock in this offering. The calculation below is based on the initial public offering price of $16.00 per share, before deducting underwriting discounts, placement agent fees and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percentage	Amount	Percentage	
	(in thousands, except share, per share and percent data)				
Existing stockholders before this offering[(1)]	102,450,201	80.4%	$ 815,575	67.1%	$ 7.96
New investors purchasing shares in this offering	25,000,000	19.6%	400,000	32.9%	$ 16.00
Total	127,450,201	100.0%	$ 1,215,575	100.0%	

(1) The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases that existing stockholders may make through our directed share program or otherwise in this offering.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares of our common stock is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 78.1% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to 21.9% of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on 102,450,201 shares of common stock outstanding as of December 31, 2025 after giving effect to the automatic conversion of outstanding shares of our preferred stock into shares of common stock upon the completion of this offering, and excludes:

- 20,422,301 shares of common stock issuable upon exercise of outstanding stock options as of December 31, 2025 under our 2019 Plan, with a weighted average exercise price of $5.91 per share;
- 441,076 shares of common stock issuable upon exercise of outstanding stock options granted after December 31, 2025 pursuant to our 2019 Plan, with a weighted average exercise price of $11.75 per share;
- 3,404,855 shares of common stock reserved for future issuance as of December 31, 2025 under the 2019 Plan, which ceased to be available for issuance at the time that our 2026 Plan became effective;
- 98,749 shares of our common stock issuable upon exercise an outstanding warrant to purchase Series A preferred stock with an aggregate exercise price of $150,000 that will become a warrant to purchase common stock upon the completion of this offering;
- 11,852,719 shares of our common stock reserved for future issuance under our 2026 Plan, which became effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, which number includes an aggregate of 4,799,160 shares of our common stock, based upon the initial public offering price of $16.00 per share and the Black-Scholes value of the options, which were granted to certain of our executive officers, directors and employees at the time of effectiveness of the 2026 Plan with an exercise price equal to the initial public offering price per share, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2019 Plan that expire or are repurchased, forfeited, cancelled or withheld; and
- 1,481,589 shares of common stock reserved for future issuance under our ESPP, which became effective on the date immediately prior to the effectiveness of the registration

statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

To the extent any outstanding options or warrants are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional equity or convertible debt securities in the future, there will be further dilution to new investors.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and related notes and other financial information included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage generative biology company pioneering the AI revolution in biotechnology and drug design and development. Our vision is to program biology to generate optimal therapeutics for the greatest impact on human health. Central to our vision is the Generate Platform, designed to be a therapeutic area and protein modality agnostic system integrating computational innovation with scalable biohardware to address therapeutic challenges beyond the reach of traditional technologies. We have built our Generate Platform to be a tight and fully-integrated loop (design–build–test–learn) to create proprietary, therapeutically relevant data and differentiated molecular solutions for the biological challenges we aim to address. In addressing these challenges, the Generate Platform can engineer solutions against therapeutic targets starting from either existing reference proteins or by suggesting completely novel ones without a reference starting point, also known as *de novo* design. The Generate Platform's therapeutic potential has been demonstrated by successfully progressing three computationally engineered proteins into human clinical testing, the most advanced of which is GB-0895, an investigational long-acting anti-thymic stromal lymphopoietin ("TSLP") monoclonal antibody, which is enrolling patients in pivotal Phase 3 clinical trials for severe asthma. Also, we expect to advance two additional computationally generated oncology product candidates into Phase 1 clinical trials in 2026.

Since our inception, we have devoted substantially all of our resources to drug discovery, the development of our Generate Platform and the advancement of GB-0895 and our other product candidates, along with multiple preclinical programs in immunology and oncology. In addition to our research and development efforts, we have invested in establishing and protecting our intellectual property portfolio, raising capital and obtaining financing, organizing and staffing our company, and providing general and administrative support for these operations. We do not have any products approved for sale.

To date, we have not generated any revenue from product sales, and we have principally raised capital through the private placement of our Series A, Series B and Series C convertible preferred stock, par value $0.001 per share (collectively, the "preferred stock"), the issuance of convertible notes, payments from Amgen Inc. ("Amgen") and Novartis Pharma AG ("Novartis"), and cost-sharing payments from our other partnership, collaboration or licensing arrangements. Through December 31, 2025, we had received aggregate gross cash proceeds in excess of $934.0 million from such transactions, including $805.3 million from sales of our preferred stock, $12.0 million from our repaid term loan, $7.5 million from our now fully-converted convertible notes, and $110.0 million of payments under our collaboration agreements with Novartis and Amgen. We also have benefited from cost-sharing arrangements in our collaboration arrangements with The University of Texas M.D. Anderson Cancer Center ("MD Anderson"), Roswell Park Comprehensive Cancer Center ("Roswell Park") and Pioneering Medicines 02, Inc. ("PMCo"). Upon the execution of the underwriting agreement for this offering, we will acquire PMCo. At that time, our collaboration, including our cost-sharing arrangements, will terminate and we will become obligated to make certain payments to PMCo's parent based on net sales. As needed, we will seek additional funding through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. We may not be able to obtain funding on acceptable terms, or at all. The terms of any future financing may adversely affect the holdings or the rights of our current stockholders.

If we are unable to obtain funding, we could be forced to delay, limit, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

We have incurred significant operating losses since inception, and we expect to continue to incur substantial losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates and any additional product candidates we may develop. Our net losses were $181.4 million and $223.0 million, of which $7.6 million and $19.8 million was attributable to a non-controlling interest for the years ended December 31, 2024 and 2025, respectively. As of December 31, 2025, we had an accumulated deficit of $676.3 million.

We anticipate that our expenses and operating losses will increase substantially for the foreseeable future if and as we:

- expand the number of our research and development programs;
- continue or expand our scope of research or development of our current programs and product candidates in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical or other studies for our programs and product candidates, including pursuant to some of our partnership, collaboration and licensing arrangements;
- change or add additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our product candidates and products;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license technologies;
- make payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We do not expect to generate revenue from product sales unless and until we or our collaboration partners successfully complete the clinical development or future clinical development of, and obtain regulatory approval for, one or more of our current or future product candidates, including any jointly-developed product candidates, which will not be for several years, if ever. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, manufacturing, marketing, market access and distribution.

Our net losses may fluctuate significantly from period to period, depending on the timing of our current and potential future clinical trials and expenditures related to our research and developmental activities. Furthermore, following the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant audit, legal and regulatory expenses, as well as director and officer insurance premiums and investor relations costs that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such a time when we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. Our failure to raise capital or enter into such agreements or arrangements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition, including potentially requiring us to delay, limit, reduce or eliminate product development or future commercialization efforts, or grant rights to develop and market current or future development product candidates that we would otherwise prefer to develop and market ourselves.

As there are numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As a result, we will need substantial additional capital to support our continuing operations and pursue our strategy. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $221.5 million. These amounts are not expected to be sufficient to fund our operations for at least twelve months from the date of issuance of the consolidated financial statements included elsewhere in this prospectus. Therefore, there is substantial doubt about our ability to continue as a going concern. Our management has developed plans to fund our operations, which primarily consist of raising additional capital through one or more of the following: public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise, and we may be unable to obtain sufficient additional capital. If we are not able to secure sufficient additional capital in the near term, we will need to implement additional cost reduction strategies, which could include delaying, limiting, further reducing or eliminating both internal and external costs related to our operations and research and development programs. For more information, refer to "*—Liquidity and Capital Resources*" below and Note 1 to our consolidated financial statements included elsewhere in this prospectus.

Components of Results of Operations

Revenues

We have not generated any revenues from the sale of products to date and do not expect to generate any revenues from the sale of products for the next several years, if at all. If our development efforts for our current or future product candidates are successful and result in regulatory approval, we may generate revenues in the future from product sales. For the foreseeable future, we expect substantially all of our revenues to be generated from our current collaboration arrangements with Novartis and Amgen. For more information on our collaboration agreements with Novartis and Amgen, please see "*Collaboration Agreements"* below and Note 5 to our consolidated financial statements included elsewhere in this prospectus.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of external and internal costs incurred for our research and development activities, including development of our platform, our product discovery efforts and the development of our future product candidates. These expenses include:

- external expenses, including expenses incurred under arrangements with third-parties, such as contract development and manufacturing organizations ("CDMOs"), contract research organizations ("CROs"), providers of sponsored research, consultants and our scientific advisors;
- costs related to compliance with regulatory authorities;
- direct costs of conducting internal research and development for our internal preclinical programs;
- intellectual property and related future payments should certain development and regulatory milestones be achieved;

- personnel-related costs, including salaries, bonuses, benefits and stock-based compensation for employees engaged in research and development functions;
- expenses incurred for the procurement of materials, third-party license fees, laboratory supplies and non-capital equipment used in the research and development process; and
- depreciation, amortization and other direct and allocated expenses, including rent, insurance, maintenance of facilities and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

We record accruals for estimated ongoing research costs and receive updated estimates of costs and amounts owed on a monthly basis from our third-party service providers. When evaluating the adequacy of the prepaid expenses and accrued liabilities, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted cost estimates from its third-party service providers. Estimates are made in determining the balances at the end of any reporting period.

We use our personnel and infrastructure resources for our research and development efforts, including the advancement and development of our platform, product candidates and managing external research and development efforts. A significant portion of our research and development costs have been, and will continue to be, external costs. External expenses, which are specific to a program, are tracked on a program-by-program basis for partner programs or upon development candidate nomination. Due to our ability to use certain resources across several programs, personnel-related expenses and indirect or shared operating costs incurred for our research and development programs are not recorded or maintained on a program-by-program basis.

We anticipate that our research and development expenses will increase substantially for the foreseeable future in connection with our ongoing clinical trials and our planned clinical development activities in the near term and in the future. However, we cannot reasonably estimate the costs or timing of the efforts that will be necessary to complete the development of any of our product candidates due to the numerous risks and uncertainties associated with their development, including the uncertainty of:

- the scope, timing, costs and progress of clinical development activities related to GB-0895, including expansion into other indications, and our other product candidates;
- the number and scope of additional preclinical and clinical programs we decide to pursue, and the number of product candidates we decide to develop further;
- our successful enrollment in and completion of clinical trials;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others;
- third-party maintaining existing, or arranging for new CDMOs, to support clinical trials of our product candidates;
- seeking regulatory approvals for any of our product candidates that successfully complete clinical trials;
- securing access rights to external products, technologies or intellectual property;
- hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the terms and timing of any partnership, collaboration, or license arrangement, including the terms and timing of any milestone or royalty payments thereunder, if any; and
- general economic conditions, including inflation.

Any changes in the outcome of any of these variables with respect to the development of our programs and product candidates or any future programs and product candidates that we may identify could result in a significant change in the costs and timing associated with the development of that program or product candidate. For example, if the U.S. Food and Drug Administration, the European Medicines Agency or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate would be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never succeed in achieving regulatory approval for any of our product candidates or any future product candidates that we may identify.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits and stock-based compensation expenses for employees in executive, accounting and finance, business development, human resources, legal and other administrative functions. Other significant general and administrative expenses include allocated facility related costs including depreciation, legal fees relating to corporate and intellectual property matters and other corporate matters, professional fees for accounting, auditing and tax services, consulting fees and insurance costs.

We anticipate that our general and administrative expenses will increase as we increase our headcount to support our research and development activities and the potential commercialization of our product candidates, if approved. Additionally, these increases will likely include increased costs related to the hiring of additional personnel, among other expenses. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the Securities and Exchange Commission's (the “SEC”) requirements, director and officer insurance costs, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest income generated from interest bearing cash, cash equivalents and marketable securities, change in fair value associated with the preferred stock warrant liability, realized and unrealized gains and losses on foreign currency transactions and interest expense associated with our finance lease of lab equipment. We classified the preferred stock warrants as a liability on our consolidated balance sheets. The preferred stock warrant liability was initially recorded at fair value upon the issuance date of the warrant and is subsequently remeasured to fair value at each reporting date. The resulting change in the fair value of the preferred stock warrant liability is recorded as a component of other income (expense) in our consolidated statements of operations. We will continue to recognize changes in the fair value of this preferred stock warrant liability at each reporting period until each respective warrant is exercised, expires or qualifies for equity classification.

Income Taxes

Income tax expenses (benefit) consists of U.S. federal and state income taxes. As of December 31, 2025, we had $331.8 million and $287.6 million of U.S. federal and state net operating loss ("NOL") carryforwards, respectively. The federal NOL carryforwards are not subject to expiration and the state NOL carryforwards begin to expire in 2042. These loss carryforwards are available to reduce future federal and state taxable income, if any.

Utilization of our NOL carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions. These "ownership changes," as defined by Section 382 of the Code, may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 of the Code results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. In the third quarter of 2021, we had an ownership change as defined by Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our pre-ownership change NOL carryforwards and other pre-change tax attributes to offset such taxable income may be subject to limitations, which could result in increased future tax liability to us and could have an adverse effect on our future results of operations.

Income taxes are determined at the applicable tax rates adjusted for non-deductible expenses and other permanent differences. Our income tax provision may be significantly affected by changes to our estimates.

Loss attributable to non-controlling interest

In connection with our agreement with PMCo, we determined that we are the primary beneficiary of PMCo, and therefore we consolidated PMCo. However, we do not have any equity interest in PMCo, therefore all net losses associated with PMCo are attributable to the non-controlling interest holders. The net losses attributable to non-controlling interest holders is the loss absorbed by the holders of the ownership interest of PMCo, which consist primarily of research and development costs that were reimbursed by PMCo under our collaboration agreement with PMCo. On February 4, 2026, we entered into an agreement to acquire the non-controlling interest under the Stock Purchase Agreement with PM LLC, contingent upon the execution of the underwriting agreement for this offering. Upon the closing of the Stock Purchase Agreement, we will no longer allocate net income (loss) to the non-controlling interest as we will own 100% of the equity of PMCo.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2025

The following table summarizes our results of operations for the years presented (in thousands):

	YEAR ENDED DECEMBER 31,		
	2024	2025	Change
Revenue:			
Collaboration revenue	$ 20,459	$ 31,893	$ 11,434
Operating expenses:			
Research and development	175,311	224,698	49,387
General and administrative	42,087	42,260	173
Total operating expenses	217,398	266,958	49,560
Loss from operations	(196,939)	(235,065)	(38,126)
Other income (expense), net			
Change in fair value of preferred stock warrant liability	(154)	(113)	41
Interest expense	(2,118)	(1,136)	982
Interest income	18,118	13,661	(4,457)
Foreign currency exchange loss	(79)	(149)	(70)
Total other income (expense), net	15,767	12,263	(3,504)
Loss before provision for income taxes	(181,172)	(222,802)	(41,630)
Provision for income taxes	(212)	(163)	49
Net loss	$ (181,384)	$ (222,965)	$ (41,581)
Net loss attributable to non-controlling interests	(7,613)	(19,811)	(12,198)
Net loss attributable to Generate Biomedicines, Inc. stockholders	$ (173,771)	$ (203,154)	$ (29,383)

Collaboration Revenue

Collaboration revenue consists entirely of revenue from the Novartis and Amgen Agreements. Revenue under these agreements is recognized as we conduct research activities related to the research program or target program within the respective agreements based on costs incurred to conduct those activities relative to the total estimated costs. Collaboration revenue increased from $20.5 million for the year ended December 31, 2024 compared to $31.9 million for the year ended December 31, 2025. The $11.4 million increase in collaboration revenue for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to the progress in research and development of the product candidates under the Novartis Agreement which commenced in the third quarter of 2024. Our advancement resulted in total revenue recognized of $25.1 million from Novartis during the year ended December 31, 2025 compared to $2.3 million during the year ended December 31, 2024. The increase reflects progress in fulfilling our performance obligations under the agreement which will be completed in 2027. Additionally, under the Amgen Agreement we recognized revenue of $6.7 million from Amgen during the year ended December 31, 2025 compared to $18.2 million during the year ended December 31, 2024. The decrease was due to us nearing completion of our performance obligations under the Amgen Agreement, which we expect will be completed in 2026.

Research and Development Expense

The following table summarizes our research and development expenses for the years presented (in thousands):

	YEAR ENDED DECEMBER 31,		
	2024	2025	Change
External research and development costs by program:			
GB-0895	$ 17,443	$ 43,530	$ 26,087
Discovery and other programs	19,940	25,910	5,970
Other research and development costs:			
External - early research and infrastructure	48,519	57,482	8,963
Personnel-related (excluding stock-based compensation)	65,292	74,554	9,262
Stock-based compensation	9,114	10,157	1,043
Depreciation expense	15,003	13,065	(1,938)
Total research and development expense	$ 175,311	$ 224,698	$ 49,387

Research and development expenses increased from $175.3 million for the year ended December 31, 2024 compared to $224.7 million for the year ended December 31, 2025. The $49.4 million increase in research and development expenses for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to an increase of $26.1 million in spending on GB-0895, an increase in external discovery and other program related costs of $6.0 million, and an increase in external early research and infrastructure costs of $9.0 million and an increase in personnel-related costs of $9.3 million.

External research and development expenses related to the GB-0895 program for the years ended December 31, 2024 and 2025 were $17.4 million and $43.5 million, respectively. The increase of $26.1 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily driven by the continued advancement of our GB-0895 program, including our Phase 1B clinical trial in COPD and the commencement of our global Phase 3 clinical trial in severe asthma during the year ended December 31, 2025, including related CMC costs.

External discovery and other program costs increased by $6.0 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily driven by an increase in CMC and toxicology activities for development candidates. External early research and infrastructure costs increased by $9.0 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 due to increases in facilities costs, consumables, and computational storage and processing capacity costs associated with our platform.

Personnel-related expenses and stock-based compensation increased by $9.3 million and $1.0 million in the year ended December 31, 2025, respectively, compared to the year ended December 31, 2024, primarily driven by an increase in average headcount. Depreciation expense decreased by $1.9 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily due to certain property and equipment becoming fully depreciated and a decrease in purchases of property and equipment during the year.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years presented (in thousands):

	YEAR ENDED DECEMBER 31,		
	2024	2025	Change
Personnel-related (excluding stock-based compensation)	$ 17,515	$ 17,668	$ 153
Stock-based compensation	10,350	10,420	70
Professional fees	9,399	9,222	(177)
Other costs	4,823	4,950	127
Total general and administrative expense	$ 42,087	$ 42,260	$ 173

General and administrative expenses increased from $42.1 million for the year ended December 31, 2024 to $42.3 million for the year ended December 31, 2025. The $0.2 million increase in general and administrative expenses for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to an increase of personnel-related costs, including stock-based compensation, of $0.2 million and an increase in other costs of $0.1 million, which was offset by a $0.2 million decrease in professional fees.

Other Income (Expense), Net

Other income (expense), net decreased from $15.8 million for the year ended December 31, 2024 to $12.3 million for the year ended December 31, 2025. The $3.5 million decrease for the year ended December 31, 2025 compared to the year ended December 31, 2024 in other income (expense), net for the year ended December 31, 2025 was primarily related to a decrease in interest income of $4.6 million due to decreases in our cash, cash equivalents and marketable securities, which was offset by a $1.0 million decrease in interest expense due to the expiration of certain financing leases during the year ended December 31, 2025.

Loss Attributable to Non-Controlling Interest

Loss attributable to non-controlling interest increased from $7.6 million for the year ended December 31, 2024 to $19.8 million for the year ended December 31, 2025. The $12.2 million increase for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily related to the increase in the loss absorbed by the holders of the ownership interest of PMCo of $12.2 million. The loss consists primarily of research and development costs that were reimbursed by PMCo under the Prior PMCo Agreement (as defined below).

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any of our product candidates, which are in clinical or preclinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. To date, we have financed our operations primarily through private placements of our convertible preferred stock, the issuance of convertible notes, payments from Amgen and Novartis, and cost-sharing payments from our other partnership, collaboration or licensing arrangements. Through December 31, 2025, we had received aggregate gross cash proceeds in excess of $934.0 million from such transactions, including $805.3 million from sales of our preferred stock, $12.0 million from our repaid term loan, $7.5 million from our now fully-converted convertible notes, and $110.0 million of payments under our collaboration agreements with Novartis and Amgen. In addition, we have benefited from cost-sharing arrangements in our collaboration arrangements with MD Anderson, Roswell Park and PMCo. Upon the execution of the underwriting agreement for this offering, we will acquire PMCo. At that time, our collaboration, including our cost-sharing arrangements, will terminate and we will become obligated to make certain payments to PM LLC based on net sales.

Cash Flows

The following table provides information regarding our cash flows for the years presented (in thousands):

	YEAR ENDED DECEMBER 31,		
	2024	2025	Change
Net cash provided by (used in):			
Operating activities	$ (117,750)	$ (200,619)	$ (82,869)
Investing activities	(57,725)	116,767	174,492
Financing activities	91,327	28,059	(63,268)
Net increase (decrease) in cash and cash equivalents	$ (84,148)	$ (55,793)	$ 28,355

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in research and development of our platform, product candidates, including preclinical studies, clinical trials, manufacturing and manufacturing process development. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges, which are generally due to stock-based compensation, depreciation and amortization and non-cash lease expense, as well as changes in components of operating assets and liabilities, which are generally due to deferred revenue, increased expenses and timing of vendor payments.

For the year ended December 31, 2024, operating activities used $117.8 million of cash, primarily resulting in a net loss of $181.4 million, which was partially offset by changes in operating assets and liabilities that provided $28.1 million in cash and net non-cash expenses of $35.5 million.

For the year ended December 31, 2025, operating activities used $200.6 million of cash, primarily resulting in a net loss of $223.0 million, which was partially offset by changes in net non-cash expenses of $36.9 million and further impacted by changes in operating assets and liabilities that used $14.6 million in cash, primarily driven by a decrease in deferred revenue, which was partially offset by an increase in accrued expenses and other current liabilities.

Investing Activities

During the year ended December 31, 2024, net cash used in investing activities was $57.7 million, which primarily consisted of purchases of marketable securities and equipment, offset by sales of marketable securities.

During the year ended December 31, 2025, net cash provided by investing activities was $116.8 million, which primarily consisted of sales and maturities of marketable securities, offset by purchases of marketable securities and equipment.

Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities of $91.3 million primarily related to proceeds received from issuance of our Series C preferred stock, net of issuance costs and contributions from our non-controlling interest, offset by payments on finance lease obligations.

During the year ended December 31, 2025, net cash provided by financing activities of $28.1 million primarily to proceeds received from issuance of our Series C preferred stock , net of issuance costs and contributions from our non-controlling interest, offset by payments on finance lease obligations.

Future Funding Requirements

We expect our future capital requirements to increase substantially over time in connection with our ongoing research and development activities, particularly as we advance our current and planned clinical development of our product candidates and maintain the research efforts and preclinical activities associated with our other existing programs and discovery platform. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to product sales, marketing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Further, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation had a material effect on our consolidated financial statements included elsewhere in this prospectus. However, the United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase, it may affect our expenses, such as employee compensation and research and development charges due to, for example, increases in the costs of labor and supplies.

As of December 31, 2025, we had total cash, cash equivalents and marketable securities of $221.5 million. We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the first half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. However, our forecast for the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties and actual results could vary materially. Additionally, the process of conducting preclinical studies and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain. We will need to raise substantial additional capital in the future.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into collaborations with third-parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the progress, results and costs of, discovery and preclinical studies for our programs and development candidates;
- our ability to advance our clinical-stage product candidates into later-stage trials, which we expect will be required in order to seek marketing approval of our product candidates;
- the costs associated with maintaining and improving our Generate Platform;
- our ability to scale up our manufacturing processes and capabilities, or arrange for a third-party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- our ability to seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- the costs associated with acquiring or in-licensing products, product candidates or technologies or intellectual property;
- the costs associated with maintaining, expanding, enforcing, defending and protecting our intellectual property;
- the costs associated with hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future product candidate is approved; and
- the costs associated with making any milestone, royalty or other payments under any collaboration or license agreements that we enter into.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Our expectation with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned. If we are unable to raise this capital when needed, we may be forced to delay, limit, reduce or eliminate one or more of our research and development programs or other operations.

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or issuance of convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through partnership, collaboration or licensing arrangements with third-parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or development product candidates or grant licenses on terms that may not be favorable to us. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. For instance, if we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market development product candidates to third-parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

Leases

We lease office space in Somerville, Massachusetts under a non-cancelable operating lease that expires in June 2032 and lease office and laboratory space in Andover, Massachusetts under a non-cancelable operating lease, as amended, that expires in December 2034. Our operating lease in Andover, Massachusetts includes an option of early termination allowing us to terminate the lease on or after December 31, 2031. We also entered into a finance lease agreement for the purchase of lab equipment. Additionally, we have entered into a service agreement with a CRO in relation to the conduct of our phase 3 clinical studies for GB-0895, which contains embedded leases for certain equipment. Future minimum commitments under these leases are $68.5 million as of December 31, 2025. These commitments are also recognized as operating lease liabilities and finance lease liabilities on our balance sheet as of December 31, 2025. See Note 15 in our audited consolidated financial statements appearing elsewhere in this prospectus for more information on our lease obligations.

Purchase and Other Obligations

We enter into contracts in the normal course of business with third-party CROs, CDMOs and other third-party vendors for preclinical, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation generally consist of payments for services provided or expenses incurred up to the date of cancellation, including non-cancelable obligations of our service providers and, in some cases, wind-down costs. For further information regarding certain of our license agreements and amounts that could become payable in the future under those agreements, please see Note 5 in our audited consolidated financial statements appearing elsewhere in this prospectus.

License, Collaboration and Other Agreements

Below is a summary of the key terms for certain of our license and collaboration agreements. For a more detailed description of these agreements, see the section titled "*Business—License and Collaboration Agreements.*"

Agreement with Novartis

On September 19, 2024, we entered into a Collaboration and License Agreement with Novartis (the "Novartis Collaboration Agreement") to discover, develop, manufacture and commercialize protein therapeutics using our Generate Platform. The collaboration covers multiple collaboration targets, conducted under applicable research plans during defined research terms. As consideration for the collaboration, we received a $50.0 million upfront payment. Novartis also purchased 1,265,822 shares of our Series C preferred stock for $15.0 million. We are eligible to receive up to $1.0 billion across all programs upon the achievement of certain performance-based milestones, including $130.0 million in development and regulatory milestones and $210.0 million in commercial milestones per research program. None of such milestones have been achieved to date. Novartis is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit to a low tens percentage on worldwide net sales of any licensed product, subject to specified reductions and offsets.

Agreement with Amgen

On December 24, 2021, we entered into a Collaboration and License Agreement, as amended by the First Amendment dated October 5, 2022 and the Second Amendment dated December 12, 2023 (as amended from time to time, the "Amgen Collaboration Agreement"), with Amgen to identify biologic proteins and antibodies directed against specified targets. The Amgen Collaboration Agreement initially covered five collaboration targets. In addition, Amgen has the option to nominate up to five additional collaboration targets, at additional cost, the first of which was exercised in December 2023 related to the sixth target. As consideration for the collaboration, we received a $50.0 million upfront payment. In connection with the Second Amendment, which added an additional collaboration target, we received an additional payment of $5.0 million. We are eligible to receive up to $370.0 million for each program upon the achievement of certain milestones, including $160.0 million in development and regulatory milestones and $210.0 million in commercial milestones per program. Amgen is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit up to a low tens percentage on worldwide net sales of any licensed product, subject to customary reductions and offsets. Additionally, the Amgen Collaboration Agreement contemplated an investment by Amgen of $25.0 million in our equity, at the offering price, if we consummated certain future equity offerings. Amgen purchased 2,109,704 shares of our Series C convertible preferred stock for approximately $25.0 million on May 9, 2023.

Agreements with PMCo and PM LLC

On June 22, 2023, we entered into a collaboration agreement (the "Prior PMCo Agreement"), with PMCo, an affiliate of Flagship Pioneering and a wholly owned subsidiary of PM LLC, pursuant to which the parties agreed to collaborate on research and development activities with respect to the licensed products containing certain antibodies against TSLP and/or IL-4Rα and share research and development costs, with us bearing 65% and PMCo bearing 35% of all fully-burdened research costs and development expenses, which percentage commitments were subject to adjustment. In addition, concurrently with the Prior PMCo Agreement, we and PM LLC entered into a Drag-Along Agreement pursuant to which PM LLC agreed to, among other things, vote in favor of certain transactions with respect to PMCo.

On February 4, 2026, we entered into a stock purchase agreement ("Stock Purchase Agreement") with PM LLC, pursuant to which we have agreed to purchase, and PM LLC has agreed to sell, all of the issued and outstanding equity interests in PMCo. In consideration for such sale, PMCo, PM LLC and we have agreed to terminate the Prior PMCo Agreement and the Drag-Along Agreement, and we have agreed to pay PM LLC a portion of our net sales, if any, arising from the sale of certain products covered by certain patents or containing certain know-how ("Generate Products") developed under the Prior PMCo Agreement. The closing of the Stock Purchase Agreement is scheduled to occur concurrently with the execution of the underwriting agreement for this offering.

We will generally be obligated to make payments equal to a high-single digit percentage of net sales of Generate Products, including any Generate Product that contains GB-0895. However, if a Generate Product (i) does not contain GB-0895, (ii) binds to at least one of TSLP or IL-4Rα, and (iii) binds to other proteins in addition to TSLP or IL-4Rα, then the sales payment is reduced based on the composition of the product. Further, if we exclusively license our rights to exploit a Generate Product in one or more countries to a third party, and the royalties on net sales of such Generate Product to be paid by such third party are subject to certain specified reductions, then we may be allowed to further proportionally reduce the sales payment due to PM LLC, depending on the relative value of the future royalties due to us from such third party as compared to the total deal consideration.

Critical Accounting Policies, Estimates and Significant Judgments

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this prospectus, we believe the following accounting policies used in the preparation of our consolidated financial statements are the most critical for fully understanding and evaluating our financial condition and results of operations.

Collaboration Revenue

Our collaboration revenue to date is comprised of amounts recognized from our collaboration agreements with Amgen and Novartis. We recognize revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606").

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In order to achieve this core principle, we apply the following five steps when recording revenue: (i) identify the contract, or contracts, with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when, or as, performance obligations are satisfied.

The promised goods or services in our arrangements typically consist of license rights and research and development services. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own and whether the required expertise is readily available. In addition, we consider whether the customer can benefit from a promise for its intended purpose without the receipt of the remaining promises, whether the value of the promise is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises and whether it is separately identifiable from the remaining promises. We allocate the transaction price to the identified performance obligations based on the estimated standalone selling price. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated cost. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

We use judgment to determine whether milestones or other variable consideration, except for royalties and sales-based milestones where such payments principally relate to a license of intellectual property, should be included in the transaction price. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. The transaction price is allocated to each performance obligation based on the relative standalone selling price of each performance obligation in the contract. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for each performance obligation.

For research and development services performed under a collaboration agreement in which the performance obligation is satisfied over time, we measure the progress of the activities using input methods. The input methods used are based on the effort expended or costs incurred toward the satisfaction of the related performance obligation. We estimate the amount of effort expended, including the time we estimate it will take to complete the activities, or costs incurred in a given period, relative to the estimated total effort or costs to satisfy the performance obligation. This approach requires estimates and the use of significant judgement. If the estimates or judgements change over the course of the collaboration, they may affect the timing and amount of revenue recognized in the current and future periods.

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of its licensing arrangements.

Research and Development Expenses and Related Accruals and Prepaid Expenses

Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs and laboratory supplies, depreciation, manufacturing expenses and external costs of outside vendors engaged to conduct planned clinical development, preclinical development, manufacturing and manufacturing process development and other research support activities. All costs associated with research and development activities are expensed as incurred. Research and development costs that are paid in advance of performance (if any) are capitalized as a prepaid expense and amortized over the service period as the services are provided.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued and prepaid expenses as of each balance sheet date. We make estimates of these based on facts and circumstances known to us at that time. This process involves recording accruals and prepaids for estimated ongoing research costs and receiving updated estimates of costs and amounts owed on a monthly basis from its third-party service providers. When evaluating the adequacy of the accrued liabilities and prepaid expenses, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted cost estimates from its third-party service providers.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting accrued amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Stock-Based Compensation

We have issued and continue to issue stock-based awards to our employees and non-employees in the form of incentive stock options. In addition, we historically issued a limited number of restricted stock awards. We account for stock-based compensation awards in accordance with the Financial Accounting Standards Board ("FASB") ASC Topic 718, *Compensation—Stock Compensation* (ASC 718).

We measure stock-based awards granted to employees and nonemployees based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. For stock-based awards with service-based vesting conditions, we recognize compensation expense using the straight-line method. For stock-based awards with performance-based vesting conditions, we recognize compensation expense using the graded-vesting method over the requisite service period, commencing when achievement of the performance condition becomes probable. Forfeitures are recorded as they occur.

Determination of the Fair Value of Stock-Based Awards

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model (the "Black-Scholes OPM"). The Black-Scholes OPM requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate, (iv) expected dividends and v) the fair value of common stock. Due to the lack of a public market for our common stock and lack of company-specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of publicly traded peer companies. We estimate the expected term of our stock options granted to employees and directors using the simplified method for awards that qualify as “plain-vanilla” options, whereby the expected term equals the midpoint between the vesting date and the end of the contractual term of the option. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

As of December 31, 2025, there was approximately $42.8 million of unrecognized compensation expense related to unvested stock options granted under the 2019 Equity Incentive Plan, as amended (the “2019 Plan”), which were subject to service-based vesting or performance awards for which the performance condition had been achieved and have a remaining service condition. That cost is expected to be recognized over a weighted-average period of 2.4 years.

Determination of the Fair Value of Common Stock

As there has been no public market for our common stock to date, the historical estimated fair value of our common stock has been determined by our board of directors, with input from management, considering our most recently available third-party valuations of common stock, as well as additional factors which may have changed since the date of the most recent valuation through the date of grant.

The grant date fair value of restricted common stock is calculated based on the grant date fair value of the underlying common stock less any purchase price. The fair value of the common stock is also used as an input to the Black-Scholes OPM to value stock options. Our board of directors determines the fair value of our common stock, with input from management, considering our most recently available third-party valuations of common stock, as well as additional factors which may have changed since the date of the most recent valuation through the date of grant. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

In accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, a third-party valuation firm prepared valuations of our common stock using a market approach to estimate our enterprise value, using either the option-pricing method ("OPM"), or the hybrid method, both of which used a market approach to estimate our enterprise value. In accordance with the Practice Aid, we determined the hybrid method was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The hybrid method is a weighted blend of an OPM and a probability-weighted expected return method ("PWERM"), where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of our future values, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability-weighted to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuation of our common stock of $7.49 per share as of May 16, 2024, $9.14 per share as of December 31, 2024, $11.07 per share as of November 24, 2025 and $11.74 per share as of December 31, 2025. Additionally, we performed a retrospective valuation as of September 5, 2025 which resulted in a value of $9.77 per share of common stock.

Given the absence of a public market for our common stock to date, our board of directors, with input from management, considered various objective and subjective factors to determine the fair value of our common stock as of each grant date.

The factors included, but were not limited to:

- our operating results and financial performance;
- the progress of our research and development efforts, including the status of our programs, and the preclinical studies, clinical trials, and manufacturing process development for our product candidates;
- the lack of marketability of our equity as a private company;
- the prices of our preferred stock sold to or exchanged between new and existing investors, and the rights, preferences and privileges of our preferred stock as compared to those of our common stock;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into strategic alliance and license agreements;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event, such as an IPO, or a sale of our company, given prevailing market conditions;
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry; and
- the third-party valuations described above.

There are significant judgments and estimates inherent in these valuations. These judgments and estimates include assumptions regarding our future operating performance, and the stage of development of our product candidates. If our board of directors had made different assumptions, our stock-based compensation expense, net loss attributable to common stockholders and net loss per stock attributable to common stockholders could have been significantly different.

Once a public trading market for our common stock has been established in connection with the consummation of this offering, it will no longer be necessary for our board of directors, or a committee thereof, to estimate the fair value of our common stock in connection with our accounting for granted stock options and other awards, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). As a result, we are able to take advantage of certain exemptions from various reporting requirements that are otherwise applicable to public companies that are not emerging growth companies, including delaying auditor attestation of internal control over financial reporting, providing only two years of audited financial statements and related management's discussion and analysis of financial condition and results of operations and reduced executive compensation disclosures.

We may remain an "emerging growth company" until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means, among other things, (1) the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In particular, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an "emerging growth company." As a result, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests. In addition, the JOBS Act provides that an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an "emerging growth company."

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934. We may continue to be a smaller reporting company even after we are no longer an "emerging growth company". We may take advantage of certain of the scaled disclosures available to smaller reporting companies, including an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements included elsewhere in this prospectus.

BUSINESS

Overview

We are a clinical-stage generative biology company pioneering the AI revolution in biotechnology and drug design and development. Our vision is to program biology to generate optimal therapeutics for the greatest impact on human health. Central to our vision is the Generate Platform, designed to be a therapeutic area and protein modality agnostic system integrating computational innovation with scalable biohardware to address therapeutic challenges beyond the reach of traditional technologies. We have built our Generate Platform to be a tight and fully-integrated loop (design–build–test–learn) to create proprietary, therapeutically relevant data and differentiated molecular solutions for the biological challenges we aim to address. In addressing these challenges, the Generate Platform can engineer solutions against therapeutic targets by either starting from existing reference proteins or suggesting completely novel ones without a reference starting point, also known as *de novo* design. The Generate Platform's therapeutic potential has been demonstrated by our successfully progressing three computationally engineered proteins into human clinical testing, the most advanced of which is GB-0895, an investigational long-acting anti-thymic stromal lymphopoietin ("TSLP") monoclonal antibody, which is enrolling patients in pivotal Phase 3 clinical trials for severe asthma. The first patient was dosed in one of the Phase 3 clinical trials on January 26, 2026. We also expect to advance two additional computationally generated oncology product candidates into Phase 1 clinical trials in 2026.

Biology is an information science. DNA encodes biological function through the way its sequence determines the structure and activity of the molecules it produces, which, in principle, makes biology programmable. In practice, however, the immense complexity of biology has made programming it very difficult. Historically, drug discovery has emphasized two general approaches to manage this complexity. One approach was an intentional, mechanically guided design approach at low-throughput. The other was a high-throughput experimental exploration approach that was generally less able to encode specific intent. We believe that dramatic reductions in the cost of compute and the cost of making and measuring DNA and proteins enable a new paradigm: intentionality at scale. In this paradigm, our generative models learn generalizable design principles from data to generate hypotheses at scale, and scalable experimental systems verify those hypotheses. The Generate Platform was built to implement this paradigm, generating large numbers of specific molecular and biological hypotheses in response to pre-specified therapeutic objectives and rapidly testing them. We believe intentionality at scale is foundational to achieving programmable biology: enabling systematic generation of medicines across therapeutic areas and protein modalities while producing proprietary data that improves our generative models over time.

The Generate Platform integrates generative and predictive models that learn design principles from proprietary data—*e.g.*, diffusion-based models (such as our Chroma model) and graph neural networks, among other architectures—with advanced experimental biohardware systems for scalable verification. Our biohardware systems include scalable DNA assembly, rapid protein production, and high-throughput, multiplexed assay miniaturization enabling us to measure up to billions of molecules per generation cycle, as well as a cryogenic electron microscopy ("Cryo-EM") core for high-content structural data generation, which has produced more than 500 high-resolution maps in 2025 alone. These capabilities significantly reduce the cost and time per assay data point, tightening the loop between generative models and real-world biological verification.

We refer to the distinct biological and molecular capabilities of the Generate Platform as "modular capabilities" or "modules." Our modules are designed to be deployed individually or in combination to engineer differentiated therapeutic candidates. We have successfully translated these modular capabilities to create programs and product candidates with therapeutic potential. For example, our lead product candidate, GB-0895, utilizes our binding affinity and developability optimization modules, and is currently enrolling patients in Phase 3 clinical trials for severe asthma and is also being evaluated in a Phase 1b clinical trial for COPD. We used binding affinity and developability optimization modules, as well as additional modules, including functional optimization, to engineer our other product candidates, including GB-4362 and GB-5267. Investigational New Drug applications ("INDs") were cleared by the FDA for both GB-4362 and GB-5267 in December 2025, and we expect to dose the first patient for both programs in 2026.

Our lead product candidate, GB-0895, is an investigational long-acting anti-TSLP monoclonal antibody in development for severe asthma that is intended to be dosed every six months (“Q26W”). Severe asthma represents a substantial unmet medical need, with industry sources suggesting only 15% to 25% of eligible patients receive biologic therapy. There are adherence and persistence challenges with existing shorter-acting biologic agents and GB-0895’s potential Q26W dosing regimen is designed to reduce injection frequency to address these challenges. We have engineered GB-0895 to have ultra-high binding affinity, reaching an estimated twenty-fold improvement over tezepelumab (106 femtomolar binding affinity) and a YTE amino acid modification, a clinically-validated half-life extension technology. A YTE amino acid modification is a specific change made to three amino acids (M252Y/S254T/T256E) in an antibody’s fragment crystallizable ("Fc") region. Preclinical and Phase 1 clinical data have demonstrated favorable safety results, long half-life (mean terminal half-life of approximately 98 days), and suppression of key biomarkers, such as blood eosinophils ("EOS"), fractional exhaled nitric oxide ("FeNO"), IL-5, and IL-13, supporting its potential Q26W dosing regimen. We are currently enrolling patients in two parallel global Phase 3 clinical trials for GB-0895 initiated in December 2025 (SOLAIRIA-1 and SOLAIRIA-2) for severe asthma, with full enrollment expected by the first half of 2028. The first patient was dosed in our SOLAIRIA-1 Phase 3 clinical trial on January 26, 2026. We intend to develop GB-0895 as a biologic-device combination product.

In parallel, we are currently conducting a Phase 1b clinical trial for moderate-to-severe chronic obstructive pulmonary disease (“COPD”) with expected data in 2026. COPD is a widespread and often fatal lung condition. Current biologics target patients with higher eosinophil counts, leaving the majority of patients without an approved biologic option. The Phase 1b COPD trial for GB-0895 is evaluating safety, tolerability, pharmacokinetics (“PK”), pharmacodynamics (“PD”) and immunogenicity. Preliminary data showed biomarker reductions and a PK profile consistent with our earlier Phase 1 trial for GB-0895 for the treatment of mild-to-moderate asthma, supporting an extended dosing interval in COPD. We plan to evaluate multiple approaches to determine the optimal development path for GB-0895 for the treatment of COPD, taking into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial.

In addition to progressing GB-0895, we are advancing additional programs and product candidates that leverage the Generate Platform’s modular capabilities. These include GB-4362, a systemically administered monoclonal antibody designed to neutralize free monomethyl auristatin E ("MMAE") as an adjunctive therapy to antibody-drug conjugate (“ADC”) molecules with an MMAE payload, as well as GB-5267, an armored, MUC16-directed CAR-T cell therapy candidate developed in collaboration with Roswell Park Comprehensive Cancer Center ("Roswell Park"), for solid tumors, initially targeting platinum-resistant ovarian cancer. Beyond these product candidates, we are advancing additional preclinical programs, including a next-generation ADC that is being developed as an internal program, along with other early stage preclinical programs. In addition, the Generate Platform’s modular capabilities underpin the confidential programs being developed in collaboration with Amgen Inc. ("Amgen") and Novartis Pharma AG ("Novartis").

We continue to advance our Generate Platform by investing in computational and biohardware innovation to scale productivity, unlock new modular capabilities and create differentiated future programs and product candidates. This should allow us to address important unmet patient needs with validated modules that offer scalable impact, at low marginal cost. Additionally, we intend to opportunistically utilize partnerships and collaborations to leverage our capabilities with sophisticated collaboration partners to work collectively to solve significant challenges, while improving the capabilities of the Generate Platform. In addition, we also intend to opportunistically explore various collaboration solutions to maximize value, secure capital, and direct our technology towards diverse therapeutic applications.

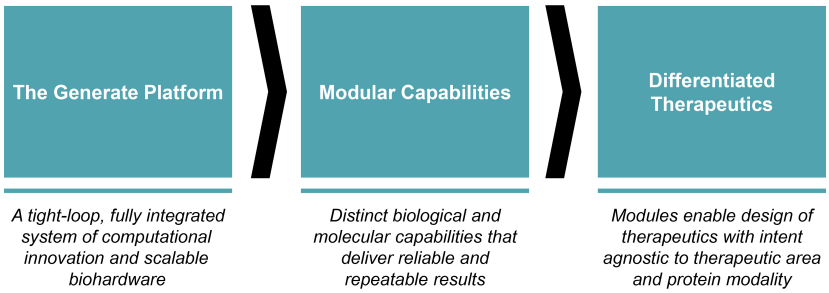
We are led by an experienced team of executives with backgrounds in leading pharmaceutical and life sciences companies and academia and deep experience in generative biology and computational sciences, supported by a distinguished board of directors. We were founded in 2018 by Flagship Pioneering, bringing together advancements in generative biology and computational protein science.

The Generate Platform and Our Modular Capabilities

Since inception, the Generate Platform was designed to create differentiated protein therapeutics and unlock the promise of a new method of designing drugs through a concept we call programmable biology. For biology to be programmable, it means that we must be able to design, write and execute biological functions with pre-specified intent, across therapeutic areas and protein modalities.

Our Generate Platform is designed to implement intentionality at scale by coupling AI models that generate large numbers of design hypotheses with scalable biohardware that verifies them. Each time we engineer, build and then test a set of hypotheses, a process which we refer to as a generation cycle, we generate experimental data that is intended to improve the Generate Platform. We package certain of these learnings into reusable modules—validated capabilities that can be applied across targets and modalities towards differentiated therapeutics.

The Generate Platform is designed to generate differentiated therapeutics

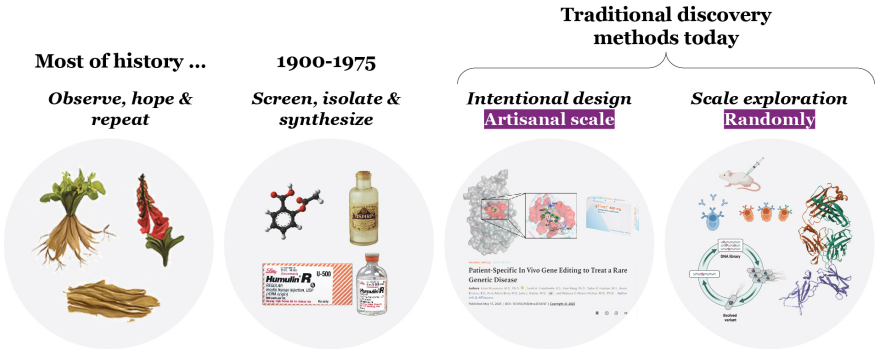


Our Generate Platform has enabled us to develop numerous modular capabilities, many of which have already demonstrated the ability to successfully translate computationally engineered proteins into human clinical testing, including our lead product candidate GB-0895, which is currently enrolling patients in Phase 3 clinical trials for the treatment of severe asthma. In addition, we are currently exploiting our modular capabilities for other potential therapeutic applications, including for use in oncology and other historically difficult to treat diseases.

Background and Context

Despite significant innovation over many decades, we believe drug discovery remains constrained by biology's complexity and the limits of conventional tools to navigate it efficiently. Traditional drug discovery methods have often relied on intentional, mechanistic hypothesis-driven molecular design, which is typically pursued in an artisanal manner and therefore with low-throughput. Alternatively, traditional drug discovery methods have also relied on high-throughput molecular exploration—from early small molecule screens to modern library display-based libraries—to find "the needle in the haystack." These techniques gain scale by generating large numbers of variants, but are less able to code specific intent.

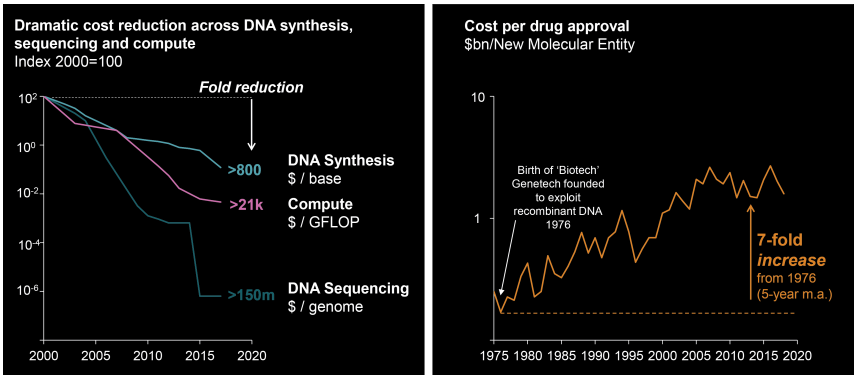
Traditional drug discovery methods today are generally limited to intentional design at low scale or random at scale exploration



While traditional drug discovery techniques have improved over time and the cost of compute, as well as DNA synthesis and sequencing, have fallen substantially, the unit economics of developing new medicines has not improved in a meaningful way. In fact, published analyses, as illustrated in the figure below, suggest that the inflation-adjusted cost per new drug approval has increased over time, including over the last several decades.

We believe the convergence of cost reduction trends in compute and DNA synthesis and sequencing, as a result of advancements in recombinant DNA technology and synthetic biology, enables intentionality at scale. This means that AI models can learn generalizable design principles from data to generate hypotheses at scale, and scalable experimental systems can verify those hypotheses at scale. We believe we are well positioned to capitalize on these advancements by utilizing our Generate Platform to provide intent and scale, which we believe unlocks a potentially new paradigm of drug design exemplified by improved speed, lower cost and enhanced probability of success. Our Generate Platform was built to implement this paradigm and we have been a pioneer in demonstrating the ability to leverage the computational revolution to scale the number of intentionally designed protein ideas to the millions. This has unlocked a large potential solution space designed to find the optimal protein that can deliver the greatest impact to patients in a given therapeutic application.

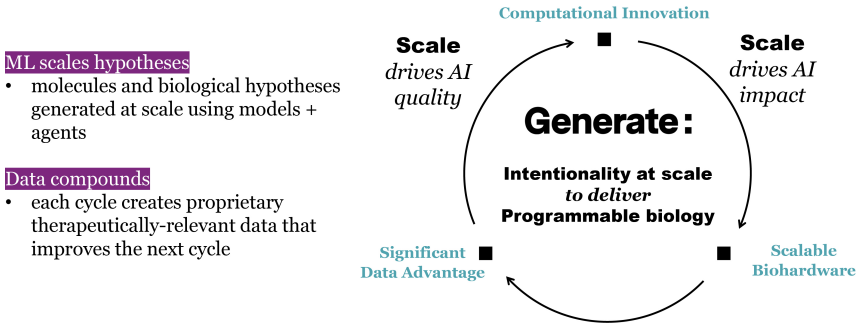
There has been significant cost reductions in DNA synthesis, sequencing and compute while the cost per new medicine has increased



The Generate Platform

We built the Generate Platform on a foundation of integrating computational innovation with scalable biohardware to create a significant data advantage and drive differentiated molecular solutions for the biological and therapeutic challenges we aim to address, as illustrated in the figure below.

The Generate Platform is designed to systematically decode and comprehend biology at speed and magnitude



Our machine learning team includes pioneers in generative protein design, demonstrated, for example, by our November 2023 publication in *Nature* of the Chroma model, one of what we believe to be the first diffusion protein models, as well as being among the leaders in graph neural networks for protein design. In parallel, we have invested in biohardware designed to deliver proprietary, therapeutically relevant data at scale. Our biohardware systems include scalable DNA assembly, rapid protein production (including cell-free protein synthesis), and multiplexed assay systems (including mRNA display, assay miniaturization and microfluidics) designed to measure large libraries efficiently. Complementing these scalable measurements, we have a Cryo-EM core that includes four microscopes, which has allowed us to scale protein complex structure determination (the structure of proteins interacting with one another) to fill highly valuable data gaps. We have resolved more than 500 high-resolution maps in 2025 alone and we continue to scale this capability while expanding to novel data types, including protein conformational ensembles (which is the capture of proteins as they move naturally). These capabilities allow us to significantly reduce the cost and time of each generation cycle and per assay data point, tightening the loop between our generative models and the verification of their hypotheses in the real-world biological setting. This makes subsequent ideas proposed by our models better and creates a compounding advantage over time.

Modular Capabilities

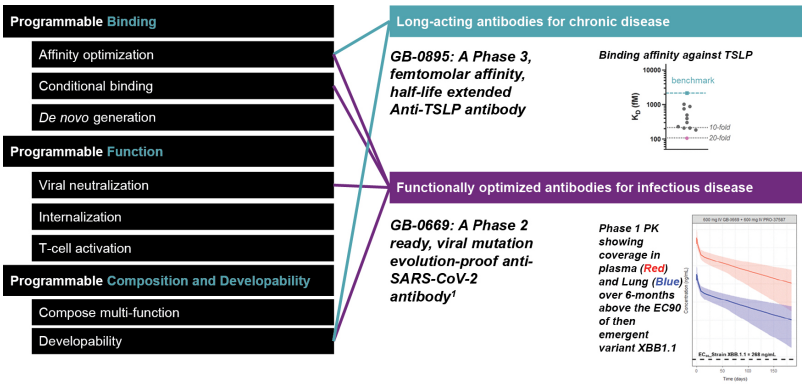
To date, we have deployed our Generate Platform to establish numerous modular capabilities, many of which we can now reliably and repeatably direct towards developing future therapeutic candidates. Our initial focus in building modular capabilities was on one of the most fundamental ways proteins mediate biology: binding. We have leveraged this starting point to expand our capabilities to include (i) binding with context, including selective and conditional target binding, and (ii) protein design for a desired function; in parallel, we have invested in a set of capabilities focused on developability. We have already seen the translational impact of our established modules in our first three clinical product candidates, as well as in two additional product candidates that are anticipated to enter clinical trials in 2026. Examples of our current modules and the intended purposes are summarized in the figure below.

Examples of modular capabilities developed to-date

Examples of Modular Capabilities Developed To-date		
Programmable Binding		
	Affinity optimization	Tune binding affinity, up or down, for desired outcomes
	Conditional binding	Bind given condition, e.g., pH, or selectively/cross reactivity
	De novo generation	Generate a completely novel binder to a specific epitope
Programmable Function		
	Viral neutralization	Therapeutically relevant neutralization across viral strains
	Internalization	Receptor internalization and payload delivery
	T-cell activation	Antigen specific T-cell activation for selective tumor killing
Programmable Composition and Developability		
	Compose multi-function	Graft and fuse protein modules with different functions
	Developability	Manufacturability, e.g., aggregation, viscosity

We have built these modular capabilities with the intent to explore and decode biological challenges with a direct link to a therapeutic opportunity. For example, many biologics require a drug developer to "tune" the binding of antibodies to a target, otherwise known as binding affinity. Previously, this would have taken multiple cycles of library generation and screening, often with limited ability to reliably reach a specific affinity window, such as very high affinities in picomolar or femtomolar ranges. In contrast, our generative models propose new proteins with intent to increase, decrease or engage in selective binding depending on what is needed in the given program context. These diverse modules can be used alone, or in combination with one or more other modules, to generate unique proteins that are designed to address important therapeutic challenges. As shown in the figure below, two examples of proteins we designed that utilize our modules include our lead product candidate, GB-0895, and a functionally optimized antibody to neutralize a virus that has otherwise demonstrated meaningful resistance against all other approved antibody therapies. These examples reflect our deep conviction: programmable biology is only possible when therapeutic intent, computational engineering and biological data generation operate as a unified system to enable intentionality at scale and a compounding data advantage over time.

Application of modular capabilities to therapeutic applications



[1] Development paused for commercial reasons.

As we develop our Generate Platform and its modular capabilities, we are focused on translating their potential into meaningfully differentiated therapeutics. Initially, we pursued therapeutic opportunities in which we believe our modular capability or combinations of modular capabilities are likely to solve a molecular challenge in areas of well-understood biology. We believe that this approach allowed us to shift risk to the preclinical setting, where we can quickly identify differentiated proteins with the desired attributes. If we successfully engineer desired proteins, we believe it will unlock our ability to develop therapeutic candidates that can be moved into clinical testing with lower risk and a potentially differentiated product profiles, thereby creating the potential for outsized patient impact and value. One or more of these modules can also be deployed to address therapeutic opportunities with potential partners, enabling an additional value generation route for us, as exemplified by our Amgen and Novartis collaborations.

Potential Therapeutic Impact

We use the Generate Platform to engineer differentiated product candidates for therapeutic opportunities. Using a modular approach, which combined our binding affinity and developability optimization capabilities, we developed our lead product candidate, GB-0895. We engineered GB-0895 to be a long-acting, anti-TSLP monoclonal antibody for severe asthma, COPD and other indications, intended for Q26W dosing.

Across chronic inflammatory diseases, there is a significant unmet need for biologic solutions that improve patient adherence and outcomes. We believe long-acting therapies like GB-0895, if approved, could address this need. To effectively achieve the desired clinical response over our proposed Q26W dosing schedule, we believe an anti-TSLP antibody must have both ultra-high binding affinity to sustain target engagement and an extended half-life to persist in the body. Most antibodies do not remove their target from the body; rather, they simply occupy the target to prevent its activation. If a lower-affinity antibody dissociates, the target may become active again, negatively impacting the clinical response.

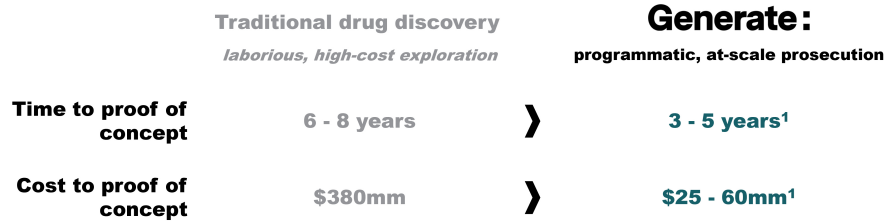
Our PK/PD modeling predicted that even with a validated half-life extension technology, such as a YTE mutation, reaching the proposed dosing interval would still require femtomolar binding affinity to the TSLP target. We used our Generate Platform to engineer, in just two generation cycles, an antibody that was designed with these characteristics, incorporating 106 femtomolar binding affinity—an estimated 20-fold improvement over tezepelumab, based on published data—and the half-life extension technology.

We further applied our binding affinity and developability optimization modules to an investigational antibody targeting IL-13 currently in Phase 1 clinical trials in healthy volunteers, and have engineered several other product candidates that we believe are valuable and validated targets in chronic disease. These include antibodies targeting TL1A and IL-23p19 for inflammatory bowel disease and OX40L for several immune conditions. In each case, we have observed 20- to 500-fold improvements in binding affinity relative to benchmark antibodies while retaining desired specificity and developability characteristics. Beyond Immunology and Inflammation indications, we have applied this technology to optimize binding of antibodies, for example, to small molecules with our investigational MMAE product candidate, GB-4362, which is being developed as a combination partner to ADCs with MMAE payloads. An IND for GB-4362 was cleared by the FDA in December 2025.

In addition to binding affinity optimization and developability, we deployed other modular capabilities to a variety of additional programs. Our first clinical product candidate, GB-0669, required us to use our cross-reactive binding, viral neutralization and binding affinity optimization and developability modules to enable what we believe was the first clinical monotherapy candidate targeting the variant-resistant S2 domain on the spike protein of SARS-CoV-2. We have more recently applied these modules to optimize for chimeric antigen receptor (“CAR”) function and expression in our collaboration with Roswell Park (as defined below), which resulted in the GB-5267 product candidate. Roswell Park submitted an IND for GB-5267, which was cleared by the FDA in December 2025.

Through deploying our Generate Platform towards therapeutic opportunities, we have seen a significant impact on the speed, cost and probability of success of drug design and development as summarized in the below figure. Our future programs may not be developed within time frames or at costs comparable to our existing programs, and factors such as program reprioritization, funding constraints, and unforeseen technical or scientific challenges may extend drug discovery timelines.

Impact of the Generate Platform relative to traditional drug discovery



Generate demonstrated success in translating our technology to product candidates:
- 8 programs successfully reached candidate nomination
- Created 5 clinical / clinic-ready product candidates
- 2 / 2 product candidates for which we initiated proof of concept trials achieved clinical proof of concept

[1] Referring to Generate's GB-0895 and GB-0669 programs.

Building on these efficiency gains, we are deploying our reusable modular capabilities to tackle increasingly complex biological challenges, such as engineering receptor-mediated internalization or conditional binding, each tightly linked to significant therapeutic opportunities. Capabilities such as these are being deployed in our early-stage pipeline. In parallel, we continue to innovate and invest across the Generate Platform to further lower the time and cost required to design, build and test each new hypothesis, so we can learn faster from real-world biology and build a compounding advantage over time. We believe this will expand the modular capabilities we can deploy, broaden the set of challenges we can reliably address, and ultimately translate into differentiated future product candidates.

Our Strategy

Our vision is to program biology to generate optimal therapeutics for the greatest impact on human health. We believe that this vision will be enabled by deploying generative biology at scale. Since our formation, we have focused on investing in our differentiated Generate Platform to unlock a new way of designing and developing drugs by integrating computational and experimental innovations. We believe these investments move us closer to a paradigm of programmable biology where drug discovery becomes more akin to engineering than traditional methods.

To move the company toward our vision, we focus on the following key strategic initiatives:

1. **Progress our advanced clinical-stage lead product candidate, GB-0895.**

   GB-0895 is the first known anti-TSLP monoclonal antibody designed to be dosed every six months ("Q26W") to initiate Phase 3 development. TSLP is a key epithelial cytokine implicated in the pathogenesis of severe asthma. We believe that targeting TSLP has demonstrated a strong clinical rationale for reducing exacerbations and improving disease control. The clinical rationale for the inhibition of TSLP in patients with severe asthma is based on the FDA approval of tezepelumab, an anti-TSLP monoclonal antibody for severe asthma patients, which is dosed every four weeks (Q4W). We are currently enrolling patients in two Phase 3 trials, SOLAIRIA-1 and SOLAIRIA-2, in patients with severe asthma. The first patient was dosed in our SOLAIRIA-1 Phase 3 clinical trial on January 26, 2026.

   GB-0895 offers what we believe is a unique opportunity for us to unlock a "pipeline-in-a-product." In parallel to our Phase 3 trials in severe asthma, we are assessing GB-0895 in an ongoing Phase 1b expansion trial in moderate-to-severe COPD patients. Given the safety and tolerability results seen in our Phase 1b trial as of the November 7, 2025 data cutoff date, we see potential for GB-0895 as a biologic in COPD, which is an area of high unmet need. We plan to evaluate multiple approaches to determine the optimal development path for GB-0895 for the treatment of COPD, taking into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial. As part of such evaluation, we plan to seek engagement with

regulatory authorities to discuss our development strategy and obtain regulatory feedback on our proposed approach in 2026.

With the broader relevance of the TSLP blockade in Type 2 and Non-Type 2 inflammation in asthma and other epithelial barrier-driven conditions, we also believe there is potential for multiple longer-term expansion opportunities for GB-0895 beyond lower airway diseases. In this regard, we may also seek to evaluate GB-0895 in combination with other targeted therapies, such as IL-13 and OX40 ligand, to address residual disease activity in selected immunology and inflammation ("I&I") patient populations.

Our GB-0895 development efforts are supported by our highly experienced clinical development team, who brings deep Phase 3 expertise and a proven track record in designing and executing pivotal trials across respiratory and immunology indications.

2. **Advance our next wave of clinical and preclinical product candidates in a broad range of indications, starting with oncology.**

We are applying our Generate Platform to engineer and develop additional product candidates in areas of high unmet need, with an initial focus on oncology. INDs for GB-4362 and GB-5267 were cleared by the FDA in December 2025, and we received from the FDA a Fast Track designation for GB-4362 for the prevention and/or reduction of enfortumab vedotin-induced toxicity in urothelial cancer patients on January 23, 2026. These product candidates are among the initial potential clinical applications of the Generate Platform in areas of significant unmet need outside of I&I. Should either product candidate prove successful in their respective Phase 1 clinical trials, we believe there could be opportunities to push directly toward registration-intent trials soon thereafter.

In addition to these two product candidates, we are exploring whether to advance additional preclinical oncology programs, including a potential ADC molecule.

3. **Advance our Generate Platform to scale productivity, unlock new modular capabilities and translate additional differentiated programs and product candidates.**

We plan to continue investing in the development of computational and biohardware innovations to achieve our vision of programming biology and unlocking differentiated therapeutic applications. We believe that these investments will enable the identification and validation of new modular capabilities, which can be used to create additional differentiated product candidates to address important unmet patient needs. Once validated, these modules generally have the potential to offer scalable impact at low marginal cost, supporting efficient future therapeutic development.

As we consider additional programs, we intend to prioritize opportunities that we believe our Generate Platform has a differentiated advantage compared to traditional drug discovery methods. We anticipate that our investments have the potential to yield several new programs over the next two years.

4. **Establish additional partnerships and collaborations to maximize value from and for our Generate Platform.**

Given the breadth of our capabilities, we intend to continue to evaluate partnerships and collaborations designed to maximize the value of our Generate Platform and accelerate the impact of our product candidates. We may engage in additional strategic collaborations similar to our Amgen and Novartis collaborations, which enable us to leverage our distinct capabilities to help our collaboration partners solve significant challenges that seem to be unachievable with traditional methods, while at the same time allowing us to improve our own Generate Platform capabilities. We may also enter into certain research or technology collaborations, such as our existing collaborations with Roswell Park and MD Anderson, which extend the Generate Platform’s reach into valuable applications by leveraging partner expertise across modalities that are not fully protein-based or that require external capabilities in other areas of significant unmet need (*e.g.*, CAR-T manufacturing, adding payload or linker technology to an internally developed ADC and other research and technological expertise). Lastly, as we advance our programs and product candidates, we may also opportunistically explore licensing, commercialization and other partnership and collaboration arrangements with global pharmaceutical companies to enhance our development or commercialization efforts. These types of partnership, collaboration and other arrangements could enable us to pursue additional programs and product candidates, secure additional capital and maximize the potential of our technology toward solutions for patients suffering from a wide range of diseases.

Our Team

Our company is led by a team of executives who collectively bring decades of experience from leading pharmaceutical and life sciences companies and academia and deep experience in generative biology and computational sciences. Our Chief Executive Officer, Michael Nally, M.B.A., joined us in 2021 after an 18-year career at Merck & Co., Inc. ("Merck"), where he served as Chief Marketing Officer overseeing global strategy for a $40 billion portfolio and as President of Global Vaccines. Our Co-Founder and Chief Technology Officer, Dr. Gevorg Grigoryan, Ph.D., is a leading protein scientist who drives the development of our Generate Platform and has authored more than 50 peer-reviewed publications in journals including *Nature*, *Science* and *PNAS*. Our President and Chief Financial Officer, Dr. Jason Silvers, M.D., J.D., brings more than 20 years of finance experience, previously serving as a Partner at Goldman Sachs & Co. LLC, where he advised on more than $400 billion in global transactions and where he most recently co-led the EMEA healthcare investment banking group.

Our Chief Scientific Officer, Dr. Aarif Khakoo, M.D., M.B.A., is a physician-scientist with extensive experience in drug discovery and development. Previously the Chief Scientific Officer and Head of Research and Development at Scribe Therapeutics, Inc., he has also held senior R&D leadership roles at Calico Life Sciences LLC and Amgen, where he advanced multiple programs into the clinic and oversaw translational medicine and early clinical development across multiple therapeutic areas. Dr. Laurie Lee, M.D., our Chief Medical Officer for Immunology & Inflammation, leads late-stage clinical development across our immunology portfolio and previously held senior R&D roles at CSL Behring LLC and GSK plc, where she led development of the Trelegy Ellipta asthma program from Phase 2 through global regulatory submissions that led to approval. Dr. Dinesh de Alwis, Ph.D., our Senior Vice President and Head of Clinical Drug Development, is an accomplished drug developer with more than 25 years of industry experience, including a decade at Merck contributing to the development of pembrolizumab.

Beyond our exceptional leadership team, we have assembled a multi-disciplinary team with deep scientific, clinical, technological, and operational expertise across biotechnology, machine learning and drug discovery and development. In this regard, as of December 31, 2025, we employed 138 M.D.s and Ph.D.s with advanced degrees and experience across multiple therapeutic areas and in fields such as biologic engineering, biochemistry, biomedical engineering, biophysics, biostatistics, chemistry, physics, computer science and PK/PD.

Our leadership team is guided by a board of directors with distinguished scientific and industry leadership, including Dr. Noubar B. Afeyan, Ph.D., Founder and CEO of Flagship Pioneering, Inc. ("Flagship Pioneering"); Dr. Frances Arnold, Ph.D., Nobel Laureate and Professor at the California Institute of Technology; Stéphane Bancel, Chief Executive Officer of Moderna, Inc.; Marsha Fanucci, former Chief Financial Officer of Millennium Pharmaceuticals, Inc.; Jane Mendillo, former Chief Executive Officer of Harvard Management Company; Paul Parker, Managing Partner at Flagship Pioneering; Dr. Nancy Simonian, M.D., former Chief Executive Officer of Syros Pharmaceuticals, Inc.; Rupert Vessey, BM, BCh. DPhil, FRCP, Chief Scientist and Executive Partner of Flagship Pioneering and former President, Research and Early Development at Bristol-Myers Squibb Company; and Michael Nally, M.B.A., our Chief Executive Officer. Our board of directors provides extensive experience in drug discovery, commercialization, investment and governance.

Our Beginnings: Generate and Flagship Pioneering

Flagship Pioneering founded Generate in 2018 as Flagship VL56, Inc., working together with Dr. Gevorg Grigoryan, Ph.D., our founding Chief Technology Officer. In 2019, Flagship VL56, Inc. was combined with complementary generative biology explorations from another Flagship company, Flagship VL57, Inc. Flagship Pioneering invents and builds platform companies, each with the potential for multiple products that transform human health, sustainability and beyond. Generate's founding team is the Flagship Pioneering origination team led by co-founders Noubar B. Afeyan, Ph.D., Founder and Chief Executive Officer of Flagship Pioneering, Dr. Geoffrey von Maltzahn, Ph.D., Dr. Avak Kahvejian, Ph.D., Dr. Molly Gibson, Ph.D., other scientists at Flagship Pioneering, and Dr. Grigoryan.

Generate was based on an exploration of the following question: What if we could generate novel protein therapeutics using generative AI tools, without having to discover them through trial and error? The team set out to explore whether advances in generative AI, large-scale protein sequence and structural data, and high-dimensional modeling could unlock a systematic, AI-first approach to creating new therapeutic proteins.

Recognizing the deep scientific synergy between Flagship Pioneering's data-driven exploration and Dr. Grigoryan's pioneering insights into the learnable, recurring structural patterns that govern how proteins

fold and function, Flagship Pioneering brought these efforts together to launch the world's first generative biology platform capable of learning the underlying rules of protein function and generating novel therapeutic candidates on demand. Since our inception, we have continued to build on this foundation, advancing our platform, expanding our discovery and development capabilities, and assembling a leadership team committed to translating this new approach into transformative medicines for patients.

Translation of our technology into differentiated therapeutics—the first wave of product candidates

We leveraged our initial Generate Platform modular capabilities to develop our first product candidates with differentiated features that focused on targets with well validated disease biology. This approach allowed us to significantly decrease the time and, we believe, the risk to advance our first product candidates to late-stage clinical development.

Our current pipeline of product candidates is summarized in the figure below:

Our pipeline

	Proposed Indication(s)	Target	Modality	Preclinical	Phase 1	Phase 2	Phase 3	Next Milestone	Collaborations
IMMUNOLOGY & INFLAMMATION									
GB-0895	Severe Asthma	TSLP	Antibody					Fully enrolled Ph 3 studies (2H27/1H28)	
GB-0895	COPD	TSLP	Antibody					Ph1b data (1H26)	
ONCOLOGY									
GB-4362[1]	Various in combo with MMAE ADCs	Free MMAE	Antibody					Ph1 initiation (2026)	
GB-5267[1]	Metastatic Ovarian Cancer	MUC-16	Armored CAR-T					Ph1 initiation (2026)	Roswell Park 50:50

[1] IND "Study May Proceed" notification received in December 2025

Beyond this pipeline, we are also leveraging the Generate Platform and its modular capabilities to:

- Advance multiple innovative preclinical programs, each designed with differentiated characteristics that we believe are beyond the reach of traditional technologies, including a next-generation ADC we are progressing toward product candidate nomination (this preclinical program utilizes one of our modular capabilities to enhance internalization and cytotoxicity against a target with naturally low internalization rates); and
- Establish platform collaborations to help our collaboration partners address therapeutic challenges while maximizing the potential of our technology, including:
  - Six confidential collaboration programs with Amgen, first announced in January 2022; and
  - Multiple confidential collaboration programs with Novartis, first announced in September 2024.

We have not received regulatory approval for any product candidate to date, have incurred significant operating losses since inception and anticipate continuing to incur substantial losses for the foreseeable future.

GB-0895: An Anti-TSLP Monoclonal Antibody

Overview

GB-0895 is long-acting anti-TSLP monoclonal antibody intended to be dosed every six months ("Q26W") designed using our Generate Platform to address unmet needs in respiratory diseases. We are initially developing for the treatment of severe asthma. TSLP is a clinically and commercially validated target in severe asthma and has demonstrated broad potential in Type 2 and Non-Type 2 inflammatory diseases in clinical trials by third-parties. We are currently enrolling patients in two Phase 3 clinical trials of GB-0895 for the treatment of patients with severe asthma (SOLAIRIA-1 and SOLAIRIA-2) following promising data in mild-to-moderate asthma patients in our Phase 1 clinical trial. The first patient was dosed in our SOLAIRIA-1 Phase 3 clinical trial on January 26, 2026. In parallel, we are also assessing GB-0895 in an ongoing Phase 1b expansion trial in moderate-to-severe COPD patients. Preclinical and clinical data demonstrated ultra-high affinity inhibition of TSLP signaling, with a 106 femtomolar binding affinity for TSLP and a mean terminal half-life of approximately 98 days in adults with mild-to-moderate asthma, which, together with quantitative PK/PD modeling, support evaluation of a subcutaneous Q26W dosing regimen. If approved, this dosing regimen, which is being evaluated in our Phase 3 clinical trials, would represent a potentially significant improvement to approved biologic therapies, which are typically dosed every two to eight weeks.

Mechanism of Action and Rationale

TSLP is an epithelial cell-derived cytokine implicated in initiating and amplifying multiple pathways that drive lung inflammation in severe asthma. TSLP protein expression is increased in the airway epithelium and lamina propria of patients with asthma compared with healthy individuals, and higher TSLP levels are associated with more severe disease and airflow obstruction. TSLP gene expression and a T helper 2 ("Th2") gene-expression signature have been observed in bronchial biopsy specimens from patients with asthma, and increased TSLP expression has been shown to correlate with reduced forced-expiratory volume in one second/forced vital capacity ("FEV_1/FVC") ratios. Collectively, we believe these findings support a role for TSLP as an alarmin at epithelial barriers such as the lung that initiates inflammation involving multiple downstream cytokines, including IL-5 and IL-13, which in turn contributes to clinical manifestations of asthma. Given this that TSLP is produced at the top of the inflammatory cascade, or prior to IL-5 and IL-13, specific targeting of TSLP has the potential to broadly modulate airway inflammatory responses across diverse inflammatory phenotypes.

Technology Approach and Molecular Characteristics

GB-0895 was designed using our Generate Platform, which was applied to optimize multiple molecular attributes, including affinity and developability. In addition to this approach, GB-0895 was also engineered to incorporate YTE half-life extension technology in the fragment crystallizable ("Fc") region, which was intended to enhance binding to the neonatal Fc receptor ("FcRn") and prolong systemic exposure. In a Phase 1 clinical trial in adults with mild-to-moderate asthma, GB-0895 demonstrated a mean terminal half-life of approximately 98 days.

In preclinical studies, GB-0895 also exhibited ultra-high affinity binding to TSLP, with femtomolar binding to human TSLP, which represents an estimated 20-fold improvement over tezepelumab. This improvement was determined using in vitro KinExA (Kinetic Exclusion Assay) technology to measure the affinities (expressed in K_D) of GB-0895 and tezepelumab. In these KinExA assays, a variant of GB-0895 with no Fc YTE mutations bound human TSLP with a K_D of 0.106 pM (106 fM) and tezepelumab bound human TSLP with a K_D of 2.24 pM. Further, as measured by KinExA, this GB-0895 variant bound cyno TSLP with a K_D of 1.25 pM compared to 9.05 pM for tezepelumab. We believe that the unique combination of ultra-high affinity TSLP binding and extended half-life is the critical enabler for GB-0895's sustained neutralization of TSLP and downstream pathway suppression over extended intervals. Most antibodies do not remove their target; they simply "occupy" it to prevent it from becoming active. If the antibody dissociates, as lower affinity antibodies frequently do, then the target once again becomes "active" and can negatively impact the clinical response. We determined through PK/PD modeling that if we applied a validated half-life extension technology (in this case a YTE mutation (M252Y/S254T/T256E)), femtomolar binding affinity to the TSLP target would likely still be required to reach a Q26W dosing regimen. These findings are based on in vitro, preclinical binding measurements and GB-0895 may perform differently in in vivo studies. In addition, binding to non-human (including cynomolgus) TSLP may differ from binding to human TSLP, and non-human binding results may not be predictive of human performance.

These engineered molecular properties—ultra-high affinity TSLP binding and YTE-mediated half-life extension—supported evaluating a Q26W dosing regimen of GB-0895 in patients with severe asthma and COPD. In our Phase 1 trial, GB-0895 demonstrated durable serum exposure and PD effects at the 300 mg dose, and our ongoing Phase 3 severe asthma product candidate is designed to assess whether a 300 mg six-monthly dosing regimen can provide clinically meaningful reductions in exacerbations and improvements in other outcomes.

GB-0895 for the Treatment of Severe Asthma

Asthma Disease Overview

Asthma is a heterogeneous disease characterized by chronic airway inflammation and variable respiratory symptoms, including wheezing, shortness of breath, chest tightness and cough, together with variable expiratory airflow limitation. The disease can be caused or triggered by various factors with both the immune system and the environment playing a role in the disease. The two main phenotypes of asthma are Type 2, typically allergen-driven with onset typically in childhood, and Non-Type 2 disease, typically environment-driven that is later-onset. Both types are assessed using eosinophils and fractional exhaled nitric oxide ("FeNO") levels as biomarkers. Type 2 disease is characterized by inflammation driven by Th2 cytokines (including IL-4, IL-5 and IL-13) that increase production of immunoglobulin E ("IgE"), activate eosinophils, and raise FeNO levels, producing allergic or eosinophilic inflammation. In contrast, non-Type 2 asthma is characterized by Th1 and/or Th17-cell mediated inflammation rather than the Th2-cell mediated inflammation, resulting in lower eosinophil and FeNO levels. Non-Type 2 asthma patients typically do not respond well to inhaled steroids and have been poor candidates for biologics historically.

Asthma Market Opportunity

Asthma remains a major global health burden. In the United States alone, asthma affects approximately 27 million adults and five million children, making it one of the most common chronic respiratory diseases in the United States. Approximately 5% to 10% of all asthma patients have severe disease, defined as asthma that remains uncontrolled despite optimized treatment with high-dose inhaled corticosteroids plus additional controllers, or that requires such therapy to prevent loss of control. These patients often have symptoms that substantially impair quality of life, require multiple concomitant medications (including bronchodilators and systemic corticosteroids), experience frequent exacerbations and incur substantial excess medical costs each year.

Within this severe segment, a large unmet need persists despite several approved biologics today. It is estimated that approximately 85% of people with severe asthma, or roughly 1.9 million individuals across the U.S., EU5, and Japan, meet eligibility criteria for at least one approved biologic; however, industry sources suggest only 15% to 25% of eligible patients are receiving biologic therapy. Poor adherence and persistence with existing agents, together with barriers to initiation, contribute to suboptimal symptom control, ongoing exacerbations and unnecessarily increased healthcare resource utilization.

Of these approved biologics, only one drug targeting the TSLP pathway, tezepelumab (marketed as TEZSPIRE by Amgen and AstraZeneca plc ("AstraZeneca")), has been approved to date for the treatment of severe asthma in patients 12 years and older and is the only severe asthma biologic without phenotype or biomarker limitations in its label, reflecting the position of TSLP at the top of the inflammatory cascade relative to downstream cytokines. Approximately 80% of patients with severe asthma have blood eosinophil counts <300 cells/μL, where the effectiveness of most approved biologics is reduced. Furthermore, approximately 40% of patients with severe asthma are estimated to have blood eosinophils $\leq$150 cells/μL, for which tezepelumab is the only approved, effective biologic option for these patients.

By contrast, biologic use is more established in certain other immune-mediated diseases. In psoriasis, for example, multiple biologics targeting the TNF, IL-12/23, IL-17 and IL-23 pathways are now becoming the standard of care for moderate-to-severe disease, and biologic penetration has reached approximately 45% of new starts in this population. We believe there is similar potential for biologic penetration to increase in severe asthma over time.

Despite relatively modest current penetration of biologic therapies in severe asthma, the asthma biologic therapeutics market is already substantial and is expected to grow as guideline-recommended use of advanced therapies expands. In 2024, global sales of biologics for severe asthma grew to approximately $9 billion and are projected to reach $13 billion by 2034. We believe that therapies capable of addressing a broad range of severe asthma phenotypes, including patients across eosinophil strata, and offering more convenient dosing regimens, will be well-positioned to drive this growth, subject to demonstration of safety and efficacy and to payer and access dynamics.

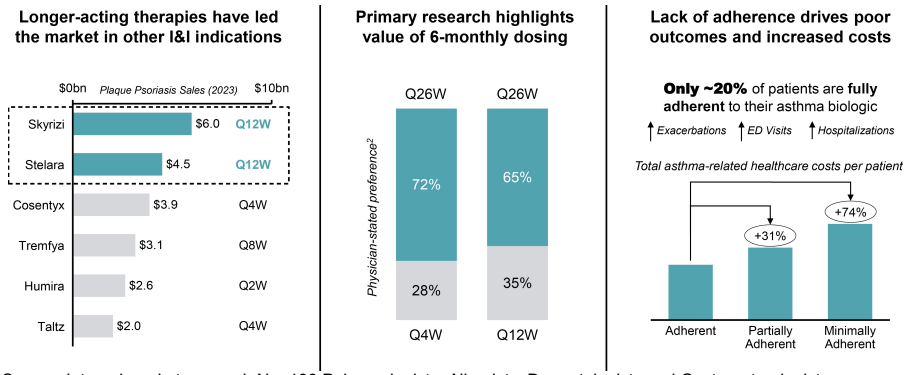
Asthma Unmet Need and Our Value Proposition

GB-0895 is designed to address several dimensions of unmet need, including the high burden of frequent dosing, challenges with adherence and persistence, and limited options for patients with lower blood eosinophil counts.

In the United States and other major markets, approved biologics for severe asthma include omalizumab (anti-IgE), mepolizumab and reslizumab (anti-IL-5), benralizumab (anti-IL-5 Rα), dupilumab (anti-IL-4Rα) and tezepelumab (anti-TSLP). Product labels and pivotal trial publications show that these biologics are generally administered subcutaneously or intravenously at intervals ranging from every two to eight weeks, with eligibility defined by combinations of exacerbation history, maintenance therapy requirements and biomarkers such as blood eosinophil counts, serum immunoglobin E ("IgE") levels and fractional exhaled nitric oxide. Tezepelumab is currently the only approved anti-TSLP biologic and the only severe asthma biologic without biomarker-based restrictions in its label, consistent with the position of TSLP at the top of the airway inflammatory cascade. In third-party clinical trials, tezepelumab has demonstrated clinical efficacy in severe asthma, as well as placebo-adjusted reductions in key biomarkers over 12 months including EOS (-50%), FeNO (-12%), IL-5 (-58%) and IL-13 (-45%).

Real-world data highlight the extent of adherence and persistence challenges with currently available biologics in severe asthma. In a large U.S. claims-based analysis of more than 10,000 patients treated with asthma biologics, only approximately 20% of patients were classified as adherent (defined as a patient taking their therapy 80% of the time) and roughly half of the patients discontinued treatment within 12 months. Non-adherent and discontinuing patients had substantially higher asthma-related and all-cause healthcare costs and greater healthcare utilization than adherent patients. Additionally, primary market research, conducted internally and shown in the figure below, highlighted a strong physician-stated preference for a Q26W dosed anti-TSLP therapy.

Longer-acting therapies have demonstrated market leadership, have been preferred in market research by physicians and could address the existing adherence issue in asthma



Source: Internal market research N = 133 Pulmonologists, Allergists, Dermatologists and Gastroenterologists

We believe these observations suggest that, even after patients overcome barriers to initiating available biologics therapies, maintaining long-term use of regimens dosed every two to eight weeks can be challenging in routine practice, leading to avoidable exacerbations, hospitalizations and increased healthcare system costs. GB-0895's potential for a Q26W dosing regimen is designed to reduce the number of injections and treatment decisions required over time, and, if successfully developed and approved, may help address the key structural barriers to adherence and persistence.

We are not aware of any other TSLP inhibitor, beyond tezepelumab, that has entered Phase 3 development to date. We believe that GB-0895's combination of durable target suppression in the Phase 1 clinical trial, potential for a Q26W dosing regimen, potential speed to market, and positioning in severe asthma could differentiate it within the evolving landscape of Type 2 biologics and those targeting cytokines at the top of the inflammatory cascade.

Asthma Clinical Development

In its Phase 1 clinical trial for the treatment of mild-to-moderate asthma patients, GB-0895 demonstrated a favorable safety profile, long half-life and suppression of key biomarkers supportive of a Q26W dosing regimen using a single 300 mg subcutaneous injection:

- Long half-life showed sustained drug concentration for the full six-month period.
- EOS, FeNO, IL-13 and IL-5 biomarkers indicated deep and sustained reductions over six months.
- Total TSLP demonstrated target saturation.
- GB-0895 was generally well tolerated, with low ADA and no impact from ADA observed on PK profile.

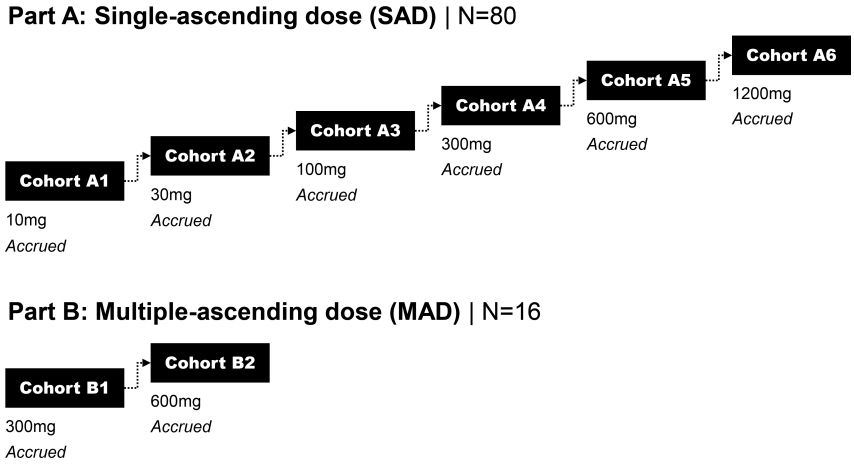
Phase 1 clinical trial

Overview

The Phase 1 clinical trial (GB-0895-101) of GB-0895 was a randomized, double-blind, placebo-controlled, first-in-human trial designed to evaluate the safety, tolerability, PK/PD and immunogenicity of GB-0895. The trial enrolled 96 adult subjects with mild-to-moderate asthma, with inclusion criteria requiring blood eosinophil levels of at least 150 cells/μL. GB-0895 was administered subcutaneously, and the trial was designed to identify a dose capable of sustaining PD effects for approximately six months to support Phase 3 dose selection, and, together with other support, potentially obviate the need for a separate Phase 2 dose-ranging trial.

As depicted in the figure below, the trial consisted of two parts: Part A (single ascending dose ("SAD")) and Part B (multiple ascending dose ("MAD")). Part A enrolled a total of 80 patients across six dose cohorts (10 mg, 30 mg, 100 mg, 300 mg, 600 mg and 1200 mg). Part B enrolled a total of 16 patients, and GB-0895 or a placebo was administered subcutaneously every 12 weeks for a total of two doses. The primary objective of the trial was to evaluate the safety and tolerability of GB-0895, with secondary objectives including characterization of PK, evaluation of the dose-response relationship for blood eosinophil suppression and assessment of immunogenicity. Exploratory objectives included evaluation of additional PD biomarkers and surrogates of clinical activity. These objectives were not powered for statistical significance.

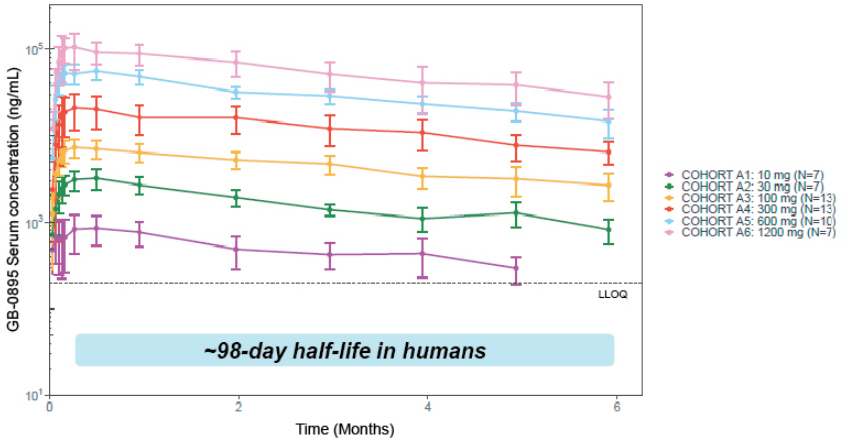
Overview of Phase 1 clinical trial design (GB-0895-101)



Pharmacokinetics

As shown in the figure below, PK data from the Phase 1 clinical trial demonstrated that GB-0895 exhibited dose-proportional PK without evidence of target-mediated drug disposition across the 10 mg to 1200 mg dose range, with a mean terminal half-life of approximately 98 days.

Observed mean serum concentrations of GB-0895 over six months by dose cohort



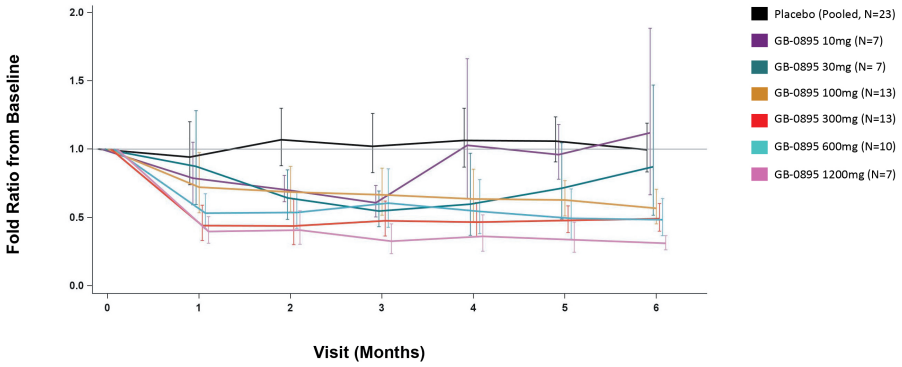
PK data from ongoing Phase 1 study of GB-0895 after SC administration in mild-moderate asthma patients.

At the higher dose levels (300 mg, 600 mg and 1200 mg), serum GB-0895 concentrations remained well above the lower limit of quantification, noted by the dotted line on the above chart, throughout the six-month observation period, consistent with sustained systemic exposure. Low rates of anti-drug antibodies ("ADAs") were observed; treatment-emergent transient ADA responses occurred in a small number of subjects and did not affect PK half-life, as half-life was similar between ADA-positive and ADA-negative subjects.

Pharmacodynamics and Biomarker Suppression

The Phase 1 clinical trial was designed to collect biomarker data over a wide dose range (10 mg to 1200 mg) to characterize the dose/exposure-response relationship for pharmacologically relevant biomarkers. As shown in the figure below, by Week 4, reductions from baseline in blood eosinophil counts were observed across all GB-0895 dose levels compared to placebo, with larger reductions at 300 mg and above, indicating a dose-response relationship.

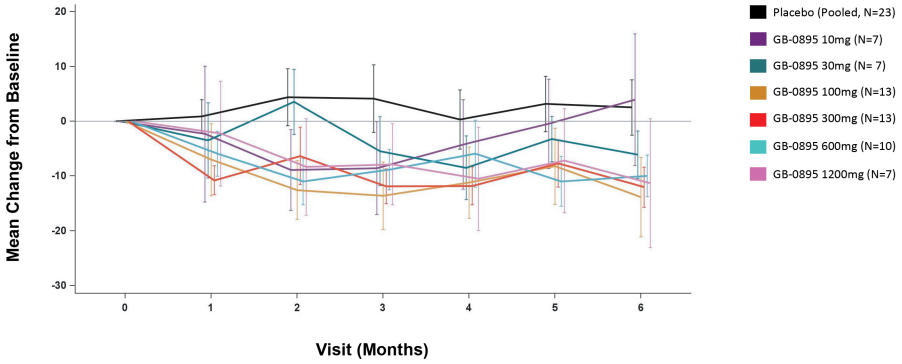
Blood eosinophil fold ratio (of geometric means) from baseline over six months, with +/- 95% confidence interval



Data presented is fold ratio (of geometric means) from baseline +/- 95% confidence intervals. November 10, 2025, data extract.

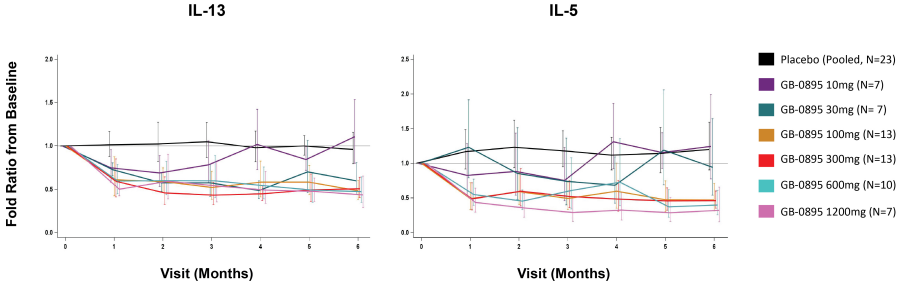
As shown in the figures below, we also observed reductions in additional PD biomarkers relevant to anti-TSLP mechanism of action, including FeNO, IL-5 and IL-13.

FeNO in parts per billion (ppb) mean change from baseline +/- standard error



Data presented in mean change from baseline +/- standard error. November 10, 2025, data extract.

IL-13 and IL-5 fold ratio (of geometric means) from baseline +/- 95% confidence intervals



Data presented is fold ratio (of geometric means) from baseline +/- 95% confidence intervals. November 10, 2025 data extract.

Durable reductions in FeNO, IL-5 and IL-13 were seen at the 300 mg dose level, with sustained suppression maintained through Month 6. These biomarker reductions demonstrated that GB-0895 drove PD changes consistent with TSLP inhibition.

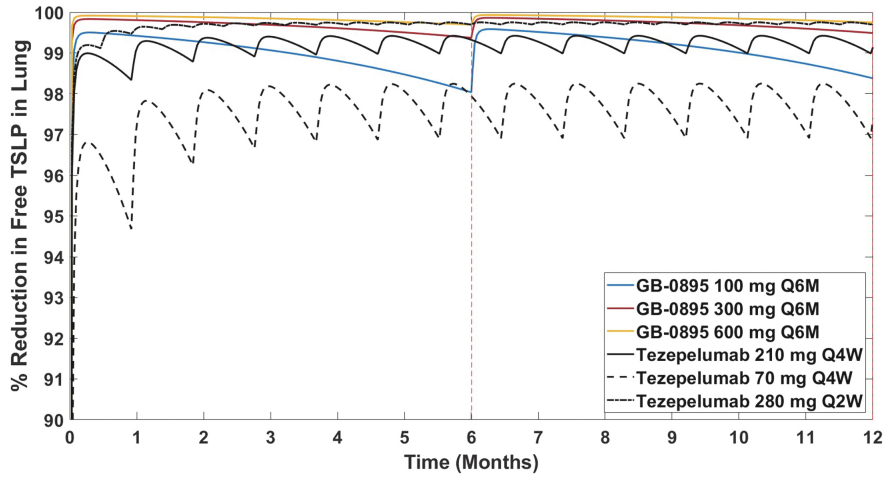
Impact of GB-0895 across PD biomarkers

% Reduction in PD Biomarkers from Baseline Relative to Placebo				
	EOS	FeNO	IL-5	IL-13
GB-0895 6-Month (300 mg single dose)	51%	55%	74%	45%

Target Saturation

A site-of-action PK/PD model was developed to predict TSLP suppression in lung epithelial lining fluid as a function of dose and regimen. The model was simulated for both GB-0895 and tezepelumab (considering differences in affinity and PK half-life) over a physiologically relevant range of TSLP concentration in lung epithelial lining fluid and lung partition coefficient. The simulated range of TSLP concentration covered asthma patients across disease severity (mild-moderate to severe asthma patients) as well as across EOS levels. In these models, tezepelumab simulations identified benchmark TSLP suppression associated with a clinically efficacious dose and regimen. Across all simulation scenarios, 300 mg of GB-0895 dosed Q26W resulted in TSLP suppression in lung tissue comparable to the approved 210 mg dose of tezepelumab dosed Q4W. We believe this results from the tighter binding affinity and longer half-life of GB-0895, although we have not conducted head-to-head clinical studies of GB-0895 against tezepelumab, and note that ongoing and future clinical trials for GB-0895 may produce differing clinical activity and tolerability results.

PK modeling of GB-0895 compared to tezepelumab



Safety and Tolerability

As of the November 7, 2025 data cutoff date, GB-0895 demonstrated generally favorable safety and tolerability results.

SAD Cohorts (N=80)

Adverse events in SAD cohorts

Subject Incidence of:	Cohort A1 (10mg) N=10	Cohort A2 (30mg) N=10	Cohort A3 (100mg) N=18	Cohort A4 (300mg) N=18	Cohort A5 (600mg) N=14	Cohort A6 (1200mg) N=10	Total N=80
Any TEAE	9 (90.0%)	8 (80.0%)	18 (100%)	17 (94.4%)	13 (92.9%)	9 (90.0%)	**74 (92.5%)**
Any Treatment-Related AE	1 (10.0%)	0 (0.0%)	1 (5.6%)	3 (16.7%)	4 (28.6%)	1 (10.0%)	**10 (12.5%)**
Any ISR*	1 (10.0%)	0 (0.0%)	1 (5.6%)	3 (16.7%)	4 (28.6%)	1 (10.0%)	**10 (12.5%)**

*ISRs include AEs reported under the MedDRA High Level Term 'Injection Site Reactions'
TEAE = Treatment emergent adverse event; ISR = Injection Site Reaction; SAE = Serious adverse event; PT = Preferred Term
Note: A treatment-related TEAE is defined as TEAE assessed as being related to study treatment, per investigator.
Date of Data Extract: November 10, 2025.

In the SAD cohorts, a total of 80 subjects received a single subcutaneous dose of GB-0895 or a placebo and were followed for at least 26 weeks. Treatment-emergent adverse events ("TEAEs") were reported in 74 subjects (92.5%) across all treatment groups. The most common TEAEs (incidence ≥10% across all treatment groups) were nasopharyngitis, headache and rhinitis. No deaths occurred, and no TEAEs led to trial discontinuation. There was no trend toward increased incidence or severity of TEAEs with increasing dose across the 10 mg to 1200 mg range.

Three serious adverse events ("SAEs") were reported during the trial: two in the 100 mg cohort and one in the 300 mg cohort. All three SAEs were Grade 3 in severity and were assessed by investigators to be not related to GB-0895. The SAEs included: (i) hospitalization for an acute asthma exacerbation triggered by influenza A infection; (ii) hospitalization for surgical repair of an ankle fracture following a motorcycle injury; and (iii) hospitalization for an anaphylactic reaction after an allergic reaction to a concomitant medication (metamizole). All other TEAEs were mild to moderate in severity (Grade 1-2). No TEAEs greater than Grade 3 occurred, and no treatment-related adverse events ("TRAEs") greater than Grade 2 were reported.

TRAEs in SAD cohorts

Subject Incidence of Treatment-Related AEs (TRAE):	Cohort A1 (10mg) N=10	Cohort A2 (30mg) N=10	Cohort A3 (100mg) N=18	Cohort A4 (300mg) N=18	Cohort A5 (600mg) N=14	Cohort A6 (1200mg) N=10	Total N=80
Any TRAE	1 (10.0%)	--	1 (5.6%)	3 (16.7%)	4 (28.6%)	1 (10.0%)	**10 (12.5%)**
Any Grade 1-2 TRAE	1 (10.0%)	--	1 (5.6%)	3 (16.7%)	4 (28.6%)	1 (10.0%)	**10 (12.5%)**
Any Grade 3 TRAE	--	--	--	--	--	--	--
Any Treatment-Related SAE	--	--	--	--	--	--	--
TRAEs by Preferred Term (PT)	Injection Site Erythema		Injection Site Erythema	Injection Site Pain, Injection Site Erythema	Injection Site Erythema, Injection Site Induration, Injection Site Bruising, Hot Flush	Injection Site Erythema	

TEAE = Treatment emergent adverse event; SAE = Serious adverse event; PT = Preferred Term
Note: A treatment-related TEAE is defined as TEAE assessed as being related to study treatment, per investigator.
Date of Data Extract: November 10, 2025.

TRAEs were reported in 10 subjects (12.5%), all of which were Grade 1 injection site reactions ("ISRs"), including injection-site erythema, pain, induration and bruising.

MAD Cohorts (N=16)

In the MAD cohorts, a total of 16 subjects across two cohorts received 300 mg (Cohort B1, N=8) or 600 mg (Cohort B2, N=8) administered subcutaneously every 12 weeks for a total of two doses. TEAEs were reported in all 16 subjects (100%) and were all mild to moderate in severity (Grade 1-2). No TEAEs greater than Grade 2 and no SAEs were reported in the MAD cohorts. There was no evidence of a relationship between dose and the incidence or severity of adverse events. No deaths occurred and no TEAEs led to discontinuation.

TRAEs in MAD cohorts

Subject Incidence of Treatment-Related AEs (TRAE):	Cohort B1 (300mg) N=8	Cohort B2 (600mg) N=8	Total N=16
Any TRAE	1 (12.5%)	3 (37.5%)	**4 (25%)**
Any Grade 1-2 TRAE	1 (12.5%)	3 (37.5%)	**4 (25%)**
Any Grade 3 TRAE	--	--	--
Any Treatment-Related SAE	--	--	--
TRAEs by Preferred Term (PT)	Headache, Hyperhidrosis, Injection Site Reaction, Nausea, Vomiting[1]	Injection Site Bruising, Injection Site Erythema, Injection Site Pain	

TEAE = Treatment emergent adverse event; SAE = Serious adverse event; PT = Preferred Term
Note: A treatment-related TEAE is defined as TEAE assessed as being related to study treatment, per investigator.
Date of Data Extract: November 10, 2025.

TRAES were reported in four subjects (25%), all Grade 1-2. The most common TRAEs were ISRs, including injection-site erythema, pain and bruising. Other treatment-related events included headache, hyperhidrosis, nausea and vomiting, which all occurred in the same subject.

Immunogenicity

Low rates of ADAs were observed in the Phase 1 clinical trial. ADA data were available for 69 subjects. Treatment-emergent ADAs were detected in seven subjects, and all but one of these responses were transient, becoming ADA-negative within approximately one month. The development of ADAs had no observable impact on GB-0895 PK, as half-life was similar in ADA-positive and ADA-negative subjects.

Asthma Next Steps

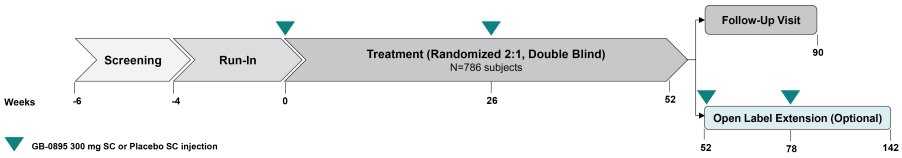
GB-0895 is being advanced in severe asthma through parallel global Phase 3 trials that we intend to use as the primary basis for global registrations of the product. We are enrolling patients in two randomized, double-blind, placebo-controlled Phase 3 trials, SOLAIRIA-1 and SOLAIRIA-2, each evaluating a single 300 mg subcutaneous dose of GB-0895 administered once every 26 weeks as adjunctive therapy in adults and adolescents with severe uncontrolled asthma. Both trials are currently in the enrollment phase. The Q26W dosing regimen in these trials were informed in part by results from our Phase 1 asthma trial, in which GB-0895 demonstrated a mean terminal half-life of approximately 98 days and deep suppression of key Type 2 inflammatory biomarkers at the 300 mg dose, supporting evaluation of whether sustained target engagement and disease control can be maintained over a six-month dosing interval.

Phase 3 Severe Asthma Program (SOLAIRIA-1 and SOLAIRIA-2)

The SOLAIRIA-1 and SOLAIRIA-2 trials share a common design intended to provide two independent, confirmatory data sets. In each trial, we plan to enroll approximately 786 adults and adolescents aged 12 to 80 years with a physician diagnosis of asthma for at least two years, who remain symptomatic and at high risk for exacerbations despite treatment with medium- to high-dose inhaled corticosteroids plus at least one additional controller therapy, with or without stable low-dose oral corticosteroids. Eligible subjects must have a well-documented history of at least two exacerbations requiring systemic corticosteroid treatment in the prior year. Subjects are not required to have a minimum eosinophilic count to participate in the trial.

As shown in the figure below, participants are randomized 2:1 to receive GB-0895 300 mg or placebo, administered as a single subcutaneous injection at Week 0 and Week 26, on top of their background standard of care. The double-blind treatment period extends over 52 weeks, followed by either a safety follow-up period or an optional open-label extension, during which all participants may receive GB-0895 300 mg every six months. The trial is being conducted globally, with sites planned across North America, Europe, Latin America and Asia, and is designed to enroll a balanced population across higher and lower blood eosinophil strata.

Overview of Phase 3 SOLAIRIA-1 and SOLAIRIA-2 clinical trial design



For both SOLAIRIA trials, the primary objective is to evaluate the efficacy of a 300 mg dose of GB-0895 administered every 26 weeks in reducing clinically significant asthma exacerbations over 52 weeks in adults and adolescents with severe uncontrolled asthma. The primary endpoint is the annualized asthma exacerbation rate over 52 weeks, defined as exacerbations requiring systemic corticosteroids and/or hospitalization or emergency department visits requiring systemic corticosteroids. A key secondary objective is to assess the same endpoint in subjects with baseline blood eosinophil counts below 300 cells/µL, reflecting our intent to understand GB-0895's potential across both more eosinophilic and less eosinophilic phenotypes. Additional key secondary endpoints include measures of lung function (such as change from baseline in pre-bronchodilator FEV_1 at Week 52), patient-reported asthma control and quality of life, time to first exacerbation and other exacerbation-related outcomes. Exploratory endpoints include health-related quality-of-life instruments, rescue medication use, home peak flow and multiple PK and PD readouts—including blood biomarkers, FeNO and peripheral eosinophil counts—which are expected to further characterize the relationship between long-acting TSLP blockade, biomarker modulation and clinical outcomes.

Regulatory Strategy

We have developed our Phase 3 program and dose/regimen selection in severe asthma in the context of prior interactions with the FDA, including a Model-Informed Drug Development ("MIDD") meeting and at the End-of-Phase 1, as well as interactions with European and U.K. regulatory authorities through scientific advice and other formal engagements. These engagements focused on the use of Phase 1 PK and biomarker data, along with quantitative modeling, to support selection of the 300 mg Q26W dosing regimen and an exacerbation-based primary endpoint in a broad severe asthma population. Our current regulatory strategy is to pursue severe asthma as the lead indication for GB-0895, seeking initial approval based primarily on the SOLAIRIA-1 and SOLAIRIA-2 trials together with our earlier clinical and preclinical data. We also plan to evaluate multiple approaches to determine the optimal development path for GB-0895 for the treatment of COPD, taking into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial. As part of such evaluation, we plan to seek engagement with regulatory authorities in 2026 to discuss our development strategy and obtain regulatory feedback on our proposed approach. We will also consider whether to pursue other indications in the future.

CMC Strategy

In parallel with the clinical development program, we are executing an integrated chemistry, manufacturing and controls ("CMC") strategy intended to provide sufficient drug substance and drug product to support global Phase 3 development of GB-0895 and, if approved, commercial supply. We do not own or operate, and currently have no plans to establish, any manufacturing facilities. All of our preclinical and clinical drug supply development, manufacturing, storage, distribution and testing are outsourced to third-party manufacturers and facilities. Drug substance is produced by our CDMO using an established monoclonal antibody platform process that has been scaled to 1,000-liter single-use bioreactors for Phase 1 and Phase 3 supply, with a planned scale-up to 2,000 liters at a commercial-ready facility to support anticipated launch volumes. We are developing a high-concentration liquid formulation designed to deliver the full 300 mg dose in a single subcutaneous injection, and early stability data support storage at standard refrigerated temperatures for extended periods, with ongoing trials to define the product's final shelf life. Consistent with other biologics programs, we plan to complete process performance qualification for both drug substance and drug product, along with validation of analytical methods, in advance of any Biologics License Application ("BLA") submission in the U.S. or any marketing application elsewhere.

Commercial Presentation and Device Strategy

Our commercial presentation strategy for GB-0895 in severe asthma is centered on subcutaneous self- or clinician-administered formats. We currently plan to use a pre-filled safety syringe ("PFS") presentation as the primary configuration for late-stage clinical development and initial commercialization, subject to completion of the necessary formulation, stability, human factors and device-related regulatory work. Our early clinical trials have used a syringe and vial presentation, and we intend to transition to the PFS presentation via protocol and regulatory amendments so that the pivotal Phase 3 trials and subsequent commercial supply align to a single, high-concentration formulation and PFS presentation.

In parallel, we are advancing an autoinjector presentation using the same or a closely-related formulation. This program is anticipated to include additional human factors studies and device performance testing and, where required, a PK bridging trial in healthy volunteers to demonstrate comparability to the PFS. Based on our current planning, we view the PFS as the base case for initial regulatory filings and, if approved, commercial launch, with the autoinjector as a potential follow-on presentation that could be introduced shortly after initial launch, subject to successful completion of the additional device work and supplemental regulatory review.

From a regulatory perspective, we currently expect both the prefilled syringe and autoinjector presentations of GB-0895 to be regulated as biologic–device combination products, with the biologic constituent part providing the primary mode of action. We anticipate pursuing approval under the BLA pathway, with device-related requirements addressed as part of the FDA's combination product review. Any subsequent autoinjector presentation would be submitted through a supplemental biologics license application following approval of the initial prefilled syringe presentation, if approved, and would follow the same combination product pathway for review of an autoinjector presentation of the product.

GB-0895 for the Treatment of COPD

COPD Disease Overview

COPD is a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum production and exacerbations) due to airway abnormalities (bronchitis, bronchiolitis) and/or alveolar damage (emphysema), resulting in persistent, often progressive, airflow obstruction. It is typically caused by long-term exposure to inhaled irritants, most commonly cigarette smoke, and people with a history of asthma are also at increased risk. COPD encompasses both Type 2 and Non-Type 2 inflammatory phenotypes. Patients are prone to acute worsening of symptoms that often require targeted preventive and treatment strategies. Exacerbations are frequently triggered by respiratory infections and environmental exposures such as air pollution and temperature extremes that contribute to further disease progression and mortality.

Treatment of COPD has historically relied on inhaled corticosteroids and bronchodilator inhalers (long-acting β2-agonists and long-acting muscarinic antagonists), with oxygen therapy and surgery reserved for advanced disease. As of 2025, only two biologics—dupilumab (DUPIXENT) and mepolizumab (NUCALA)—have been approved for the treatment of COPD, each only gaining approval for this indication in the last two years after studying applications for use in approximately 10% and 28% of the total COPD population in Phase 3 trials, respectively. These medicines have been studied in patients with blood eosinophil counts ≥300 cells/μL, leaving patients with lower eosinophil counts without any approved biologic treatment options.

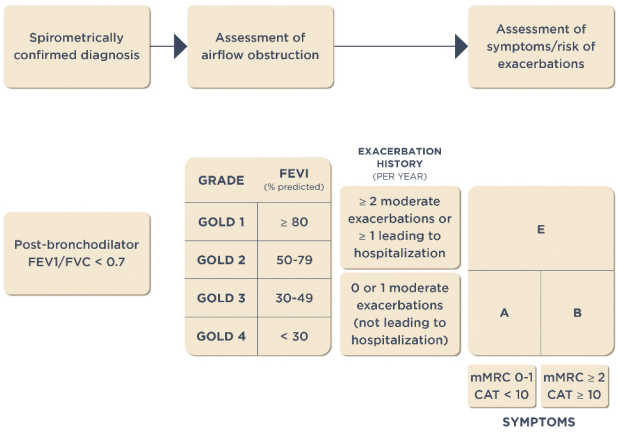
In the Phase 2a COURSE trial in COPD, tezepelumab demonstrated potential benefit, with numerically greater, though not statistically significant, reductions in annualized exacerbation rates compared with both dupilumab and mepolizumab in patients with higher (≥300 cells/μL) and lower (≥150 cells/μL) blood eosinophil counts. Larger, confirmatory Phase 3 trials are required to determine whether these findings translate into clinically and statistically meaningful benefit; however, the COURSE data suggest that TSLP blockade may have therapeutic potential in COPD, including in the EOS ≥150 cells/μL patient segment who currently have no biologic options.

COPD Market Opportunity

COPD represents an opportunity for GB-0895 that is distinct and complimentary of GB-0895 in patients with severe asthma. Recent global analyses estimate that COPD affects more than 400 million people worldwide and remains among the leading causes of death globally, accounting for more than three million deaths annually. In the United States, COPD affects approximately 11.7 million adults and accounts for hundreds of thousands of emergency department visits and tens of billions of dollars in healthcare costs annually. COPD is also historically underdiagnosed; as of 2015, roughly four out of five (approximately 80%) of spirometry-defined COPD cases had never received a COPD diagnosis.

Biologics have only recently begun to enter COPD treatment algorithms. In September 2024, dupilumab was approved in the United States as the first biologic therapy for COPD as an add-on maintenance treatment for adults with inadequately controlled COPD and an eosinophilic phenotype. mepolizumab was approved more recently in May 2025. To date, the patient populations targeted by these biologics align with the Global Initiative for Chronic Obstructive Lung Disease ("GOLD") Group E (formerly Groups C and D), which comprises individuals at higher risk of exacerbations (as illustrated in the figure below). At present, biologic penetration in COPD is at a very early stage, with less than 1% of the approximately 3.0 million biologic-eligible patients treated receiving biologic treatment in 2024, reflecting the recency of approvals and the time required for incorporation into guidelines and medical practice. While there were less than $1.0 billion in global biologic sales for COPD in 2024, global biologic sales are expected to reach more than $23 billion in 2034, highlighting the potentially large and untapped market opportunity for COPD.

Global initiative for GOLD assessment criteria



COPD Unmet Need and Our Value Proposition

Approximately 70% of COPD patients have blood eosinophil counts <300 cells/µL, while only about 30% have eosinophil counts ≥300 cells/µL. As a result, the two approved COPD biologics, which have been studied and approved primarily in higher-eosinophil populations, do not address the majority of patients with lower eosinophil counts, who currently lack any approved biologic options. We therefore view COPD as an area of significant remaining unmet need and as a potential opportunity for additional biologic mechanisms, including TSLP inhibition, subject to the success of ongoing and future clinical development.

COPD Clinical Development

The Phase 1b COPD expansion trial (GB-0895-101 Part C) is an extension of our Phase 1 clinical trial and is a randomized, double-blind, placebo-controlled, multiple-dose trial and is designed to evaluate the safety, tolerability, PK/PD and immunogenicity of GB-0895. This expansion builds on the safety and PK data generated in the Phase 1 asthma trial (Parts A and B) to characterize GB-0895 in patients with COPD. The trial enrolled adult patients (≥40 years of age) with moderate-to-severe COPD and with a blood eosinophil count of at least 200 cells/µL.

The trial includes two dose cohorts of GB-0895, 300 mg and 600 mg, administered subcutaneously. The trial enrolled 40 patients across these two cohorts, with 20 patients per cohort randomized 3:1 to GB-0895 or placebo. GB-0895 or placebo is administered and PK profile and PD effects are characterized over an extended observation period. The primary objective of the trial is to evaluate the safety and tolerability of GB-0895 in patients with moderate-to-severe COPD. Safety assessments include monitoring of TEAEs, SAEs, ISRs, clinical laboratory parameters, vital signs and electrocardiograms. Secondary objectives include characterization of the PK profile of GB-0895 in COPD patients, assessment of PD biomarkers relevant to TSLP inhibition (including EOS, FeNO and inflammatory cytokines such as IL-5 and IL-13) and evaluation of immunogenicity through assessment of ADAs. Exploratory endpoints include evaluation of clinical activity surrogates, such as FEV_1, patient-reported outcomes including the St. George's Respiratory Questionnaire (the "SGRQ") and COPD Assessment Test (“CAT”) scores, and COPD exacerbation frequency. The trial is designed to provide initial data on the PD effects of GB-0895 in patients with COPD and to inform dose selection for potential future Phase 2 or Phase 3 development in this indication.

As of January 15, 2026, preliminary data for GB-0895 from the ongoing trial showed reductions in key biomarkers and a PK profile generally consistent with the Phase 1 mild-to-moderate asthma trial. The results below reflect descriptive least square mean estimates based on emerging data and will be refined as additional subjects complete month 3 and subsequent follow-up:

- Preliminary EOS data showed ~50% reductions from baseline at month 3.
- Preliminary FeNO data showed ~20% reductions from baseline at month 3, though similar reductions are also observed in the placebo cohort.
- Preliminary IL-13 and IL-5 data showed ~50% reductions from baseline at month 3.

The above data represents mean estimates across 300 mg and 600 mg doses. Reported sample sizes were as follows: EOS: n=15 (300 mg), n=15 (600 mg), n=10 (placebo). FeNO: n=15 (300 mg), n=15 (600 mg), n=10 (placebo). IL-13: n=14 (300 mg), n=9 (600 mg), n=7 (placebo). IL-5: n=15 (300 mg), n=9 (600 mg), n=8 (placebo).

As of the January 15, 2026 data cutoff, the safety results observed have been favorable and, together with other data, suggests support for further clinical development of GB-0895 for the treatment of COPD. However, we do not have yet have a complete Phase 1b data package. The Phase 1b trial remains ongoing and blinded; as of January 15, 2026, 40 subjects with COPD have received a single dose of GB-0895 or placebo (20 subjects in the 300 mg cohort and 20 subjects in the 600 mg cohort). The emerging safety data indicate that GB-0895 has been generally well tolerated, with most TEAEs reported as mild to moderate in severity (Grade 1-2). One SAE (Grade 3, back pain) has been reported and was assessed by the investigator as not related to GB-0895/placebo.

COPD Next Steps

We are currently evaluating multiple approaches for the future development path for GB-0895 in patients with COPD, taking into account, among other things, likely speed to market, expected development costs and the robustness of the evidence base. We plan to seek engagement with the FDA to discuss our development strategy and obtain regulatory feedback on a proposed approach.

Our future development strategy is expected to be informed by the complete Phase 1b data package, any feedback from regulatory authorities and our assessment of the balance between development speed, cost and regulatory expectations.

Preclinical Data

Preclinical studies of GB-0895 were designed to characterize its pharmacology, PK and toxicology in support of first-in-human dosing, subsequent clinical development and the planned Q26W dosing regimen. In such studies, GB-0895 showed high affinity and selective binding to TSLP, potent functional pathway blockade in human-relevant systems, activity in TSLP-driven asthma models, extended systemic exposure in cynomolgus (“cyno”) monkeys consistent with its Fc engineering, and favorable preclinical safety data, supporting progression into patients.

In Vitro Pharmacology and Selectivity

In *in vitro* pharmacology studies, GB-0895 bound human TSLP ("hTSLP") and cynomolgus TSLP ("cyno TSLP") with very high affinity and neutralized TSLP-driven signaling. Binding studies showed that GB-0895 recognized human and cynomolgus TSLP but did not bind rodent TSLP, supporting the use of cynomolgus monkeys as the pharmacologically relevant species for toxicology. An analog antibody without the YTE half-life extension mutations (internally known as PRO-17101), which is otherwise sequence-identical to GB-0895, bound human TSLP with sub-picomolar affinity and cynomolgus TSLP with similarly high affinity and exhibited comparable potency to tezepelumab in these assays, as shown in the figure below.

PRO-17101 and tezepelumab binding affinities to hTSLP and cyno TSLP as determined by KinExA

	tezepelumab	**PRO-17101 (GB-0895 with no Fc YTE mutations)**
KinExA K_D (pM)	2.24	0.106
KenExa K_D (pM) Cyno TSLP	9.05	1.25
Cyno K_D Fold/Human K_D	4.04	11.79

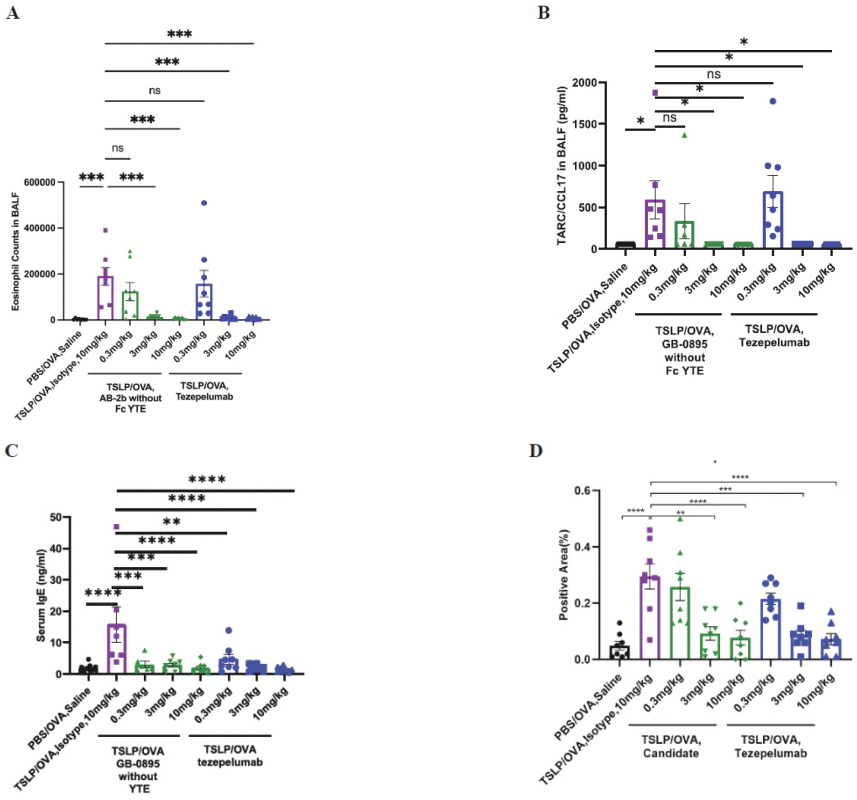
Functional studies in human primary myeloid dendritic cells, peripheral blood mononuclear cells, whole blood and cynomolgus peripheral blood mononuclear cells showed that GB-0895 robustly inhibited TSLP-induced downstream readouts, including STAT5 phosphorylation and production of chemokines, such as macrophage-derived chemokine (MDC/CCL22) and thymus and activation-regulated chemokine (TARC/CCL17), with inhibitory concentrations in the low tens of nanograms per milliliter range. GB-0895 also competed with a benchmark anti-TSLP antibody with the same sequence as tezepelumab for binding to human TSLP in a proximity-based binding assay, consistent with recognition of an overlapping epitope and a shared mechanism of pathway blockade.

Selectivity assessments of GB-0895, including a cell-based microarray of more than 6,000 human proteins and a tissue cross-reactivity study on normal human tissues, showed binding only to TSLP, and we observed no unexpected tissue cross-reactivity, supporting a low likelihood of off-target pharmacology.

In Vivo Pharmacology

The *in vivo* pharmacology of GB-0895 was evaluated using PRO-17101 in TSLP/TSLP receptor (“TSLPR”) humanized mouse models of allergic asthma, in which mouse TSLP and its receptor were replaced with their human counterparts to preserve TSLP pharmacology. As depicted in the Figure below, co-administration of TSLP and ovalbumin (“OVA”) induced features characteristic of Type 2 inflammation, including: increased serum IgE, IL-4, IL-13, as well as chemokines such as TARC/CCL17 in bronchoalveolar lavage fluid ("BALF"), eosinophilic inflammation in the lung and mucus hypersecretion. Treatment with PRO-17101 decreased total leukocyte and eosinophil counts in BALF (figure A below), significantly reduced BALF IgE, IL-4, IL-13 and TARC/CCL17 levels (figure B below) and serum IgE (figure C below), and attenuated inflammatory cell infiltration and mucus production in lung tissue (figure D below). In these models, a benchmark anti-TSLP antibody with the same sequence as tezepelumab produced similar effects. We believe these data support that high-affinity TSLP neutralization by GB-0895 can suppress cytokines at the top of Type 2 airway inflammation cascade and improve multiple biomarkers and histologic features relevant to severe asthma. While the ultra-high binding affinity of GB-0895, coupled with data supporting long half-life, supports sustained activity over a prolonged timeframe, this phenomenon was not predicted to be shown in this *in vivo* wild-type mouse study because the therapeutic antibodies were administered only twice over a short timeframe to maximize acute target engagement and biological activity *in vivo*. Further the experiment used a version of GB-0895 without a YTE half-life extension, since the impact of YTE on antibody exposure in wild-type mice can be variable and often limited.

GB-0895 without Fc YTE mutations reduced hallmarks of asthma in a preclinical hTSLP/hTSLPR asthma mouse model



hTSLPR=human TSLPR; PBS=phosphate buffered saline. ns = not significant ($p \geq 0.05$), * = $p < 0.05$, ** = $p < 0.01$, *** = $p < 0.001$, **** = $p < 0.0001$.

Toxicology and Safety Pharmacology

The toxicology and safety pharmacology program for GB-0895 relied on cynomolgus monkeys as the single relevant species, supplemented by local tolerance studies in rabbits. In a single-dose trial in cynomolgus monkeys, GB-0895 was generally well tolerated after both intravenous and subcutaneous administration in doses up to 25 mg/kg, with no adverse clinical, clinical pathology or gross pathological findings.

Opportunities for Development in Additional Indications

TSLP is an epithelial-derived cytokine produced at multiple barrier sites, including the lung, skin and gastrointestinal tract, where it acts on dendritic cells, T-cells, B cells, mast cells, eosinophils and innate lymphoid cells to promote Type 2 inflammatory responses. Tezepelumab is approved for severe asthma and, more recently, was approved for chronic rhinosinusitis with nasal polyps (“CRSwNP”), underscoring the broader relevance of TSLP biology beyond lower airway disease. Recent mechanistic and translational work, as well as third-party clinical development of other TSLP-targeting agents, supports the potential relevance of TSLP blockade in additional Type 2 and epithelial barrier-driven conditions, including CRSwNP, eosinophilic esophagitis (“EoE”), chronic spontaneous urticaria (“CSU”), atopic dermatitis (“AD”) and severe food allergies.

Based on independent literature and the ongoing clinical evaluation of other anti-TSLP monoclonal antibodies, we view CRSwNP, EoE, CSU, AD and severe food allergy as potential longer-term indication expansion opportunities for GB-0895. We expect to consider a variety of relevant criteria in making any decisions to pursue these indications, including outcomes and results from our ongoing clinical trials of GB-0895, the results of external anti-TSLP trials in these diseases, regulatory feedback and our overall portfolio and capital allocation priorities.

We may also seek to evaluate GB-0895 in combination with other therapies in Type 2 and epithelial barrier-driven diseases such as antibodies targeting IL-13 and OX40 ligand. Subject to emerging data, we believe that rational combination approaches that incorporate GB-0895 could have the potential to address residual disease activity in selected patient populations.

GB-4362: An MMAE Payload Neutralizer Monoclonal Antibody

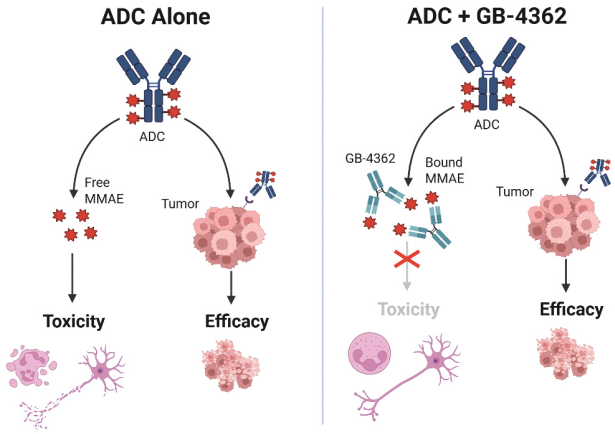
Overview

We utilized our Generate Platform to develop GB-4362, a systemically administered monoclonal antibody candidate designed to neutralize free MMAE, which we are initially developing as an adjunctive therapy to ADCs armed with an MMAE payload. For MMAE-based ADCs, off-target exposure to free MMAE is now recognized as the primary driver of dose-limiting toxicities such as neutropenia and peripheral neuropathy. GB-4362 is designed to selectively bind and clear circulating MMAE released from ADCs while preserving intratumoral payload delivery and anti-tumor activity of the ADC. We received the IND "Study May Proceed" notification from the FDA on December 31, 2025 for GB-4362. We subsequently received Fast Track Designation on January 23, 2026 for this program, and we expect to initiate a Phase 1 dose-escalation trial in combination with enfortumab vedotin (“EV”) plus pembrolizumab in first-line metastatic urothelial cancer patients in 2026. This clinical trial is designed to primarily assess GB-4362’s safety and tolerability, characterize the PK/PD effects of GB-4362, including reductions in free MMAE, and identify a recommended Phase 2 dose. In the expansion portion of this clinical trial, we intend to evaluate GB-4362's safety, PK/PD and impact on free MMAE reduction. We are considering using this expansion portion of the clinical trial as an early proof of concept, and if we determine to proceed, we plan to evaluate the impact of GB-4362 on progression from Grade 1 to Grade 2 peripheral neuropathy in patients who develop their first sustained Grade 1 peripheral neuropathy while receiving EV plus pembrolizumab for the treatment of first-line metastatic urothelial cancer ("1L muC"). In preclinical mouse and non-human primate (“NHP”) studies, GB-4362 demonstrated dose-dependent reductions in systemic MMAE exposure. Preclinical data suggest that a 50% or greater reduction in free MMAE may improve tolerability, reduce dose-limiting toxicities, and maintain ADC dose intensity. As development progresses, we may explore the potential of GB-4362 in additional combinations with approved or in development MMAE-ADC regimens. This is intended to allow us to broaden our focus to additional tumor types where MMAE-related toxicities limit therapeutic benefit.

Potential Mechanism of Action and Rationale

ADCs are designed to deliver highly potent cytotoxic payloads directly into tumors, and yet only a small fraction of the cytotoxic payload typically reaches cancer cells due to premature linker cleavage. Free MMAE is the term for this prematurely released cytotoxic payload from MMAE-based ADCs that ends up in circulation causing systemic toxicity. As illustrated in the figure below, payload-mediated toxicities could arise from premature linker cleavage and passive diffusion of free payload into healthy tissues. For MMAE-based ADCs, this off-target exposure to free MMAE is now recognized as the primary driver of dose-limiting toxicities such as neutropenia and peripheral neuropathy. These off-target payload-mediated toxicities consistently manifest across ADCs that share the same payload, independent of their antigen target.

Mechanism for ADC toxicity and GB-4362 mechanism



Technology Approach and Molecular Characteristics

We designed GB-4362 to reduce systemic exposure to free MMAE by selectively binding and neutralizing only the unconjugated, systemically circulating MMAE while preserving the tumor-directed clinical activity of ADC-conjugated MMAE. GB-4362 is a recombinant, humanized Immunoglobulin G ("IgG") 1 monoclonal antibody candidate engineered to selectively bind and neutralize free MMAE. The antibody was engineered using our Generate Platform, leveraging structural information on MMAE and publicly available data on MMAE-binding antibodies. Computationally engineered variants were screened *in vitro* for (i) high-affinity binding to free MMAE, (ii) no binding to MMAE while conjugated to ADCs, and (iii) maximal neutralization of circulating MMAE.

High potential candidates were further evaluated across an extensive developability panel to select and identify what we believe to be an optimized clinical candidate suitable for large-scale manufacturing. GB-4362 also incorporates Fc-engineering and is thereby designed to minimize Fc-mediated effector functions while maintaining favorable PK.

Market Opportunity

Bladder cancer is the most common urinary tract malignancy, with more than 573,000 new cases globally in 2020 and incidence projected to nearly double by 2040. In the United States, bladder cancer is the sixth most common cancer overall with approximately 83,000 incident cases in 2024 and the fourth most common in men, disproportionately affecting older adults. Urothelial cancer represents over 90% of all bladder cancers and is characterized by high recurrence rates and substantial morbidity. More than 50% of such patients recur or progress to locally advanced or metastatic urothelial cancer ("mUC"), where prognosis remains poor despite therapeutic advances, with historical median overall survival of 12-16 months and five-year survival below 10%.

The introduction of immune checkpoint inhibitors and, more recently, ADCs has transformed the treatment landscape. The combination of EV plus pembrolizumab demonstrated a doubling of progression-free and overall survival versus platinum chemotherapy in previously untreated mUC, and has become the preferred first-line standard of care per National Comprehensive Cancer Network guidelines.

Despite these advances, MMAE-related toxicities remain a fundamental limitation of ADC therapies, including EV, with peripheral neuropathy emerging as the most frequent and clinically consequential adverse event. In the EV-103 Phase 3 trial conducted by Astellas Pharma Inc. ("Astellas") and Seagen Inc., which evaluated EV plus pembrolizumab for the treatment of 1L mUC, peripheral neuropathy of any grade occurred in 65% of patients and was one of the leading causes of treatment interruption (18%), dose reduction (17%) and discontinuation (20%). Onset is cumulative and delayed, typically occurring after 5-6 cycles of therapy, and resolution is uncommon. Peripheral neuropathy is a recognized toxicity with EV and requires clinicians to monitor and manage with dose modifications. In practice, significant neuropathy can influence subsequent therapy decisions (including platinum-based chemotherapy) and eligibility for some clinical trials.

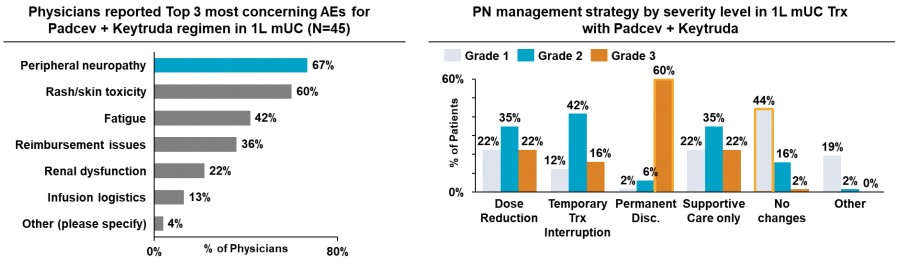
Unmet Need and Our Value Proposition

There are currently no FDA-approved agents for preventing or mitigating toxicities caused by free MMAE, and current management of toxicities relies solely on dose reduction, interruption or discontinuation, which can compromise the delivery and effectiveness of life-prolonging therapy. Given the growing adoption of MMAE-based ADCs—more than 10,000 U.S. patients with advanced or mUC alone receive EV-containing regimens each year—there is a substantial unmet need for interventions that can reduce systemic MMAE exposure without diminishing anti-tumor activity.

We designed GB-4362 for its potential to directly address this need. As a systemically administered antibody candidate that selectively binds and neutralizes free circulating MMAE while preserving ADC-mediated intracellular payload delivery, GB-4362 has the potential to reduce treatment-limiting toxicities, maintain ADC dose intensity, and improve clinical outcomes for patients receiving EV plus pembrolizumab and other MMAE-based ADCs.

Primary market research we conducted internally with 45 oncologists in 2025 showed strong physician willingness to adopt an MMAE neutralizer alongside EV plus pembrolizumab if it could meaningfully reduce MMAE-related toxicities. EV plus pembrolizumab is already widely used in 1L mUC, with most oncologists reporting treatment durations of approximately six months or longer. Physicians consistently identified peripheral neuropathy as the most concerning toxicity of the regimen and emphasized that it often emerges within four to six treatment cycles and it is a major driver of dose reductions, interruptions and discontinuations, despite the regimen's robust clinical activity profile, as illustrated in the figure below.

Generate market research outlining AE concerns for EV plus pembrolizumab regimen and management of peripheral neuropathy in 1L mUC (N=45)

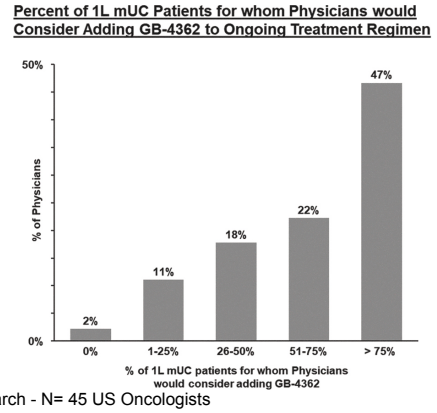


Source: Internal Market Research - N= 45 US Oncologists

EV is marketed as PADCEV by Astellas and Pfizer Inc. ("Pfizer") and pembrolizumab is marketed as KEYTRUDA by Merck.

Surveyed oncologists indicated that a meaningful reduction (approximately 50%) in peripheral neuropathy would lead them to incorporate an MMAE neutralizer in a large majority of 1L mUC patients, as illustrated in the figure below.

Generate market research outlining physicians' appetite for addition of GB-4362 to EV plus pembrolizumab in 1L mUC patients



Source: Internal Market Research - N= 45 US Oncologists

Physicians also expressed interest in using a neutralizer in MIBC and across other MMAE-based ADC regimens, reflecting broad recognition that MMAE-driven toxicities remain a class-wide challenge. Overall, we believe these market research findings point to significant clinical pull-through potential and broad adoption if GB-4362 demonstrates meaningful reduction in treatment-limiting MMAE toxicities.

Opportunities for Indication Expansion

We believe there are several expansion opportunities for GB-4362 beyond the initial indication. In addition to mUC, EV-based regimens have been explored in other indications across the bladder-cancer care continuum, including muscle-invasive bladder cancer ("MIBC"). This highlights the urgent need to mitigate toxicity for a growing population of bladder cancer patients. Moreover, toxicity caused by premature release of free MMAE payload is a challenge that extends beyond EV. All five FDA-approved MMAE-containing ADCs share the same MMAE payload and demonstrate similar patterns of dose-limiting peripheral neuropathy and hematologic toxicity. Numerous next-generation MMAE ADCs, including disitamab vedotin and sigvotatug vedotin, are in development, potentially further expanding the population exposed to MMAE-associated toxicities.

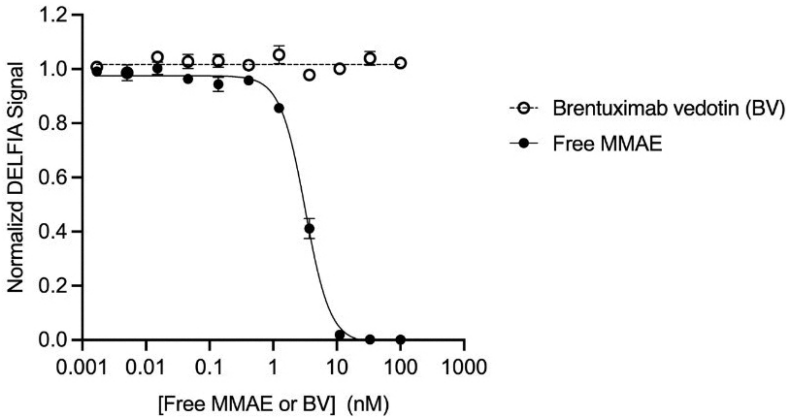
Preclinical Data

In preclinical studies *in vitro* and *in vivo*, GB-4362 was selective for free MMAE and, when dosed in combination with an MMAE-based ADC, showed a clear dose-dependent reduction in free MMAE and preserved the MMAE-based ADC activity. GB-4362 also showed an impact on free MMAE related toxicities and reduced neutropenia and skin toxicity in a dose-dependent fashion. GB-4362 was also generally well tolerated in GLP toxicity studies, supporting progression into the clinical stage of development.

In Vitro Pharmacology and Selectivity

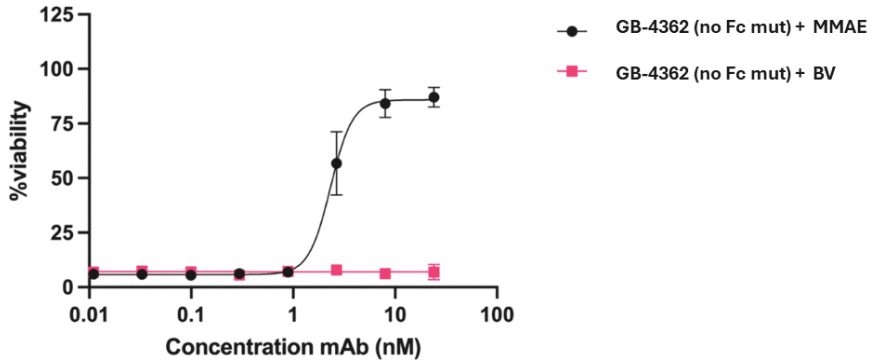
In *in vitro* pharmacology studies, GB-4362 bound free MMAE with picomolar affinity and showed no measurable binding to MMAE when it was conjugated to an ADC linker. In competition assays using free MMAE and brentuximab vedotin ("BV"), which is an FDA-approved MMAE-based ADC, we further observed this specificity by measuring normalized fluorescent signal (DELFIA). In such assays, we observed that GB-4362 binding was displaced by free MMAE but not BV, leading to signal decrease in a dose-dependent fashion, and thereby demonstrated that GB-4362 exclusively recognized unconjugated MMAE, as illustrated in the figure below.

GB-4362 binding was specific to free MMAE



This mechanistic selectivity translated into functional selectivity in cell-based assays. In a version of GB-4362, where Fc mutations were removed, we observed that this GB-4362 version candidate neutralized the cytotoxicity of free MMAE in a concentration-dependent manner, and preserved the full cytotoxic activity of BV in Karpas 299 cells, as illustrated in the figure below.

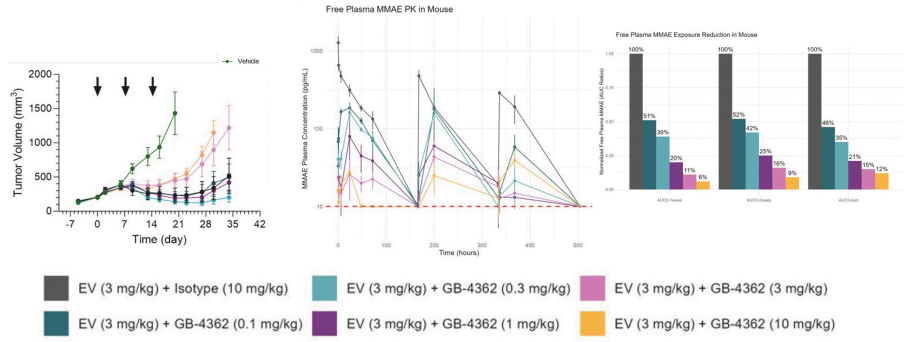
GB-4362 lacking Fc mutations blocked MMAE and not ADC cytotoxicity



In Vivo Pharmacology

In a bladder cancer patient-derived xenograft (PDX) mouse model, co-administration of GB-4362 with EV demonstrated that GB-4362 substantially lowered free MMAE in a dose dependent manner and without compromising anti-tumor activity. When 3 mg/kg EV was combined with 0.1-1 mg/kg GB-4362, free plasma MMAE exposure was reduced by up to 80% ($AUC_{0\text{-}1}$week) at 1 mg/kg, while tumor growth inhibition remained comparable to EV plus isotype control. In contrast, higher GB-4362 doses (3-10 mg/kg) produced ≥89-94% reductions in free MMAE exposure and were associated with a statistically significant loss of EV efficacy consistent with attenuation of the bystander effect, which contributes to tumor cell killing in heterogeneous solid tumors. These data support a therapeutic window in which an approximately 50-80% reduction in free MMAE maintains ADC efficacy, whereas near-complete neutralization can attenuate anti-tumor activity, and support dose selection strategies that preserve the therapeutic contribution of bystander killing.

Effect of GB-4362-mediated reduction of free MMAE on EV antitumor activity



In both good laboratory practice ("GLP") and non-GLP NHP studies, GB-4362 showed linear, dose-proportional pharmacokinetics and dose-dependent neutralization of free MMAE when co-administered with EV dosed at 3 mg/kg and 4 mg/kg respectively. As depicted in the table below, the 28-day GLP repeat-dose study further showed that GB-4362 was generally well tolerated up to 100 mg/kg weekly, in combination with EV, with no GB-4362-attributed adverse findings and a No Observed Adverse Effect Level ("NOAEL") and Highest Non-Severely Toxic Dose ("HNSTD") of 100 mg/kg.

28-Day GLP Study - Summary (Mean ± SD) of Cycle 1 free MMAE following IV administration of EV alone or in combination with GB-4362

Group	Treatment	Free MMAE C_{max} (pg/mL)	Free MMAE AUC0-7days (day*pg/mL)	C_{max} Ratio (Relative to EV alone Group 2)	AUC Ratio (Relative to EV alone Group 2)
2 *(N = 9)*	3 mg/kg EV	119 ± 37.0	524 ± 126	-	-
3 *(N = 6)*	3 mg/kg EV + 3 mg/kg GB-4362	32.3 ± 13.4	134 ± 46.3	0.271	0.255
4 *(N = 6)*	3 mg/kg EV + 30 mg/kg GB-4362	< LoQ	< LoQ	< LoQ	< LoQ
5 *(N = 10)*	3 mg/kg EV + 100 mg/kg GB-4362	8.11 ± 11.9	< LoQ	0.068	< LoQ

SD=standard deviation; LoQ= Limit of Quantification; * Reported as combined-sex. For NC, MMAE concentrations were below the lower limit of quantification. In Cycle 4 (not shown), free MMAE reduction was impacted due to emergence of ADAs.

In a 28-day non-GLP study, GB-4362 at 0.5-4 mg/kg with 4 mg/kg EV reduced free MMAE exposure (C_{max} and AUC) across all dose levels. There was decreased incidence and severity of Grade 3-4 neutropenia and EV-related skin findings, with delayed onset of neutropenia at 2-4 mg/kg, as illustrated in the table below. Additionally, in cynomolgus monkeys, a reduction in hematologic and skin toxicities was observed in a dose-dependent manner.

28-day non-GLP NHP Study: Grade 3/4 neutropenia of cynomolgus monkeys treated with EV alone or in combination with GB-4362

Group	Treatment	Grade 3+ Neutropenia (%)a	Grade 4 Neutropenia (%)b	Free MMAE % (AUC0-1week)	Free MMAE % (AUC0-2week)	Time-to-Neutropenia Grade 3+ (days)c	Time-to-Neutropenia Grade 4 (days)c
2	4 mg/kg EV	3/3 (100%)	3/3 (100%)	100	100	8 (6-8)	8 (6-9)
3	4 mg/kg EV + 0.5 mg/kg GB-4362	2/2 (100%)	2/2 (100%)	59	74	7.5 (7-8)	8.5 (8-9)
4	4 mg/kg EV + 2 mg/kg GB-4362	2/2 (100%)	1/2 (50%)	28	52	12 (10-14)	14 (14-14)
5	4 mg/kg EV + 4 mg/kg GB-4362	1/3 (33%)	1/3 (33%)	13	32	14 (14-14)	14 (14-14)

[a] Grade 3+ neutropenia is defined as ANC < 1 x 10^3 cells/µL

[b] Grade 4 neutropenia is defined as ANC < 0.5 x 10^3 cells/µL

[c] Time-to-neutropenia is defined as the time from dose administration to the first occurrence of neutropenia reported as median (min-max) days

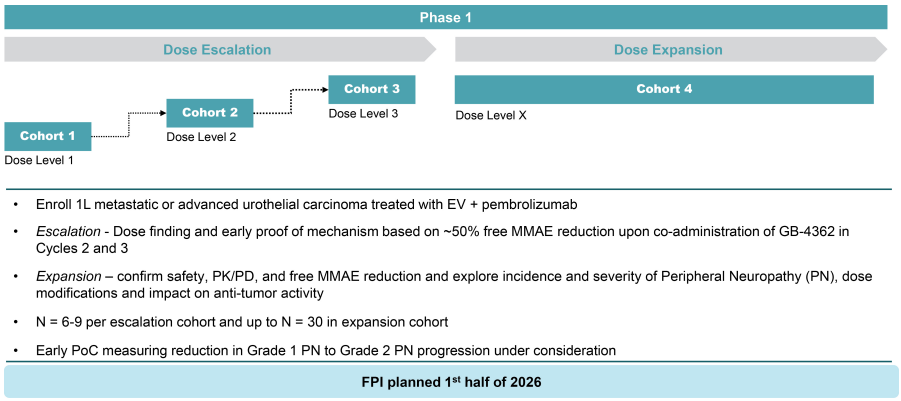
In both NHP studies, attenuation of EV-associated hematologic and skin toxicities, together with robust MMAE lowering, supported the hypothesis that roughly 50% reductions in free MMAE are expected, which should meaningfully mitigate MMAE-driven toxicity while preserving ADC activity, and provide a strong preclinical foundation for the planned clinical development of GB-4362.

While peripheral neuropathy itself is not reliably modeled preclinically, the observed dose-dependent reduction of circulating MMAE, coupled with mitigation of other established MMAE-driven toxicities in the two NHP studies, provides a mechanistically grounded basis for our belief that GB-4362 has the potential to reduce the incidence and/or severity of peripheral neuropathy in patients treated with EV.

Next Steps

We submitted an IND for GB-4362 in early December 2025 and received the IND "Study May Proceed" notification from the FDA on December 31, 2025 for GB-4362. We subsequently received Fast Track Designation on January 23, 2026 for this program and we plan to initiate a Phase 1 trial in 2026. The planned Phase 1 clinical trial is an open-label, multi-center, dose-finding trial in participants with locally advanced or metastatic urothelial cancer who are receiving standard-of-care first-line therapy with EV plus pembrolizumab. As depicted in the figure below, the planned clinical trial design includes a dose escalation portion and a dose expansion portion. In the dose escalation portion, dose levels will be evaluated in three cohorts of six participants, and free MMAE serum levels will be assessed in Cycle 1 of EV plus pembrolizumab. GB-4362 administration will begin in Cycle 2 as an IV infusion on Day 1 and Day 8 after completion of EV and pembrolizumab administration to assess safety, PK and free MMAE levels. Each cohort dose level will be determined based on the reduction of free MMAE serum exposure observed in the previous cohort.

Overview of Phase 1 clinical trial design for GB-4362



Following dose-finding, we plan to conduct an expansion cohort to evaluate GB-4362 safety, pharmacokinetics and pharmacodynamics and impact on free MMAE reduction. Our analyses of exploratory endpoints are expected to include impact on incidence and severity of peripheral neuropathy, impact on dose modifications for EV, and impact on antitumor activity. Using the expansion portion of the study as an early proof of concept is under consideration and, if we determine to proceed, we plan to evaluate GB-4362 in patients who develop their first sustained Grade 1 peripheral neuropathy while receiving EV plus pembrolizumab for the treatment of 1L muC. This single-arm signal-finding expansion would be designed to determine whether early addition of GB-4362 can prevent progression to Grade ≥2 neuropathy, a functionally limiting and often irreversible toxicity that leads to EV dose reductions, interruptions and discontinuation. Secondary measures would potentially include time to Grade ≥2 neuropathy, incidence of Grade ≥3 events, EV dose intensity and discontinuation due to neuropathy and patient-reported outcomes.

GB-5267: A MUC16 CAR-T Cell Therapy

Overview

GB-5267 is an armored, MUC16-directed CAR-T cell therapy engineered using the Generate Platform to address unmet needs in solid tumors, which we are initially developing for the treatment of platinum-resistant ovarian cancer. While CAR-T therapies have significantly advanced treatments for liquid tumors, CAR-T therapies have historically shown limited efficacy in solid tumors largely because the tumor microenvironment (“TME”) is profoundly immunosuppressive and structurally restrictive. GB-5267 was designed to have a high-affinity MUC16 binder and cytokine-based armor in order to enhance T-cell activation, proliferation and persistence within the TME while maintaining strict MUC16-dependent specificity. We are developing GB-5267 in collaboration with Roswell Park and an IND for GB-5267 was cleared by the FDA in December 2025. Pursuant to our collaboration, Roswell Park is expected to sponsor and initiate a Phase 1 clinical trial in 2026. This open-label trial will assess safety and tolerability following intravenous dose escalation and could subsequently explore in combined IV and local IP administrations in an expansion cohort. Secondary objectives are expected to include PK/PD assessments, characterization of CAR-T cell persistence, and preliminary anti-tumor activity. In preclinical studies, GB-5267 showed proliferation and cytotoxicity across multiple donors and no activity on MUC16-negative cells. As we evaluate GB-5267 clinically, we may investigate its use in earlier-line ovarian cancer settings if it shows benefit in later-line ovarian cancer.

Unmet Need and Generate Value Proposition

CAR-T therapies have transformed the treatment of hematologic malignancies because circulating tumor cells are readily accessible to engineered T cells; target antigens such as CD19 are uniformly expressed and minimally present on essential healthy tissues, and the blood and lymphoid compartments provide a supportive environment for CAR-T trafficking, expansion and persistence. In contrast, solid tumors present a far more complex therapeutic challenge: tumor antigens are often heterogeneous or shared with normal tissues, and CAR-T cells must infiltrate a dense, fibrotic stroma and overcome a profoundly immunosuppressive microenvironment enriched with checkpoint ligands, suppressive myeloid cells, regulatory T cells, hypoxia, and metabolic stressors that inhibit T-cell function. These barriers have historically limited the potency, persistence, and safety of CAR-T therapies in solid tumors, preventing the type of clinical breakthroughs achieved in liquid tumors. Our approach to addressing these challenges with GB-5267 was to design a CAR-T with high-affinity and potency, selective recognition of membrane-bound MUC16 to overcome antigen heterogeneity, and combined with cytokine armoring designed to enhance CAR-T activation, help recruit endogenous immune cells, and remodel the suppressive tumor microenvironment. Together, these attributes aim to improve trafficking, persistence, and functional activity within the peritoneal tumor bed, supporting the potential for a more durable and effective CAR-T response in ovarian cancer.

Ovarian cancer remains one of the most lethal malignancies in women. It is a major cause of cancer-related death in females in the United States, with an estimated 20,890 new cases expected in 2025 and approximately 250,000 women currently living with the disease. Because early symptoms are typically nonspecific, more than half of patients present with distant, metastatic disease at diagnosis, where outcomes are poor and effective treatment options remain limited. While five-year survival rates across all stages can approach 50%, advanced-stage survival is approximately 32%. Prognosis worsens further once disease becomes platinum-resistant, which is defined as recurrence within six months of platinum therapy, a state driven by mechanisms such as enhanced homologous recombination repair, increased drug efflux and alterations in tumor suppressor pathways.

There are no curative therapies for platinum-resistant ovarian cancer. Outcomes remain poor with objective response rate (“ORR”) under 30% when patients are treated with the current standard of care, which consists of single-agent chemotherapies. The addition of bevacizumab to chemotherapy, has improved progression-free survival but has not produced meaningful overall-survival benefit. Even targeted agents, including PARP inhibitors (*e.g.*, niraparib, olaparib and rucaparib), which originally received accelerated approval and showed promise for BRCA-mutant tumors (approximately 20% of ovarian cancers), were withdrawn for multiple platinum-resistant indications in 2022 following detrimental overall survival signals in confirmatory trials. While there has been some progress in the clinic for FRα-expressing tumors, they also reinforce that durable benefit remains elusive.

Although multiple investigational modalities are being evaluated in platinum-resistant ovarian cancer, success has been mixed so far. These challenges highlight the need for novel modalities capable of overcoming tumor-intrinsic resistance mechanisms and profoundly immunosuppressive TMEs. We believe that GB-5267 has the potential to overcome some of the challenges associated with developing cell therapy in solid tumors given its optimized design and added armoring.

Potential Mechanism of Action and Rationale

CAR-T therapies have historically failed in solid tumors due to poor tumor infiltration and accessibility and immunosuppressive TME. Solid tumors often impede T-cell trafficking and infiltration through dense stroma and abnormal vasculature, and once inside the tumor, CAR-T cells encounter high concentrations of inhibitory cytokines, suppressive myeloid cells, regulatory T cells and checkpoint ligands such as PD-L1 that blunt activation and promote exhaustion. In addition, chronic antigen exposure and metabolic stress—driven by hypoxia, low glucose, and high lactate—further limit CAR-T persistence and cytotoxic function. Together, these barriers have prevented traditional CAR-T constructs from achieving durable expansion, sustained activity, and meaningful clinical responses in most solid tumor settings.

We believe that MUC16 represents a compelling therapeutic target for the treatment of ovarian cancer, particularly platinum-resistant ovarian cancer where the unmet need remains high. MUC16 is a high-molecular-weight, membrane-anchored mucin expressed by approximately 80% of ovarian tumors, but largely restricted in normal tissues. MUC16 contributes to tumor immune evasion, adhesion and metastasis through interactions with mesothelin and activation of PI3K/AKT, MAPK, and NFκB signaling. Its high prevalence combined with limited normal-tissue expression provides an opportunity for a strong therapeutic index for targeted cell therapies.

GB-5267 is therefore engineered as a high-affinity MUC16-specific single-chain variable fragment (“scFv”) to enable precise targeting of MUC16-positive ovarian cancer cells, capitalizing on near-ubiquitous expression in advanced disease. The incorporation of a 4-1BB/CD3ζ signaling domain is intended to enhance potential T-cell proliferation, persistence and metabolic fitness, which are key determinants of durable responses in hostile solid-TMEs. The addition of armoring is designed to enable investigational GB-5267 CAR-T cells to secrete cytokines that stimulate IFN-γ production. This activity is designed to help recruit natural killer (“NK”) cells and cytotoxic T cells to the tumor site. In addition, armoring is designed to recondition the TME toward a pro-inflammatory state, potentially strengthening both CAR-mediated and endogenous immune responses.

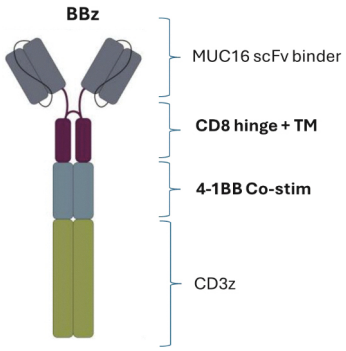
Technology Approach and Molecular Characteristics

CAR-T cells are composed of a T-cell with a CAR, which contains an extracellular binding domain, hinge region, transmembrane domain, and co-stimulatory-activation intracellular signaling domain; CARs may also contain armor such as on/off peptide switches, cytokines or chemokines.

GB-5267 was designed using our Generate Platform, which was applied to optimize multiple molecular attributes, including proliferative and functional persistence as well as robust and stable CAR expression. Within six months, we went from concept to product candidate nomination and were able to achieve molecular characteristics for our binder, surpassing our lead candidate criteria and overperforming reference constructs across key components of GB-5267.

As shown in the figure below, key design components of GB-5267 include (i) a human anti-MUC16 single-chain variable fragment (“scFv”) extracellular binding domain for targeting tumors that express MUC16; the scFv of GB-5267 is paired to a CD8 hinge and transmembrane ("TM") domain; (ii) a human 4-1BB costimulatory domain fused to CD3ζ for T-cell activation and persistence; and (iii) armoring to enhance the proliferation and recruitment of endogenous immune cells.

Key design components of GB-5267



We believe the optimized design features, including potential for expression, potency, and functional persistence of investigational GB-5267, and functional enhancement from the armoring, provide strong rationale for low dosing for patients with potential for clinical activity in the ovarian cancer TME.

Opportunities for Development in Additional Indications

While GB-5267 development is initially focused on platinum-resistant ovarian cancer; the biology of MUC16 and the modularity of the armored CAR platform could provide for label and indication expansion. Given the high MUC16 prevalence in newly diagnosed and recurrent ovarian cancer, we may consider exploring development in earlier lines of therapy for ovarian cancer. Other MUC16-positive solid tumors, such as subsets of pancreatic, endometrial and gastrointestinal tumors, could also be of interest and enable development in additional indications in the future.

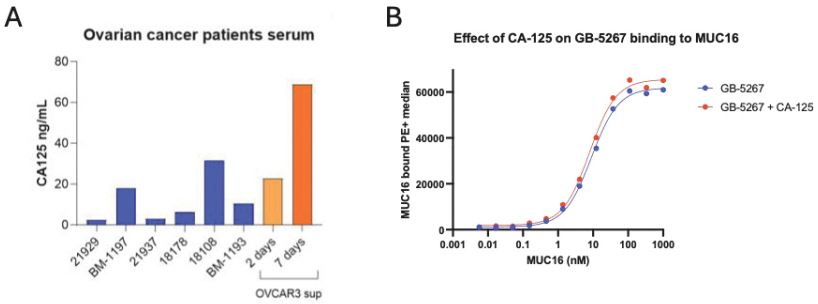
Preclinical Data

In preclinical studies, GB-5267 showed high target selectivity, antigen-dependent activation, active cytokine armoring consistent with its design, and robust *in vivo* activity across clinically relevant routes of administration, with a low predicted risk of off-tumor toxicity, supporting progression into patients.

In Vitro Pharmacology and Selectivity

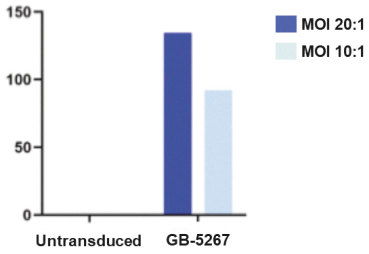
In *in vitro* pharmacology studies, GB-5267 CAR-T cells bound full-length, non-cleaved MUC16 with high specificity and showed no measurable binding to soluble CA-125 (as illustrated in the figure below). CA-125 is the cleaved, shed extracellular fragment of MUC16. It is released into the bloodstream and peritoneal fluid as tumors grow, making it one of the most widely used biomarkers in ovarian cancer for disease detection, monitoring treatment response and identifying recurrence. Potential selectivity for membrane-bound MUC16 ensures that GB-5267 engages only tumor-associated antigen rather than the abundant shed CA-125 circulating in serum, which can create an antigen sink and blunt CAR-T activity.

Impact of soluble CA125 on MUC16 binding affinity



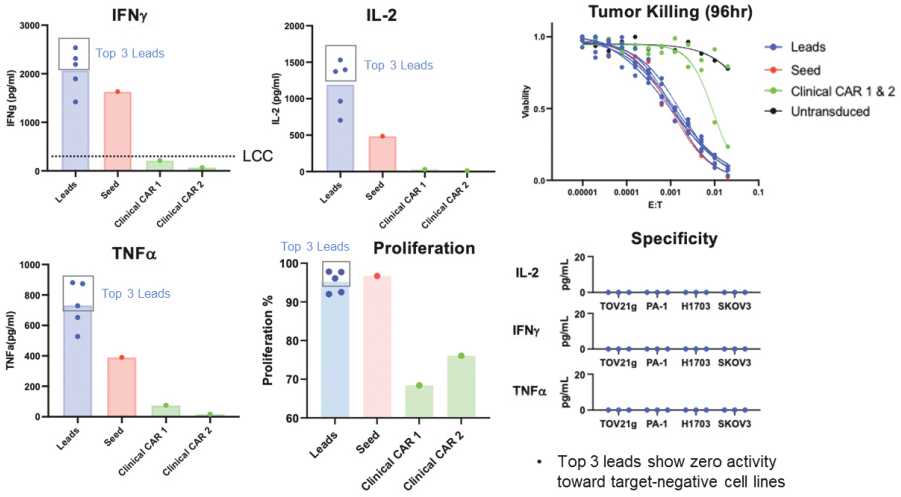
As shown in the figure below, GB-5267 also secreted armoring cytokine in a basal and antigen-enhanced manner, with cytokine output scaling with CAR expression (Multiplicity of infection ("MOI")). Untransduced T-cells did not secrete armoring cytokine under the same conditions.

Cytokine secretion (pg/mL) by GB-5267



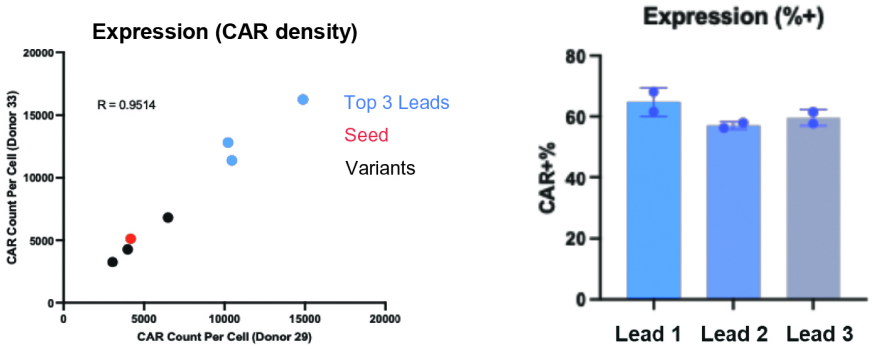
As shown in the figure below, in co-culture assays, GB-5267 induced IL-2, IFN-γ, and TNF-α secretion, proliferation, and cytotoxicity only in MUC16-positive OVCAR3 tumor cells, and we observed no activation or killing across multiple MUC16-negative epithelial or tumor cell lines.

***In vitro* cytokine production, proliferation, specificity and tumor killing for high potential leads, including GB-5267 across cell lines**



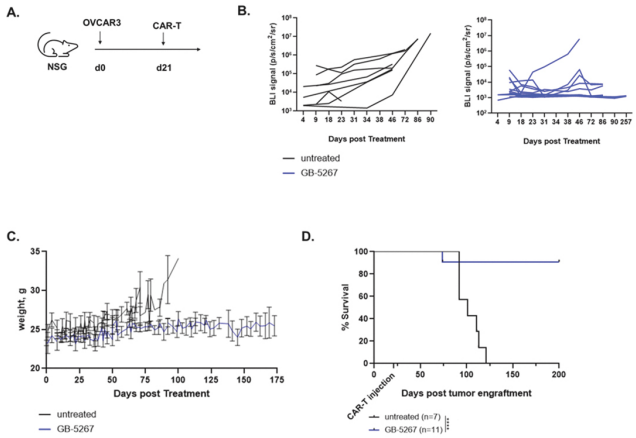
As shown in the figure below, GB-5267 showed optimized expression parameters across density with high CAR count per cell across multiple donors, as well as high percent of expressing T-cell.

CAR density and expression for high potential leads including GB-5267



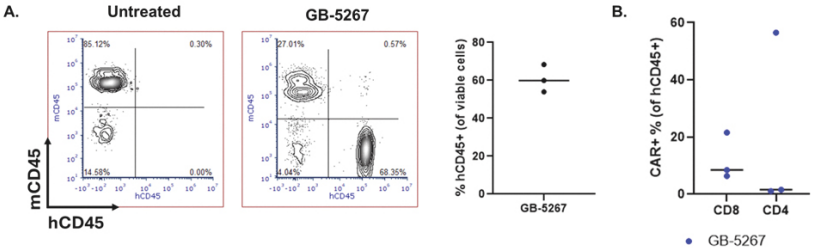
In an orthotopic intraperitoneal OVCAR3 tumor model, GB-5267 reduced tumor burden by bioluminescent imaging, delayed ascites-associated weight gain and extended survival relative to untreated controls. GB-5267 CAR-T cells persisted *in vivo*, with substantial human CD45 chimerism and CAR expression detected on CD4+ and CD8+ T-cell subsets several weeks post-infusion. Additional studies using IV, IP, and split IV plus IP routes demonstrated rapid and profound tumor debulking, supporting evaluation of both systemic and regional administration in the clinic.

***In vivo* efficacy of GB-5267 CAR-T cells in orthotopic tumor (OVCAR3 [MUC16+])**



A. Schematic of experimental design **B.** BLI images from untreated, or mice receiving GB-5267 IP at various days post treatment. Average radiance was plotted. **C.** Mouse weights monitored after treatment. **D.** Survival curves from mice in this experiment. Error bars represent SEM.

CAR-T cells persisted *in vivo* in orthotopic tumor model



A. Representative flow plots demonstrating the percentage of mouse CD45 ("mCD45") vs human CD45 ("hCD45") from viable cells isolated from peripheral blood. Blood was collected from retro-orbital bleeds 39 days post CAR-T treatment. Aggregate data of the hCD45+ percentage from all mice collected. **B.** CAR% detected on hCD8+ or hCD4+ T-cells.

Non-tumor-bearing mice engrafted with GB-5267 at pharmacologically active doses did not exhibit sustained weight loss for up to approximately 80 days, supporting preliminary tolerability within the known limitations of xenograft systems. Cross-reactivity studies across primary human cells and tissues showed strong GB-5267 binding to MUC16-positive ovarian tumor samples, with minimal binding, activation, or cytotoxicity in normal tissues and only rare, low-level signals not associated with cell death. These findings support a low predicted risk of on-target/off-tumor or off-target toxicity.

Collectively, these data suggest that GB-5267 may be a potent, MUC16-selective, armored CAR-T cell therapy candidate with antigen-dependent functional activity, durable *in vivo* persistence, and favorable preclinical safety characteristics, supporting advancement into first-in-human evaluation in platinum-resistant ovarian cancer.

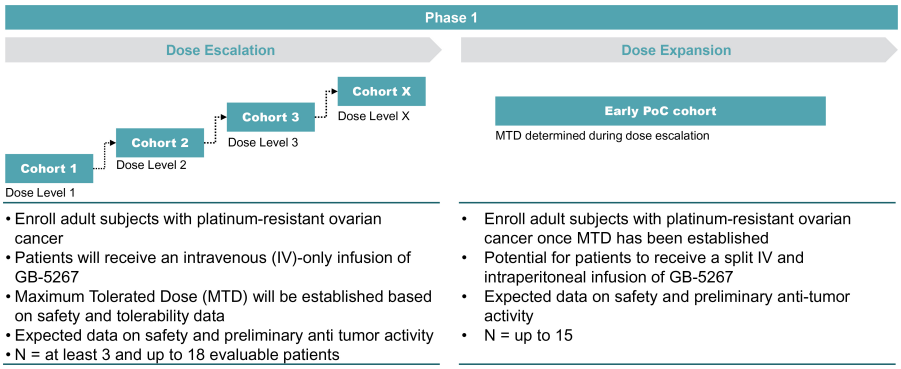
Next Steps

Our collaboration partner, Roswell Park, submitted an IND for GB-5267 in early December 2025. We received the IND "Study May Proceed" notification from the FDA on December 30, 2025. We jointly plan to initiate a first-in-human, multi-arm, open-label Phase 1 clinical trial evaluating the safety, tolerability, cellular kinetics and preliminary antitumor activity of GB-5267 in up to 18 adults with platinum-resistant ovarian cancer in 2026. As depicted in the figure below, the trial includes a dose escalation portion and a dose expansion portion. The planned primary endpoints of the trial are an assessment of safety and dose-limiting toxicities, and the secondary endpoints are an evaluation of PK and CAR-T persistence, and exploratory endpoint of preliminary clinical activity.

The trial is designed to evaluate GB-5267 first through IV administration, followed by an evaluation of combined IV and intraperitoneal regimen. Platinum-resistant ovarian cancer commonly presents with disease confined to or spreading within the peritoneal cavity, making IP administration an attractive strategy to achieve high local concentrations of therapeutic cells. However, we believe that systemic delivery via IV infusion remains critical to target potential metastatic sites outside of the peritoneal cavity to ensure adequate systemic immune activation. By combining IV and IP infusions of investigational GB-5267, the trial seeks to assess the potential benefits of both routes.

Unlike traditional CAR-T trials, the protocol does not include lymphodepleting chemotherapy prior to GB-5267 administration, a key differentiator in our clinical development approach. The potent immune-stimulatory properties of the armored construct are expected to support CAR-T expansion, activate endogenous immune pathways, and promote pro-inflammatory TME without the need for lymphodepletion. Moreover, lymphodepleting agents may attenuate the inflammatory milieu required for optimal cytokine-mediated activity. The need for lymphodepletion may be reassessed as clinical and translational data emerge and may be incorporated in future protocol amendments if deemed necessary to enhance the therapeutic profile of GB-5267.

Overview of Phase 1 clinical trial design for GB-5267



Collaboration with Roswell Park

See *"Our Collaborations with Biopharma and Beyond—Collaboration with Roswell Park"* below.

Other Preclinical Programs

The Generate Platform and its modular capabilities enable us to continue exploring and evaluating potential additional programs and product candidates across various modalities and biological applications that can deliver meaningful benefits to patients. In this regard, we are currently advancing multiple innovative preclinical programs from the Generate Platform, each designed to address areas of substantial unmet need.

One example is a next-generation ADC leveraging a modular capability for optimization for function to enhance internalization and cytotoxicity against a target with naturally low internalization rates. Traditionally discovered antibodies have demonstrated proof-of-mechanism but suffer from inconsistent efficacy, due to inefficient antigen internalization. Using our modular capabilities, our lead ADCs have shown upwards of ten-fold improved internalization and up to seven-fold greater cytotoxicity across cell lines versus benchmarks. As such, we believe we can design an antibody with meaningful improvements to internalization kinetics, anti-tumor activity and therapeutic index.

Pending upcoming preclinical data readouts, this program will be progressing towards product candidate nomination. This underscores our strategy to efficiently advance programs which apply our Generate Platform to solve a difficult biological challenge, and which have potential to deliver meaningful therapeutic impact in areas of high unmet need.

Our Collaborations and Other Arrangements

We have sought collaborations with pharmaceutical and biotechnology companies that enable us to leverage our distinct capabilities, while improving our Generate Platform. Our initial collaborations with Amgen and Novartis are more general examples of these kinds of collaborations—ones where the partner shares targets of interest with a desire to develop protein-based therapeutics where there have been significant challenges using traditional drug discovery methods. We then deploy our Generate Platform toward solving these challenges. Once achieving certain predefined criteria, the partner, at its discretion, may take on further development toward the clinic and commercialization.

Our partners have proposed programs that cover a variety of protein-based modalities, a range of therapeutic areas, and many biological challenges. The common denominator in these programs is that they leverage the protein optimization and *de novo* generation capabilities of our Generate Platform. As such, these collaborations offer valuable opportunities to deliver quality product candidates to our collaboration partner, develop the Generate Platform toward broader potential applications with the benefit of partner funding, and provide the potential for us to receive significant milestones and royalties if the partner chooses to advance programs into the clinic and commercialize.

In addition, we have a collaboration agreement with Pioneering Medicines 02, Inc. (“PMCo”), an affiliate of Flagship Pioneering, pursuant to which we and PMCo agreed to share research and development costs for GB-0895. This collaboration was established to provide funding and certain support in preclinical development that we had not yet built. Upon the execution of the underwriting agreement for this offering, we will acquire PMCo. At that time, our collaboration, including our cost-sharing arrangements, will terminate and we will become obligated to make certain payments to PMCo’s parent based on net sales. For more information about our collaborations and other arrangements with Amgen, Novartis and PMCo, see “*—License and Collaboration Agreements*.”

In addition, we also have co-development and commercialization collaborations in place with Roswell Park and MD Anderson. These collaborations have enabled us to extend the reach of our Generate Platform towards potentially valuable oncology applications while leveraging the respective CAR-T manufacturing and clinical development expertise of Roswell Park and the biology and clinical development expertise of MD Anderson, respectively. Both of these collaborations have a 50/50 style arrangement for cost- and profit-sharing.

As we consider future Generate Platform collaborations, we will particularly consider those that could provide data that improves our modular capabilities and therapeutic applications, particularly in areas that we have already prioritized, or will prioritize in the future. Our prioritized applications are expected to continue to evolve as we identify areas in which our Generate Platform exhibits differentiation in certain domains that have meaningful therapeutic opportunities should those modules be unlocked. The benefit of this targeted collaboration approach is that it provides the opportunity to unlock new modules and applications, broadening the reach of our Generate Platform in an efficient manner.

Beyond these types of collaborations, as we advance our programs and product candidates, we may also opportunistically explore licensing, commercialization and other partnership and collaboration arrangements with global pharmaceutical companies to enhance our development or commercialization efforts. These types of partnership, collaboration and other arrangements could enable us to pursue additional programs and product candidates, secure additional capital and maximize the potential of our technology toward solutions for patients suffering from a wide range of diseases.

Collaboration with Roswell Park

In October 2023, we entered into a collaboration agreement with Roswell Park to design and develop CAR-T cell therapies and armoring technologies for up to three oncology targets, including in solid tumors. The collaboration combines the programmability and scalability of the Generate Platform for rapid discovery and optimization and Roswell Park's expertise in cell therapy design, clinical development, and manufacturing. Under the agreement, we and Roswell Park agreed to share research and development expenses as well as profits generated through commercialization of any jointly-developed products. The parties will use commercially reasonable efforts to perform the development activities assigned to such party in accordance with each research and development plan. We will identify and propose to a joint development committee ("JDC") for its review and approval potential compositions for each collaboration candidate in accordance with the applicable research and development plan. Upon JDC's approval, Roswell Park will serve as a site for, and recommend lead investigator for, Phase 1 and 2 clinical trials of any jointly-developed product candidates unless otherwise agreed. GB-5267 is the first of these product candidates. The parties will use commercially reasonable efforts to perform the development activities assigned to such party in accordance with each research and development plan. We will identify and propose to a JDC for its review and approval potential compositions for each collaboration candidate in accordance with the applicable research and development plan.

Unless earlier terminated, the collaboration agreement will remain in effect for seven years from the effective date of the collaboration agreement, unless if there is a product being sold, then the collaboration agreement will remain in effect for so long as such product is being sold. Each party has the right to terminate the collaboration agreement if the other party is in material breach or is insolvent, subject to a notice period. Each party has the right to terminate the collaboration agreement for convenience, subject to a notice period.

As part of an expansion of Roswell Park's cell therapy capabilities, they have invested in cell therapy manufacturing and in clinical development expertise making them a suitable partner for us. The collaboration continues the significant momentum associated with Roswell Park's recently announced expansion, supported in part by New York State funds, which will make Roswell Park's Current Good Manufacturing Practice ("cGMP") facilities the largest academic cell therapy center in the United States. Additionally, and as a key consideration for us in entering this collaboration, Roswell Park recently recruited several leading clinicians to lead their cell therapy practice including Dr. Reinier Brentjens whose lab played a foundational role in development of several currently approved cell therapies. Dr. Brentjens together with Dr. Marco Davila and their team are among the world's leading experts in cell therapy.

Collaboration with MD Anderson

In April 2023, we entered into a co-development and commercialization collaboration agreement with MD Anderson to discover and develop protein therapeutics for up to five oncology targets. The collaboration combines our integrated machine-learning capabilities and experimental/wet lab capabilities, which are powered by the Generate Platform, with MD Anderson's clinical research expertise and the translational research and drug development capabilities of the MD Anderson's Therapeutics Discovery division. Unless earlier terminated, the collaboration agreement will remain in effect for 10 years from the effective date of the collaboration agreement, unless if there is a licensed product being sold, then the collaboration agreement will remain in effect for so long as such product is being sold. Each party has the right to terminate the collaboration agreement if the other party is in material breach or is insolvent, subject to a notice period. We have the right to terminate the collaboration agreement for convenience, subject to a notice period.

Under the agreement, we and MD Anderson agreed to share research and development expenses as well as profits generated through commercialization of any jointly-developed products. Unless otherwise agreed upon, MD Anderson will serve as a site for and recommend lead investigators for Phase 1 and 2 clinical trials of any jointly-developed product candidates.

The Generate Platform Deep-dive: How the Generate Platform Works and What it Produces

Introduction and Impact

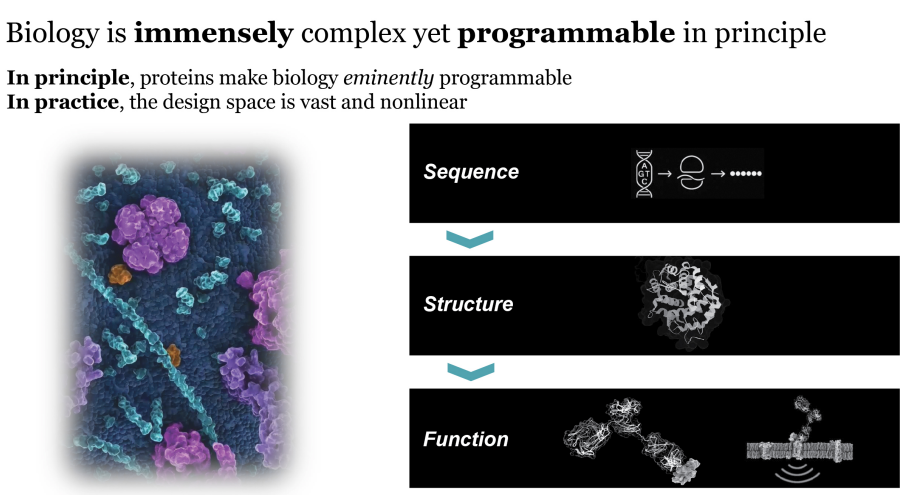
Our vision is to program biology to generate optimal therapeutics for the greatest impact on human health. Central to our vision is the Generate Platform, which is designed to be a therapeutic area and protein modality agnostic system integrating computational innovation with scalable biohardware to address therapeutic challenges beyond the reach of traditional discovery methods.

Biology is an information science. DNA encodes biological function through the way its sequence determines the structure and activity of the molecules it produces, which, in principle, makes biology programmable. In practice, however, the immense complexity of biology has made programming it very difficult. Historically, drug discovery has emphasized two general approaches to manage this complexity. One approach was an intentional, mechanically guided design approach at low-throughput. The other was a high-throughput experimental exploration approach that was generally less able to encode specific intent. We believe that dramatic reductions in the cost of compute and the cost of making and measuring DNA and proteins enables a new paradigm: intentionality at scale. In this paradigm, our generative models learn generalizable design principles from data to generate hypotheses at scale, and scalable experimental systems verify those hypotheses. The Generate Platform was built to implement this paradigm, generating large numbers of specific molecular and biological hypotheses in response to pre-specified therapeutic objectives and rapidly tests them. We believe intentionality at scale is foundational to achieving programmable biology: enabling systematic generation of medicines across therapeutic areas and protein modalities while producing proprietary data that improves our generative models over time.

The Generate Platform integrates generative and predictive models that learn design principles from proprietary data—*e.g.*, diffusion-based models (such as our Chroma model) and graph neural networks, among other architectures—with advanced experimental biohardware systems for scalable verification. Our biohardware systems include scalable DNA assembly, rapid protein production, and high-throughput, multiplexed assay miniaturization enabling us to measure up to billions of molecules per generation cycle, as well as a Cryo-EM core for high-content structural data generation, which has produced more than 500 high-resolution maps in 2025 alone. These capabilities significantly reduce the cost and time per assay data point, tightening the loop between generative models and real-world biological verification.

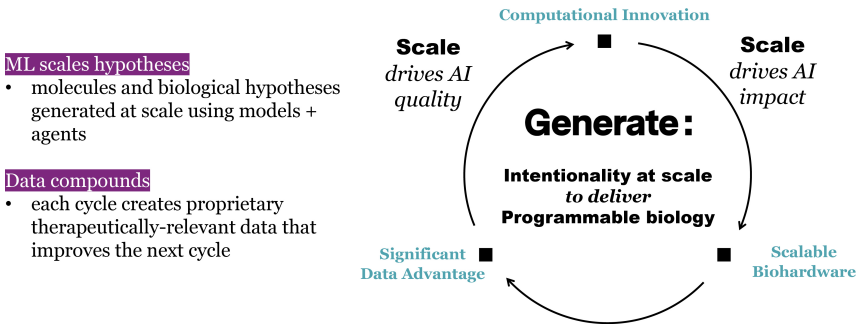
We built our Generate Platform around proteins because we believe proteins are essential to truly program biology. Proteins occupy the critical junction of biology's information flow: they bind, signal, catalyze, traffic, and assemble into complex structures that support life. The behavior of a protein is specified by its linear amino acid sequence, which is encoded in DNA. These sequences constitute biology's natural computational language, which determine how that protein folds – its structure – and from there how the protein interacts with its environment, driving protein function. Biology's natural computational language is what enables us to potentially program biological functions directly (as shown in the figure below). By specifically encoding therapeutic intent into a sequence and precisely "writing" a protein's function, we can design proteins to deliver intended therapeutic impacts. Furthermore, the nature of proteins enables an ideal closed-loop system: generative models propose sequences, DNA encodes them, and high-throughput experiments characterize these proteins, generating functional data for continuous and iterative improvement.

Therapeutic proteins: our programming interface to biology



To deliver an increasingly programmable approach to biology, our Generate Platform is a tight and fully-integrated loop of computational innovation and scalable biohardware, which allows us to generate valuable proprietary data-sets, including sequence, structure, and function, that in turn further inform and refine our computational engine to generate better protein proposals for any given biological or therapeutic challenge (as shown in the figure below), and enabling compounding improvements in the Generate Platform over time.

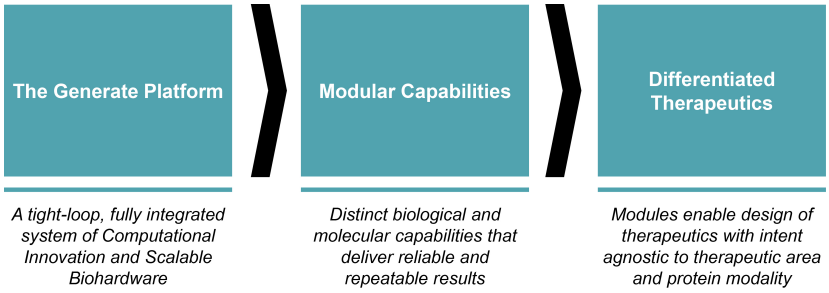
The Generate Platform is designed to systematically decode and comprehend biology at speed and magnitude



Our Generate Platform is designed to implement intentionality at scale by coupling AI models that generate large numbers of design hypotheses with scalable experimental biohardware that verifies them. Each time we engineer, build and then test a set of hypotheses, we generate experimental data that is intended to improve the Generate Platform. We package certain of these learnings into reusable modules—validated capabilities that can be applied across targets and modalities towards differentiated therapeutics.

To date, our Generate Platform has enabled us to develop numerous modular capabilities, many of which have already demonstrated the ability to successfully translate computationally engineered proteins into human clinical testing. In addition, we are currently exploiting our modular capabilities for other potential therapeutic applications, including oncology and other historically difficult to treat diseases.

The Generate Platform is oriented towards differentiated therapeutics generation



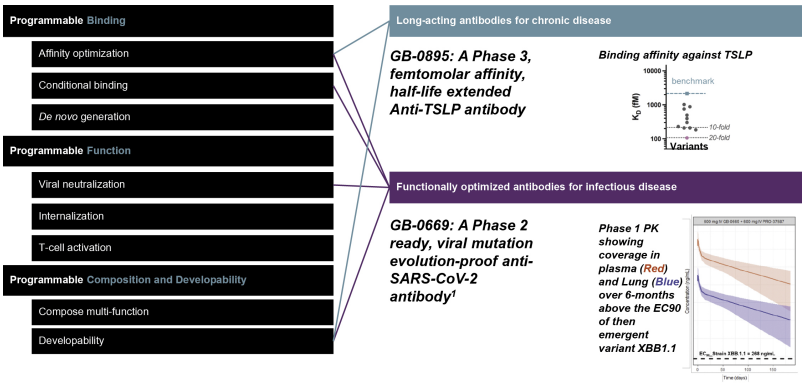
We believe this approach is scalable, reliable and reusable and enables an increasingly low-cost way of generating proteins that accurately implement specified biological intentions and allow for the exploration of significantly more ideas than a one-by-one discovery approach. Our Generate Platform and resulting modular capabilities enable us to address questions like: “What if we wanted to compare optimal internalization across five distinct epitopes of a tumor antigen?” or “What if we wanted to compare the pharmacology of selective agonism across four related but different receptors classically agonized by a single ligand?” We can now make these “many good ideas tested all at once” approaches feasible, positioning us to pursue complex biology at a low cost, potentially resulting in more rapidly developed, higher quality product candidates.

Our initial focus in building modular capabilities was on one of the most fundamental ways proteins mediate biology: binding. We have leveraged this starting point to expand capabilities to include (i) binding with context, including selective and conditional target binding, and (ii) protein design for a desired function, including viral neutralization, receptor mediated internalization, and receptor function. In parallel we have invested in a set of capabilities focused on developability, including models, data and workflows that enable us to produce candidates with drug-like properties by design, right from the point of generation. While we continue to develop additional modular capabilities, the following have been deployed in programs from our early-stage preclinical programs to our lead product candidate:

- **Programmable Binding**
  - **Affinity optimization:** Tune binding affinity, up or down, for desired outcomes, *e.g.*, PK/PD characteristics such as target engagement as for GB-0895, anti-IL-13 and other preclinical proteins targeting OX40L, TL1A and IL-23p19
  - **Conditional binding:** Bind (i) given condition, *e.g.*, bind tightly at pH 7.4 but significantly less at pH 6.0, or (ii) with selectivity, *e.g.*, tune affinity to remove cross-reactivity of an existing ligand and allow binding to only one of two receptors – or alternatively add cross-reactivity to cause a desired binding profile to related receptors or to enable binding both human and cyno target variants
  - ***De novo* generation:** Design a completely novel binder to a pre-defined epitope, allowing intentional engagement or potentially exploration of a series of binding epitopes
- **Programmable Function *De novo***
  - **Viral neutralization:** Neutralization across virus strains, as for GB-0669
  - **Receptor internalization:** Enhance receptor internalization and payload delivery for a given binding epitope, without including pH dependence
  - **T-cell activation:** Antigen specific T-cell activation for selective tumor killing, or optimization of CAR constructs for more effective tumor killing as for GB-5267
- **Programmable Composition and Developability**
  - **Compose multi-function:** Graft and fuse protein modules with different functions
  - **Developability:** Manufacturability, *e.g.*, aggregation, viscosity, as with GB-0895, anti-IL-13, GB-4362 and other product candidates and programs

As shown in the figure below, many of our modular capabilities have now been translated into therapeutic protein product candidates across our programs and product candidates. We share some further details in two case studies below.

Overview of Modular Capability Case Studies



[1] Development paused for commercial reasons.

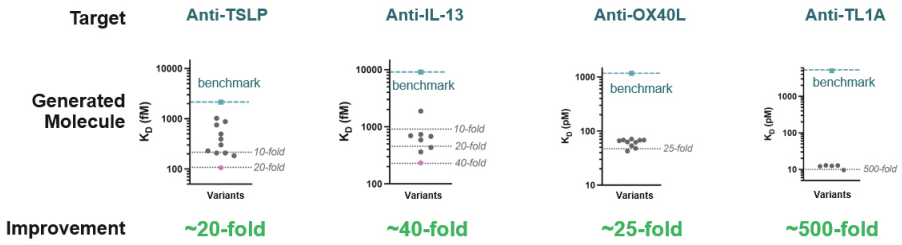
Case Study: GB-0895: An Anti-TSLP Monoclonal Antibody

We have deployed our Generate Platform to create modular capabilities designed to address rate-limiting challenges in affinity optimization and developability, which is exemplified by our lead product candidate, GB-0895, an anti-TSLP monoclonal antibody candidate for the treatment of severe asthma.

We determined through PK/PD modeling that if we applied a validated half-life extension technology (in this case a YTE mutation), femtomolar binding affinity to the TSLP target would likely still be required to reach the proposed dosing interval. We are not aware of any approach that has successfully reached this degree of improvement in binding affinity to this target. Through our Generate Platform, we deployed an affinity optimization modular capability that identifies proteins with multiple folds higher binding affinity than a given reference antibody. This capability, combined with our developability optimization modular capability, enabled us to engineer a highly developable antibody incorporating half-life extension technology and 106 femtomolar binding affinity to the TSLP target, which reached our desired molecular characteristics in two generation cycles.

Our binding affinity optimization modular capability has been refined and deployed repeatedly, delivering significant improvements reliably across many targets, as demonstrated in the figure below. This figure demonstrates that our Generate Platform has allowed a more “programmable” control of affinity optimization across three additional targets beyond GB-0895.

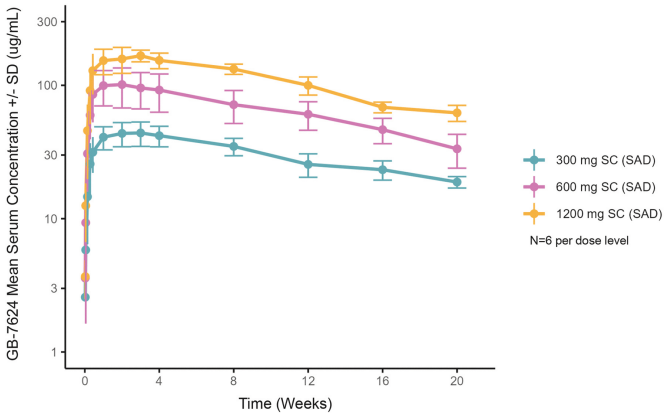
Affinity optimization across four targets demonstrated reliable improvement in binding affinity



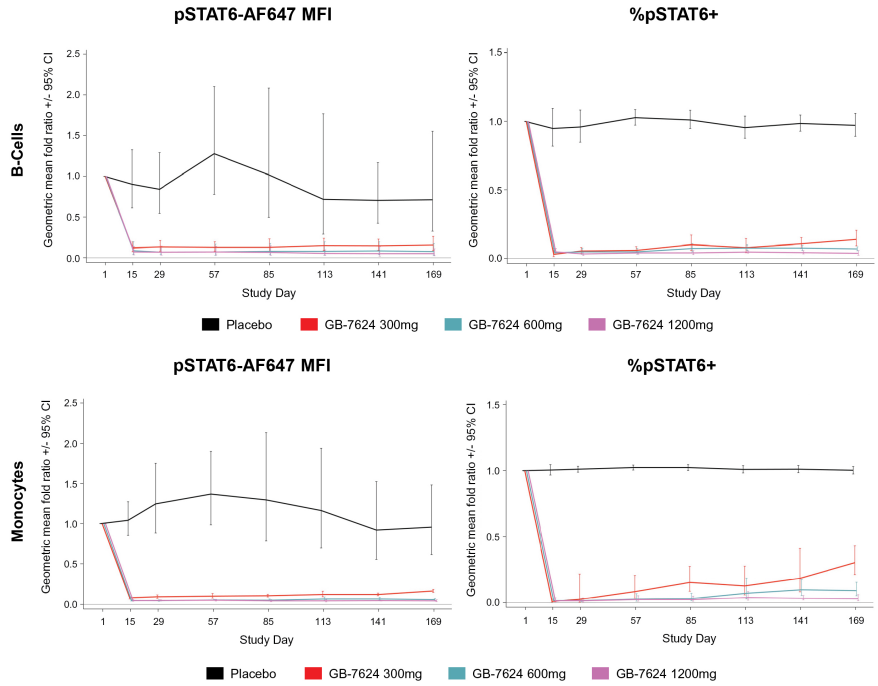
Case Study: GB-7624: An Anti-IL-13 Monoclonal Antibody

In the case of anti-IL-13, we generated a product candidate (GB-7624) with 233 femtomolar binding to IL-13, approximately 40-fold tighter binding than lebrikizumab, a leading FDA-approved anti-IL-13 antibody, based on published data. In Phase 1 clinical trials in healthy volunteers, with data as of January 23, 2026, this product candidate showed a near-complete suppression of key biomarkers, a long half-life (with a preliminary estimate of approximately 89 days) and safety data consistent with the IL-13 mechanism. Furthermore, in such trials, this product candidate demonstrated almost double the exposure compared to publicly available data on other clinical-stage long-acting anti-IL-13 antibodies at similar doses. Preliminary data from this product candidate has served as a second clinical proof point for our modular capability of binding affinity optimization and we may evaluate it as a potential combination partner to GB-0895 in the future.

Generate's anti-IL-13 product candidate demonstrated a long half life and dose-proportional PK in preliminary results from SAD cohorts of an ongoing Phase 1 trial



Generate's anti-IL-13 product candidate exhibited near-complete pSTAT suppression in B-Cells and monocytes over 300-1200mg in preliminary results from SAD cohorts of an ongoing Phase 1 trial



Geometric mean fold ratio and 95% CI are calculated as the ratio of the post-baseline and baseline assay levels. Ratios are log-transformed to obtain the mean and 95% CI, and back-transformed to the original scale value.

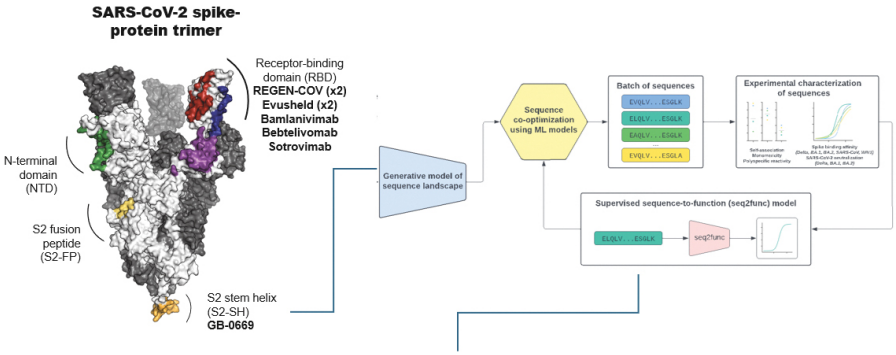
Case Study: GB-0669: A Pan-variant SARS-CoV-2 Neutralizing Antibody

We have also deployed our Generate Platform to create modular capabilities designed to address rate-limiting challenges in conditional binding, viral neutralization and developability, which is exemplified by our first product candidate, GB-0669, an investigational pan-variant anti-SARS-CoV-2 monoclonal antibody studied as pre-exposure prophylaxis (“PrEP”) for COVID-19.

Numerous antibodies have been developed and translated into the clinic as treatments or PrEP agents for COVID-19. All antibodies that received Emergency Use Authorization have seen reduced neutralization of the virus due to escape mutations in the domain they predominantly bind: the receptor binding domain of the spike protein. Other, highly conserved, mutationally resistant domains exist on the spike protein, including the S2 domain. Due to its more distant location from the receptor binding domain and the proximity to the membrane, generating a clinically-relevant neutralizing antibody was a challenge.

We developed high-throughput neutralization assay techniques to create a “modular” neutralization optimization capability, which allowed for multiple rounds of computational engineering and experimental validation across seven distinct epitopes and eighteen distinct campaigns over eight months to select the S2 domain as the targeted the optimal mechanism of action to pursue. This illustrates intentionality at scale: running many targeted design hypotheses in parallel, rapidly learning from experimental outcomes, and converging on an optimal mechanistic strategy. This modular viral neutralization capability to engineer a variant-resistant, therapeutically-relevant neutralizing monoclonal antibody resulted in nomination of GB-0669, a potent binder to the S2 domain. In preclinical studies, GB-0669, which, to our knowledge, remains the only known clinical-stage S2 domain targeted monotherapy candidate, demonstrated the potential for potent, variant-resistant neutralization in serum neutralization assays, as illustrated in the figures below. Results from a Phase 1 clinical trial of GB-0669 were presented in 2024 and published in multiple peer-reviewed publications. Development of GB-0669 was subsequently paused due to changes in the commercial landscape related to PrEP agents for COVID-19. We believe the value of this work extends beyond a single program: it validated a viral neutralization capability that can be reused across future targets and pathogens, de-risking a broader set of opportunities at low marginal cost.

Approach to engineer GB-0669, a mutation resistant anti-S2 domain neutralizing monoclonal antibody



GB-0669 Viral neutralization

EC50 (95% CI) [ng/ml]	SARS-CoV-2 D614G	SARS-CoV-2 Delta	SARS-CoV-2 BA.4/5	SARS-CoV-2 BQ.1	SARS-CoV-2 BQ.1.1	SARS-CoV-2 XBB.1.5	SARS-CoV-1	WIV1
GB-0669	18.8 (15.6, 22.8)	39.3 (30.4, 51.7)	4.8 (2.4, 8.5)	8.5 (6.4, 11.1)	5.1 (1.9, 10.4)	8.8 (6.5, 11.7)	11.7 (9.4, 14.6)	63.0 (53.1, 75.4)

≤ 50 ng/ml | 51-200 ng/ml | 201-1000 ng/ml | >1000 ng/ml

Our Approach to Programmable Biology

Together, these examples illustrate how our modular capabilities translate directly into differentiated product candidates. They also reflect our deeper conviction: programmable biology is only possible when therapeutic intent, computational engineering, and biological data generation operate as a unified system to enable intentionality at scale and a compounding data advantage over time. In the sections following, we outline our approach across:

- Modular capabilities and their translation to therapeutics;
- Computational innovations, including the models that design for protein characteristics given a set of target attributes; and
- Scalable biohardware, including our laboratory and informatics infrastructure, Cryo-EM and high-throughput systems such as microfluidics and pooled assays.

Modular Capabilities to Develop Therapeutics At Scale

The Generate Platform's repeatable modular capabilities or modules serve as building blocks that can be deployed individually or in combination to create diverse therapeutic programs and product candidates to address opportunities that are often out of reach of traditional technologies. We believe validating a module can de-risk multiple future opportunities by enabling repeatable deployment across targets and modalities.

A key focus area for our modular capabilities relates to a foundational driver of protein function: binding. We leveraged this starting point and expanded to capabilities that optimize selective and conditional binding, and molecular and biological functions that are related to, but not entirely driven by, binding. These include capabilities such as viral neutralization, receptor mediated internalization and receptor function. In parallel, we have invested in a set of capabilities focused on developability optimization, including models, data and workflows that enable us to generate candidates with drug-like properties by design from the earliest stages of discovery. Because each of these capabilities are embodied in both computational models and experimental protocols, they can often be transferred from one target or modality to another seamlessly and with considerably less effort than starting from scratch. As a result, modules can be combined to address new therapeutic objectives while building on prior learnings and data.

These modular capabilities currently cover three inter-related domains: programmable binding, programmable function and programmable composition and developability.

Programmable Binding: Affinity Optimization

One of our core modules is the ability to improve binding affinity and kinetics, often against challenging epitopes. We applied this module to multiple modalities, including monoclonal antibodies, antibody fragments, peptides, signaling proteins and CARs. In our pipeline, this work underpins, among others, the potential of our high-affinity antibodies in I&I and oncology indications. For example, we have engineered binders with up to 500-fold improvement in binding affinity, while co-optimizing for developability and selectivity across four well established immunology targets: TSLP, IL-13, OX40L and TL1A. This improvement in binding affinity is a key feature designed to enable extended dosing regimens for these immunology product candidates at low doses that we are studying to enable product candidate profiles that include potential for a single injection every six months which is meaningfully superior to typical current regimens for approved biologics.

Programmable Binding: Conditional and Selective Binding

Biological systems are context-dependent. A binder that is useful in one context may be harmful in another. We therefore invest in capabilities that tune when and where binding occurs based on environmental conditions such as pH levels or programmed selectivity to bind one receptor but not a highly similar alternative receptor. Examples include:

- Engineering pH-dependent binding, where an antibody binds tightly at one pH (for example, in the bloodstream) but releases its target at another (for example, in an endosome), which can be useful for reducing target-mediated drug disposition and other therapeutic applications.
- Engineering cross-reactive binders for both human and preclinical species targets, which can simplify translational work, *e.g.*, antigen binder for a T-cell engager, which bind both the human and NHP version of a protein.
- Enhancing selectivity between closely related targets, such as members of a cytokine or G-protein coupled receptor ("GPCR") family, to reduce off-target effects.

These modules again rely on the deep integration between targeted computational library design, multiplexed experimental assays and, where possible, structural insights from Cryo-EM or other methods.

Programmable De Novo Binder Generation

Since our founding, we have built protein design models that enable (i) optimization of existing binders towards a pre-specified set of properties and (ii) *de novo* binder generation—designing a binder without a starting reference. Importantly, these are not separate systems: the same underlying models can operate in either mode, so improvements driven by additional proprietary data strengthen both *de novo* generation and generative optimization. *De novo* binder design allows us to specify a desired epitope and binding geometry ("pose") upfront, in contrast with traditional methods that leverage either naïve libraries or immunization-based approaches to produce binders, which then must be screened to identify those that bind the intended epitope and exhibit the desired properties. Because *de novo* design is intent-driven, it enables us to:

- test precise mechanistic hypotheses (*e.g.*, binding a specific epitope to modulate receptor activation);
- pursue difficult or underexplored epitopes (including epitopes that are poorly sampled by immune-derived antibodies); and
- systematically explore epitope and pose space at scale to identify designs that achieve the desired functional outcomes.

We are applying *de novo* approaches to many of our current programs, as well as programs in collaboration with our existing partners.

Programmable Function

Our Generate Platform has been successfully applied to learn the relationship between a protein sequence and its function, rather than binding alone. For example, in receptor biology, simply binding to a receptor is not enough; the downstream signaling pathway a ligand engages can determine whether its effects are therapeutic or harmful.

To date, we have successfully optimized for the following molecular and/or biological function amongst others that can be design features of our candidates:

- **Functional Internalization:** initially for delivery to endosome in the context of a preclinical ADC program.
- **CAR function:** focused on multiple therapeutically relevant parameters such as cell killing and applied in our clinical product candidate, GB-5267.
- **T-cell engager function:** across multiple preclinical T-cell engager binders and antigen binding arms.
- **GPCR function:** focused on antagonism with preliminary preclinical work supporting optimizing for agonism.

This enables us to search for proteins that not only bind to the given target but that also demonstrate bias signaling toward beneficial pathways (for example, promoting anti-inflammatory responses while minimizing pro-inflammatory ones). In all the examples above there was a notable separation between improved affinity and improved function, demonstrating our Generate Platform's ability to optimize outside the context of binding alone. We have applied similar logic to other functional questions across diverse molecular and biological functions.

Programmable Composition

We applied our generative models to combine the composition of different protein components to create a single therapeutic protein candidate. As an example, we successfully grafted a T-cell receptor's binding domain (its complementarity-determining regions or CDRs) into a standard antibody framework – which allowed us to leverage the specificity of T-cell receptors for their target tumor antigen (often a peptide with a single amino acid difference from the healthy protein) with the robust profile of an antibody. The resultant antibodies were able to distinguish a single amino-acid difference between the target mutant peptide, which they bound with high affinity, and the corresponding healthy protein, which they avoided binding even at high concentration, while also exhibiting a robust developability profile.

Programmable composition extends our modular approach by enabling us to assemble multiple validated components into a single therapeutic protein candidate to achieve a desired overall profile. While our programs resulting from these composition applications are at an early preclinical stage, we believe they illustrate the flexibility of our Generate Platform and demonstrate promise for future therapeutics development.

Programmable Developability and Manufacturability

Clinical success will require, among other things, that our proteins are sufficiently manufacturable, stable and suitable for formulation and delivery. We therefore incorporate developability objectives from the start in our generation process, co-optimizing them in parallel with efficacy-related properties. We use a combination of:

- Developability property models trained on internal and historical data that are used directly in design to co-optimize expression, stability, aggregation risk, polyreactivity, viscosity, and related attributes;
- High-throughput developability and biophysical assays that measure these properties at scale; and
- A continual feedback loop in which assay data updates and improves our property models, enabling increasing generalizability across protein modalities.

By co-optimizing developability and activity in the same design–build–test–learn generation cycles, we aim to increase the likelihood that candidates selected for advancement are drug-like by design and to streamline downstream development.

Expanding Set of Modular Capabilities

Our current modules were developed to offer reliable and repeatable capabilities that can be applied to solve many challenges required to engineer a differentiated therapeutic. In this way, a single program may begin with one or more core modules, such as affinity or developability optimization, but as we layer in additional capabilities, such as signaling bias, internalization control or species cross-reactivity, the number of distinct product candidate profiles that can be assembled increases. As our catalog of validated modular capabilities grows, we believe we can mix and match them to address more complex biological questions, exchange one module for an improved version without redesigning an entire program, and transfer successful design strategies from one target class to another.

In practice, this means that each module has the potential to do more than advance a single program. A program that requires, for example, fine-tuned functional bias in a receptor family or highly selective recognition of closely related antigens can leave behind improved modules in those areas, which we believe can then be reused in future programs. Over time, as the number and maturity of these modules increases, our vision is for our Generate Platform to offer an expanding set of highly reliable and rapidly deployable modular capabilities that can be utilized across multiple therapeutic areas and protein modalities. We seek to translate this approach into a steady stream of highly differentiated therapeutic programs, which we can develop for both ourselves and our collaboration partners to broaden the value creation and capture impact of our Generate Platform.

Computational Innovation to Ideate and Design at Scale

Our proprietary computational stack combines generative models that propose protein designs with predictive and decision models that evaluate, prioritize, and iterate toward pre-specified therapeutic objectives. Together, these models enable us to generate large numbers of candidate sequences under explicit constraints and to jointly optimize multiple, sometimes competing, design objectives. In practice, we care not only about whether a protein folds and binds, but also how it signals, whether it is selective, whether it can be manufactured and how it behaves in formulation. Our models are built to reason jointly about attributes such as affinity, function, specificity and developability, rather than optimizing any single metric in isolation. Traditional approaches often need to focus on a single molecular attribute, optimize for that and then move onto the next. In doing so, drug developers often sacrifice one attribute to achieve a goal in another. Our approach is fundamentally different and is designed to allow for co-optimization of multiple attributes simultaneously, meaning we can explicitly manage and reduce tradeoffs relative to the way typically seen in traditional drug discovery methods.

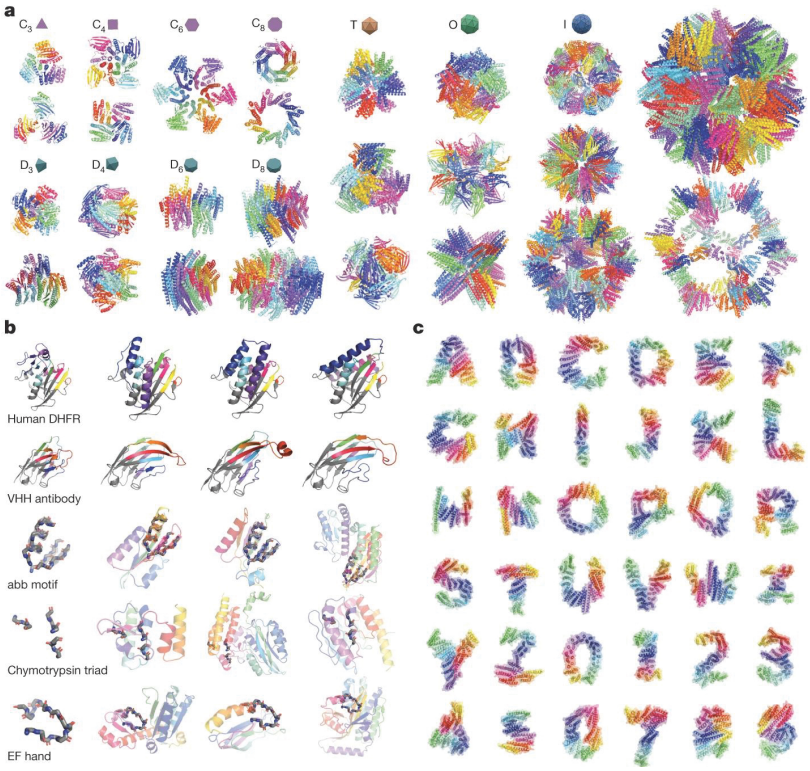
At a high level, our Generate Platform includes (i) generative models that propose new protein sequences; (ii) property predictors that estimate how those designs are likely to behave across a range of assays and (iii) decision and ranking models including models that prioritize designs for experimental testing and help orchestrate the next questions to ask in each generation cycle. The same underlying infrastructure is designed to be generalizable, meaning that it can operate across protein modalities in a consistent way, including protein modalities such as antibodies, multi-specifics, enzymes, hormones, peptides, cell therapies and multi-chain protein assemblies. We have designed protein variants across all of these diverse protein modalities.

Example Generative Model: The Chroma Model

As an illustrative example of our approach, we previously developed and published the Chroma model, a programmable generative model for protein complexes described in *Nature* in November 2023. The Chroma model is a demonstration of our approach to programmable protein generation; our internal model development has advanced substantially beyond this public example. The Chroma model learns statistical regularities in protein structures and sequences from public structural databases and then recombines those principles in novel ways to propose designs.

The Chroma model treats protein design as an inference problem: it learns a probability distribution over realistic protein shapes and sequences, and then samples from that distribution under external constraints specified by the scientist. Those constraints can describe, for example, required structural motifs, symmetry groups, overall shape, membership in a particular fold or functional class, or even text-based descriptions provided by other neural networks. In effect, the model separates what it learns about "how proteins are put together" from what we specify about "what we want this protein to do or look like," as illustrated in the figure below.

Symmetry, substructure and shape conditioning enable geometric molecular programming.

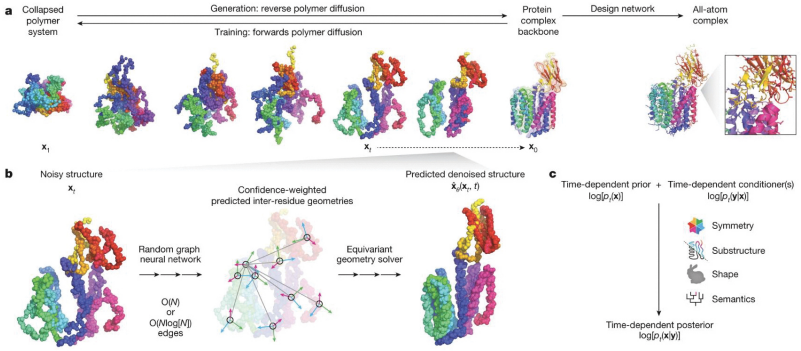


A. Sampling oligomeric structures with arbitrary chain symmetries is possible by using a conditioner that tessellates an asymmetric subunit in the energy function. Cyclic (Cn), dihedral (Dn), tetrahedral (T), octahedral (O) and icosahedral (I) symmetry groups can produce a wide variety of possible homomeric complexes. The right-most protein complex contains 60 subunits and 60,000 total residues, which is enabled by leveraging symmetries and using our subquadratically scaling architecture. **B.** Conditioning on partial substructure (monochrome) enables protein infilling or

outfilling. The top two rows illustrate regeneration (color) of half a protein (the enzyme DHFR, first row) or complementarity-determining region loops of a VHH antibody (second row). The next three rows show conditioning on a predefined motif. The order and matching location of motif segments is not prespecified here. **C.** Conditioning on arbitrary volumetric shapes is exemplified by the complex geometries of the Latin alphabet and Arabic numerals. All structures were selected from protocols with high rates of *in silico* refolding.

The Chroma model incorporated several new machine learning components tailored to molecular systems. It uses a diffusion process over protein backbones that respects the conformational statistics of polymer chains, gradually adding and then removing noise in a way that preserves realistic local geometry. It applies random graph neural networks to reason over many residues at once with computational cost that grows subquadratically in system size, enabling generation of very large proteins and complexes on commodity hardware. Equivariant layers translate predicted pairwise geometries into three dimensional atomic coordinates, and specialized low temperature sampling strategies improve the quality of the final structures drawn from the diffusion process.

The Chroma model is a generative model for proteins and protein complexes that combines structured diffusion for protein backbones with scalable molecular neural networks for backbone synthesis and all-atom design

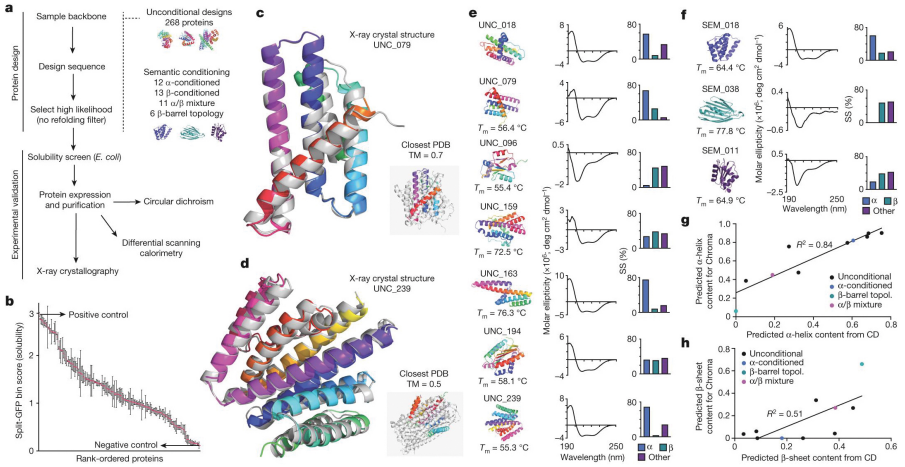


A. A correlated diffusion process with chain and radius-of-gyration constraints gradually transforms protein structures into random collapsed polymers (right to left). The reverse process (left to right) can be expressed in terms of a time-dependent optimal denoiser $\hat{x}_\theta(x_t, t)$ that maps noisy coordinates x_t at time t to predicted denoised coordinates x_0. **B.** We parameterize this in terms of a random graph neural network with long-range connectivity inspired by efficient N-body algorithms (middle) and a fast method for solving for a global consensus structure given predicted inter-residue geometries (right). Another graph-based design network (A, top right) generates protein sequences and side-chain conformations conditionally based on the sampled backbone. **C.** The time-dependent protein prior learnt by the diffusion model can be combined with composable restraints and constraints for the programmable generation of protein systems.

As the Chroma model is a joint model of sequence and structure, a single framework can support multiple tasks. It can sample completely *de novo* proteins with no close natural analogues, generate multichain complexes, redesign or “infill” portions of existing proteins while keeping other regions fixed, and morph between structural configurations. In interactive settings, the Chroma model can be conditioned on symmetry groups, secondary-structure patterns, target shapes (including arbitrary outlines such as letters and numbers) or higher level semantic signals produced by other models, illustrating how high level specifications can be compiled into concrete three dimensional designs.

The Chroma model’s capabilities were tested experimentally at scale. In our published work, we characterized hundreds of designed proteins generated by the model and observed that a substantial fraction expressed, folded and showed favorable biophysical behavior. For selected designs where crystal structures were solved, the experimentally determined backbones closely matched the model’s predictions at near atomic resolution, supporting the view that the Chroma model is capturing meaningful aspects of protein physics rather than memorizing known structures.

Experimental validation of proteins engineered with the Chroma model



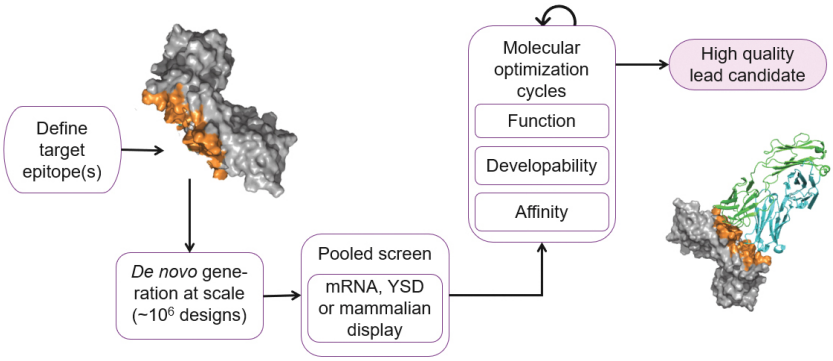
A. Protocol for protein design and experimental validation. Unconditional designs: 268 proteins. Semantic conditioning: 12 α-conditioned, 13 β-conditioned, 11 α/β mixtures and 6 with β-barrel topology. See text for details. **B.** Rank-ordered unconditional Chroma protein solubility scores by the split-GFP assay for 172 tested proteins. Red dots and error bars denote means and standard deviations, respectively, from three biological replicates. c,d, X-ray crystal structures (rainbow) of UNC_079. **C.** 1.1 Å resolution, PDB 8TNM, root-mean-square deviation (RMSD) = 1.1 Å) and UNC_239. **D.** 2.4 Å resolution, PDB 8TNO, RMSD = 1.0 Å) overlaid with Chroma-generated models (grey). Insets compare each crystal structure (rainbow) with its nearest PDB match (4NH2 and 6AFV, respectively; grey). **E.** CD data for seven purified Chroma proteins. The fraction of α-helical and β-strand content was determined using BeStSel50. Tm is the melting temperature determined by differential scanning calorimetry and SS designates secondary structure. **F.** CD data for three purified Chroma conditional designs: SEM_018 (α-conditioned), SEM_038 (β-barrel topology) and SEM_011 (α/β mixture). **G/H.** Correlation between predicted secondary-structure content in Chroma designs compared with the prediction from CD, for α-helical (g) and β-strand (h) content.

We view the Chroma model as a representative example of how we develop and validate our models: combining new architectures and sampling methods, explicit conditioning on design goals and systematic experimental characterization to close the loop between computation and reality — an approach we have continued to build on in subsequent internal model development.

Example Protein Binder Generation

A major objective for the field of protein design has been the ability to design specific *de novo* antibody binders: producing antibodies that bind specified epitopes without starting from existing binders. This capability is central to programmable biology because it enables explicit intent (where to bind and how) to be translated directly into concrete molecular designs. In our approach, we specify an "*in silico* painted" epitope that defines where on the target we want to bind. Our generative models then propose antibody sequences along with their anticipated complex structures engaging the desired epitope, subject to any pre-specified antibody framework constraints and with desired biophysical properties.

Example approach for a *de novo* binder against a single specified epitope

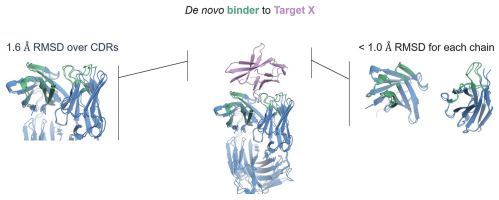


Since our founding, we have focused on developing models that enable the generation of *de novo* binders. We believe that our first successful attempts to generate *de novo* antibody binders to pre-specified, structurally defined epitopes predated published reports of such results by several years. In these early campaigns, we generated specific binders with detectable affinity and measurable function, with no prior knowledge of any antibodies that bound those sites. In this initial work, we often relied on large-scale design sets (on the order of approximately 100,000 designed sequences per campaign) to confidently identify binders and characterize hit rates.

After these initial results, we scaled up to large and systematic studies to understand hit rates and specificities, producing and testing large panels of *de novo* designs across multiple targets and epitopes in the process, with pooled assays and next-generation sequencing used to quantify enrichment for intended targets and to monitor binding to off-targets and control proteins. In so doing, we not only showed the ability to repeatedly generate *de novo* on-target proteins with low levels of non-specific binding and identified regions of design space with favorable hit rates, but we also generated large-scale data that have improved our model performance on *de novo* generation. We have therefore seen substantial advancement in our *de novo* capabilities, having now achieved “plate-scale” *de novo* generation (*i.e.*, ability to identify high-affinity, well-developable binders from a set of approximately 100 tested designs) across modalities, including antibodies and mini-proteins.

We have verified not only affinities, specificities, and other biophysical properties of our *de novo* designs, but we have also validated that they bind the desired epitope and possess the intended structural characteristics, *e.g.*, for one design (shown in the figure below), we confirmed alignment between the design and actual structure within 1.6 angstrom across the paratope. This gave us confidence that our models were able to translate high-level structural constraints into concrete antibody designs.

Structural confirmation of a *de novo* binder with approximately1.6 angstroms RMSD over the CDRs



More recent work has applied these capabilities to targets of direct therapeutic interest. We currently have numerous programs that are capitalizing on these capabilities.

Current Focus: Pushing the Frontier of Protein Generation

We continue to push the frontier of protein generation. This includes our efforts to expand the range of proteins and complexes that our models can perform well on, improve how they capture uncertainty and failure modes and extend conditioning to more complex design goals, such as multi-epitope targeting or finely tuned functional profiles while increasing hit rates across design tasks. While unconditional generation appears to be a more tractable setting, we believe the highest-value frontier is conditioned generation, where increasingly specific constraints can require the model to operate in regions of design space with less prior data and higher uncertainty.

We have built our models and workflows to learn from proprietary functional and structural assay data, and we continue to invest in deepening that integration so that our generative frameworks can operate reliably under richer biological context and more demanding conditioning.

How We Apply Our Models Today

Today, our models are deployed throughout the Generate Platform to support protein design decisions against a defined set of therapeutic targets. In a typical campaign, we begin by specifying a design objective in terms of target binding, molecular function and developability requirements, all either from an existing reference binder or from a *de novo* starting point. Our generative models are then used to propose a large and diverse set of candidate designs that satisfy the scientist's constraints and explore multiple potential solutions to the problem. Property predictors score and rank these designs based on predicted attributes and decision models help select subsets to test within our biohardware solutions.

After multiplexed assays and, where relevant, Cryo-EM or other structural measurements are run, the resulting data are fed back to inform both foundation generative and property models. In subsequent generation cycles, the models increasingly focus on regions of sequence and structure space that appear promising, while still maintaining enough diversity to avoid premature convergence. We use a similar pattern across modalities and targets, adjusting conditioning and objective functions to match the biological question.

We believe this integrated approach – combining a family of protein design algorithms, with experimental feedback supported by agentic systems – allows our Generate Platform to move beyond isolated model runs toward a more systematic, repeatable way of exploring protein design space. As such, each therapeutic pursuit is valuable in and of itself, but importantly it is valuable also in building the stack of information and experience for the Generate Platform in general to enable even better future, broader applications in more reliable ways.

Innovative Biohardware to Build and Measure Proteins at Scale

We believe that realizing intentionality at scale through generative protein design requires scalable verification: both (i) generating data at scale to train and refine our models and (ii) generating data at scale to test model proposals and learn from outcomes in real biological systems. To support this, we built scalable biohardware—integrated physical infrastructure, automation and assay technologies designed to efficiently produce proprietary, therapeutically relevant datasets across sequence, structure, and function. Underlying our data acquisition approach is the belief that data scale improves both model quality and model therapeutic impact. Two technologies that exemplify this are our multiplexed assay systems, which can assay many designs in parallel, and our structural determination technologies, which experimentally elucidate key step between protein sequence and biological action.

Example Multiplexed Data Acquisition: Synergistic Technologies to Maximize the Functional Information from Each Experiment

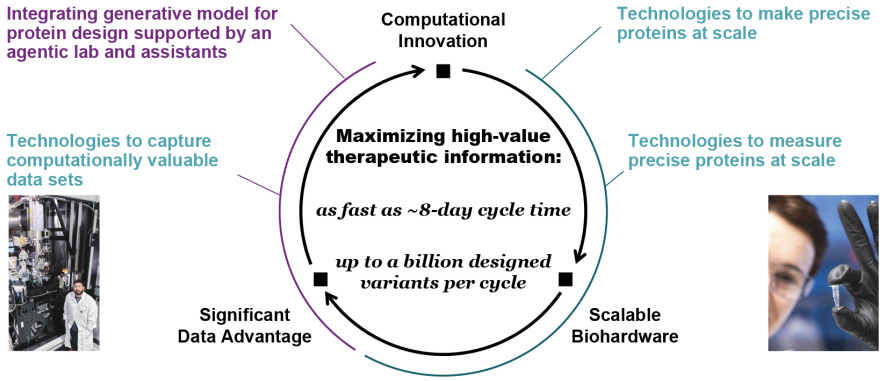
Multiplexed experimentation is focused on testing many designs in parallel in a single system, like a graphics processing unit. Instead of testing one protein at a time, like a central processing unit, we aim to test thousands to millions of related protein designs together, under well-controlled conditions, and to read out their behavior in a way that is compatible with our algorithms. This approach differs from any methods that focus on scaling the number of experiments, such as scaling 96-well plates where every well tests a single design. Rather than primarily scaling the number of discrete experiments (as is often done in precedented industrial approaches), our multiplex systems are designed to increase functional information throughput (*i.e.*, information gained per experiment) and reduce cost per variant, leveraging DNA synthesis, novel pooled cloning, and pooled screening techniques.

We engineer our DNA libraries so that each variant is uniquely barcoded or otherwise traceable, and we design our assays so that each readout can be linked back to a specific variant. As shown in the figure below, examples of multiplexed approaches we use include technologies to:

- assemble DNA to encode therapeutic length proteins
- translate DNA to proteins efficiently including cell free protein expression
- assay proteins at scale including mRNA, Yeast Surface Display ("YSD") or mammalian display

Each of these are performed in a multiplexed fashion vis-à-vis pooled experiments with the data readout de-multiplexed to provide insights on each variant.

Technologies deployed in the Generate Platform



Each of these technologies leverages proprietary DNA assembly and synthesis to create libraries of millions to hundreds of billions of intentionally designed protein sequences at a lower cost, and express them in systems such as cell-free expression systems, and then assay these libraries with high-throughput techniques including next-generation sequencing. As a result, we can implement computational designs as real proteins at an increasingly lower cost per protein. This lowering cost of proposing and verifying protein designs allows us to interrogate large regions of sequence space (either around a single hypothesis/lead protein or explore a multitude of hypotheses in parallel), and increasingly explore more unique areas of a protein to find elusive and productive designs to solve complex molecular challenges.

We believe that this focus on cost per variant, rather than cost per experiment, is a key enabler of our Generate Platform.

Example Structural Data Acquisition: Cryo-EM

Our customized Cryo-EM core is a critical data enabler that allows us to visualize proteins and protein complexes at near-atomic resolution by rapidly freezing them and imaging them with an electron beam. Historically, Cryo-EM has been used primarily as a bespoke, low-throughput tool to solve individual structures of interest, amounting to a relatively small number of structures per year solved primarily within academic settings. We have built our Cryo-EM core with a fundamentally different goal of industrializing and scaling this technique specifically as a data-generation capability.

- We operate four high-end Cryo-EM instruments, along with dedicated sample preparation and data processing infrastructure.
- We have automated large portions of the workflow, from sample grid preparation to image collection and reconstruction, enabling more predictable throughput.

- We design our campaigns to solve structures in batches (plate-scale Cryo-EM), not just single proteins, so that each campaign yields a collection of structures that can be used to train our models.
- We monitor our Cryo-EM core progress in terms of information gain and throughput, using active learning driven by our generative models to suggest the most informative structures to solve next.

This change in mindset—from Cryo-EM as a rare, artisanal measurement to Cryo-EM as a routine, multiplexed input to a learning system—is central to our Generate Platform as it enables us to fill data gaps that are highly valuable in training models but sparsely available in the public domain.

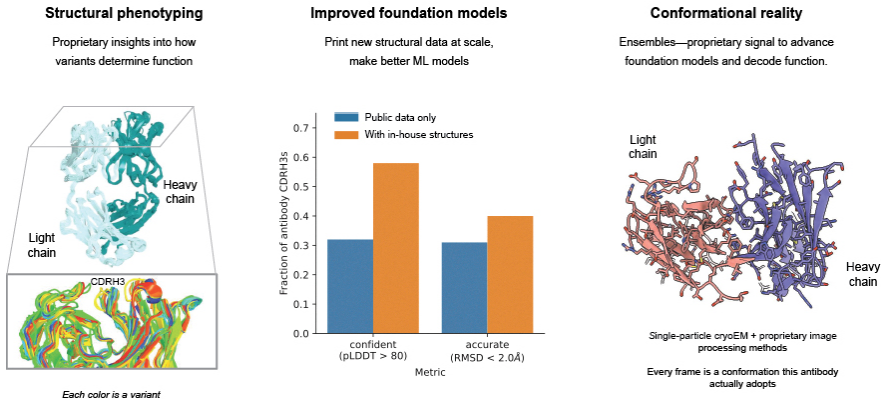
Using Cryo-EM Data as a Learning Signal

High-resolution structural data are particularly valuable for our protein design algorithms. For example, when we know, at atomic or near-atomic resolution, how a binder engages on a target, we can:

- Improve our structure-aware generative models that understand the 3D geometry of binding interfaces (*e.g.*, by including the structure in the training set or via post-training approaches).
- Identify which parts of the protein are most important for binding and which can be modified to improve other properties (*e.g.*, within a therapeutic development program).
- Systematically explore alternative binding modes, epitopes or conformations and measure how each affects function, enabling phenomenological sequence-structure-function models for specific biological scenarios.

We believe these data support both our general protein generation capabilities as well as specific protein design challenges, *e.g.*, a given antibody bound to the TL1A trimer, as well as more complex structural data such as conformational ensembles, which describe the protein structure at the next level of detail relative to the traditional "ground-state" view, which is crucial to understanding biological function. For example, our internally-determined structures have improved our computational model's performance, with as few as 250 in house antibody high-resolution maps measurably improving model confidence and accuracy in determining the structure of the challenging CDRH3 loop of an antibody, as outlined in the figure below.

Improved computational performance based on proprietary data



Our Integrated Approach Towards Therapeutic Impact and Programmable Biology

The capabilities of our Generate Platform are designed to have measurable impact on the underlying unit economics of drug design in two broad domains: reductions in the time and cost for increasingly mature capabilities to deliver high quality answers, and the ability to deploy these capabilities to challenges that were uneconomical to pursue with higher cost and longer time horizon approaches.

Reduced Time and Cost to High Quality Molecular Designs

We have invested in developing biohardware systems that have the potential to reduce cost and time to generate data for each generation cycle. These include:

- **Library creation at scale.** Using our in-house DNA assembly methods, we generated more than 130,000 DNA sequences encoding a computationally-designed antibody library in approximately two weeks, with all six CDRs designable across more than a hundred thousand sequences.
- **Protein production at scale.** Our cell-free protein synthesis systems can translate on the order of millions of proteins from computationally-designed DNA libraries within one to three days, and can express and purify up to roughly 200,000 proteins in a two-day period for more detailed characterization.
- **Functional readouts at scale.** Droplet-based microfluidic screens enabled us to evaluate more than 10,000 enzyme variants in approximately one hour. Additional multiplexed assays allow tens of thousands to millions of variants to be tested in pooled or arrayed formats across binding and functional readouts. A single experiment can yield tens of thousands to millions of labeled data points, substantially reducing the cost per datapoint relative to traditional one-variant-per-well workflows.
- **Structure determination at scale.** In our TL1A program, after having generated hundreds of variants that engage the target in subtly different ways and measured those functionally and biophysically, we used our Cryo-EM core to solve structures of 50 different variants within 72 hours from samples to deposited models, feeding the resulting insights back into models for improved generation in the next round.

Taken together, these capabilities mean that generation cycles of “design–build–test–learn” that historically might have taken months can now potentially be executed in weeks or, for certain questions, days, while generating systematic datasets that both drive programs toward their objectives and improve our models over time.

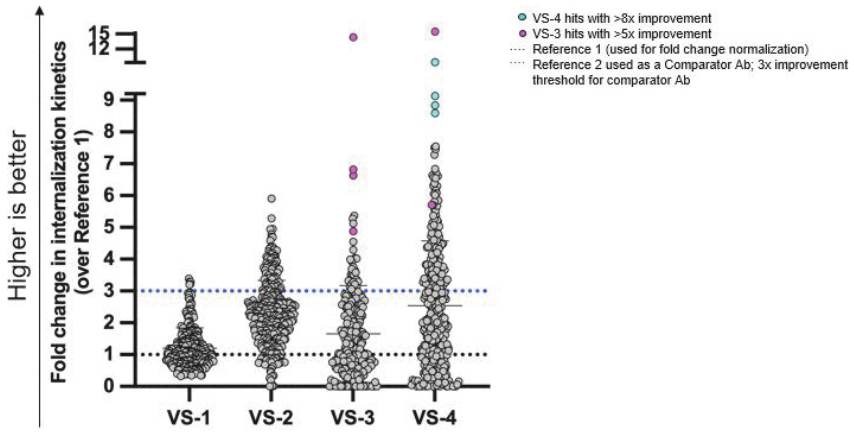
This is exemplified by a design campaign where our goal was to take a signaling protein with naturally binds two receptors and design in selectivity for a single receptor. Leveraging a set of experimental tools, our team improved the generation cycle time from four weeks to eight days.

Quality of the Answer

The reduced cost and time for protein design allows us to explore more speculative areas of opportunity and potentially identify rare and more impactful proteins, which may ultimately enable us to answer questions that were traditionally time and cost prohibitive to address.

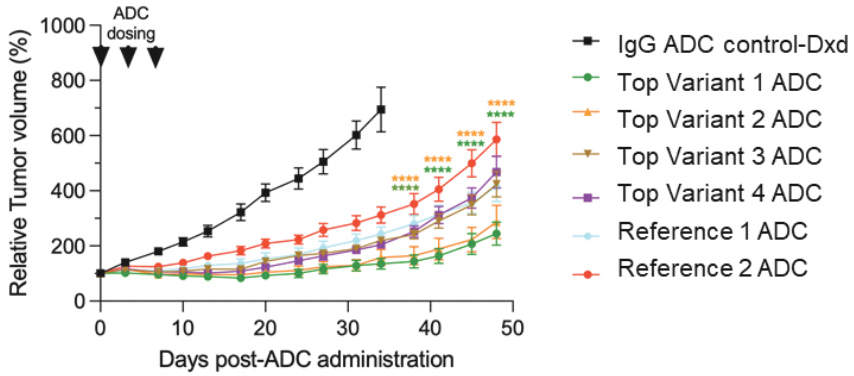
For example, we selected a historically poor-internalizing tumor-associated antigen and evaluated whether we could apply our internalization capability to meaningfully improve intracellular delivery for an ADC by changing the binding sequence alone. We identified an epitope from a clinical-stage antibody as the starting point and conducted four rounds of structure-guided machine-learning optimization to engineer variants with substantially enhanced trafficking. This effort yielded proteins with upwards of 10-fold higher internalization activity *in vitro* while maintaining affinity comparable to the reference antibody, an important feature to support distribution of the ADC throughout tumors. Importantly, these improvements were achieved without relying on pH-dependent binding or other artificial uptake mechanisms.

Internalization assay across generated rounds (IncuCyte Fluorescence)



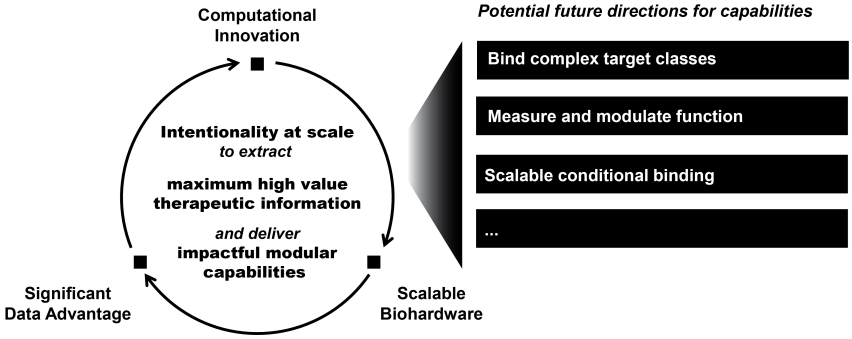
We then tested whether these improvements in internalization would translate into a superior *in vivo* profile. Reference ADCs built on the original binders produced only transient tumor-growth delay in xenograft models, underscoring the need for enhanced intracellular delivery. To test whether our optimized internalizing antibodies could overcome this limitation, we conducted an *in vivo* evaluation in a solid tumor xenograft model using both reference antibodies and top Generate Platform-derived variants, each conjugated to the same Dxd-like payload to control for linker-payload effects. Both of our top variants outperformed the conjugated references, exhibiting deeper and more durable tumor growth inhibition.

Clinical activity of generated top variants in solid tumor xenograft model



We are continuing to invest in developing our technologies, across both our algorithms and our biohardware, to reinforce and extend our Generate Platform's capabilities. We will continue directing these efforts toward building capabilities with broad and deep applicability across a variety of hard-to-solve molecular and biological challenges.

Future Generate Platform and Application Directions



Our current focus is on refining and expanding our more complex binding modular capabilities (including conditional and selective binding) and advancing biological functional design for targeted cell-surface receptor families. We intend to translate these modular capabilities into therapeutic programs, applying them, along with many of our existing modular capabilities, to create differentiated molecular profiles and potentially highly differentiated clinical profiles.

Manufacturing and CMC Strategy

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. All of our preclinical and clinical drug supply development, manufacturing, storage, distribution and testing are outsourced to third-party manufacturers and facilities. Our manufacturing strategy enables us to more efficiently direct financial resources to the research, development and commercialization of programs rather than diverting resources to internally develop and maintain manufacturing facilities. As our programs advance through development, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure our supply needs.

We have developed, or expect to develop, high yield, industry standard drug manufacturing processes suitable for preclinical, clinical and commercial scale manufacturing of our product candidates with our third-party manufacturers. While any reduction or halt in the supply of raw materials, drug substance or drug product could limit our ability to develop our programs until a replacement supplier or contract manufacturer is found and qualified, we believe that we have or will be able to manufacture sufficient clinical supply of GB-0895 and our other product candidates, as well as future pipeline product candidates, to support our planned clinical trials, and have access to sufficient manufacturing capacity to support our planned clinical development pipeline.

Commercialization

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We plan to independently commercialize our products, if approved, in the U.S. and other regions where we determine it makes commercial sense to do so. At the appropriate time, we will recruit a sales force and a medical affairs team and take other steps to establish the necessary commercial infrastructure. However, as product candidates advance through our pipeline, our plans may change.

Competition

The biopharmaceutical industry is characterized by rapid advancing technologies, intense competition, and a strong emphasis on proprietary and novel products and product candidates. We have invested significant capital, time and technical expertise to create a highly differentiated platform, the Generate Platform, that enables us to generate and experimentally validate therapeutic designs with intent and at scale, and to translate validated capabilities into product candidates, ultimately delivering scalable therapeutic impact. Our ability to remain competitive will depend in part on our ability to continue to improve the Generate Platform and to demonstrate success in our drug design and development efforts, including with respect to GB-0895, GB-4362 and GB-5267.

Our competitors have developed, are developing or may develop product candidates and products competitive with GB-0895, GB-4362, GB-5267 and our other programs and product candidates. GB-0895, GB-4362, GB-5267 and any future product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our competitors include larger and better-funded pharmaceutical biotechnological and therapeutics companies. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Moreover, we may also compete with universities, governmental agencies and other public and private research institutions that may be active in research in our target indications and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites and enrolling subjects for clinical trials and in identifying and in-licensing intellectual property related to new product candidates, as well as entering into partnerships, collaborations and license arrangements.

Specifically, there are several companies developing or marketing treatments that may be approved for the same indications and/or use the same mechanism as GB-0895. Over time, I&I markets have developed with a generally increasing number of competitors, improved efficacy and improved dosing intervals (*i.e.*, less frequent dosing). Existing therapeutics for asthma include controller medications, reliever medications and more recently, biologics from Genentech, Inc. and Novartis (Xolair; anti-IgE), Sanofi S.A. ("Sanofi") and Regeneron Pharmaceuticals, Inc. ("Regeneron") (Dupixent; anti IL-4 x IL-13 bispecific), GSK plc ("GSK") (Nucala; anti-IL-5 mAb and depemokimab; anti-IL-5 mAb), AstraZeneca (Fasenra; anti-IL-5Rα mAb), Teva Pharmaceutical Industries Limited ("Teva") (Cinqair; anti IL-5), and Amgen and AstraZeneca (tezepelumab). Of these approved biologics, only one drug targeting the TSLP pathway, tezepelumab, has been approved for the treatment of severe asthma and is the only severe asthma biologic without phenotype or biomarker limitations in its label. However, we believe there is a significant unmet need for biologic solutions that drive higher adherence through improved dosing regimens.

We are aware of multiple long-acting, anti-TSLP product candidates in clinical development for severe asthma. GSK5784283 is a long-acting TSLP candidate currently being evaluated in a Phase 2 trial by GSK and Aiolos Bio. verekitug is a mAb that binds to the TSLP receptor, instead of the ligand like tezepelumab, and is currently being evaluated in a Phase 2 trial by Upstream Bio, Inc. ("Upstream Bio"). APG333 is an extended half-life mAb targeting TSLP that is currently being evaluated in a Phase 1 trial by Apogee Therapeutics, Inc. ("Apogee"). AstraZeneca and Amgen are also developing an inhaled TSLP formulation that is currently in Phase 2 trials.

There are multiple private companies also developing product candidates that may compete with GB-0895 in the future. Solrikitug is a mAb targeting TSLP being developed by Uniquity Bio ("Uniquity"), while WIN378 is a long-acting TSLP being developed by Windward Bio ("Windward"), which is in-licensed from Kelun Biotech and Harbour BioMed. We also expect potential competition from assets currently being developed in China such as Aclaris Therapeutics and Biosion's BSI-045B, and KeyMed's CM326 and Staidson Biopharmaceuticals' STSA-1201.

In addition to monotherapy approaches, we are aware of multiple product candidates evaluating TSLP in combination with other targeted therapies including Sanofi's lunsekimig (anti IL-13 x TSLP bispecific), Pfizer's tilrekimig (anti IL-13 x TSLP x IL-4 trispecific), Teva and Biolojic Design's BD9 (anti IL-13 x TSLP bispecific), Roche Holding AG's QX031N (anti IL-33 x TSLP bispecific), Innovent's IBI-3002 (anti-IL-4Rα x TSLP bispecific) and Belenos Biosciences Inc. and Keymed Biosciences Inc.'s BEL512 (anti IL-13 x TSLP bispecific). We also may seek to evaluate GB-0895 in combination with other targeted therapies such as IL-13 and OX40 ligand in the future.

There are several approved products for COPD including inhaled corticosteroids and bronchodilator inhalers. However, there are only two biologics, Dupixent and Nucala, that have been approved for the treatment of COPD and each has only gained approval in the last two years. We are aware of anti-TSLP product candidates in clinical development for COPD, most prominently tezepelumab, which is currently being evaluated in a Phase 3 trial by both Amgen and AstraZeneca. Earlier-stage product candidates include APG333 being evaluated in a Phase 1 trial by Apogee, verekitug being evaluated in a Phase 2b trial by Upstream Bio, and solrikitug being evaluated in a Phase 2 trial by Uniquity. In addition, there is a broad landscape of targeted biologic approaches currently in development for COPD.

We are unaware of any competing clinical product candidates to GB-4362 that are targeting free MMAE as an adjunctive therapy to ADCs armed with an MMAE payload. There are early-stage clinical candidates and products in development using the MUC16 target in solid tumors, leveraging a variety of modalities. Of those, we believe Regeneron has MUC16-targeted bispecific T-cell engagers and a CAR-T product candidate. We believe there are other competitors that are in preclinical to early clinical phases of development.

If our product candidates do not offer advantages over available products, we may not be able to successfully compete against current and future competitors. The key factors affecting the success of our products, if approved, are likely to be their potential efficacy, safety, convenience and availability of reimbursement.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third-parties. We may also rely on trademarks, copyrights and trade secrets relating to our proprietary technologies and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary and intellectual property position. We additionally may rely on regulatory and other protections afforded through data exclusivity, market exclusivity and patent term extensions, where available.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions, trade secrets, and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and know-how, and operate without infringing valid and enforceable intellectual property rights of others. A discussion of risks relating to intellectual property is provided under the section titled "*Risk Factors—Risks Related to Our Intellectual Property*."

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third-parties.

As of January 30, 2026, Generate owned 27 active patent families and has exclusively in-licensed 19 active patent families from Flagship Pioneering Innovations VI, LLC ("Flagship"), an affiliate of Flagship Pioneering. These patent families relate to various aspects of our Generate Platform and molecules that we have developed using our Generate Platform.

With respect to our GB-0895 program, we have exclusively in-licensed from Flagship four patent families directed to antibodies that target TSLP and associated compositions and methods. The first patent family is directed to compositions of matter and methods of treatment, including treatment of severe asthma and COPD with GB-0895. As of January 30, 2026, the first family included one granted U.S. patent and patent applications currently pending in the United States, Australia, Canada, China, the European Patent Office, Israel, Japan, Hong Kong, Republic of Korea, Singapore, and Taiwan. These patents and pending applications, if issued, would be expected to expire in 2043, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The second patent family is directed to GB-0895 dosing regimens and, as of January 30, 2026, included one pending international ("PCT") application. Should any patents issue in this family, they would be expected to expire in 2045, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The third patent family is directed to compositions comprising antibodies targeting TSLP and IL-13 (including GB-0895 and GB-7624, respectively) and associated compositions and methods. As of January 30, 2026, this third family included two pending U.S. provisional applications, and should any patents issue from applications claiming priority to these provisional patent applications, they would be expected to expire in 2046, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The fourth patent family is directed to bispecific antibodies targeting TSLP and IL-13 (including bispecific antibodies with arms comprising sequences corresponding to those of GB-0895 and GB-7624, respectively) and associated methods. As of January 30, 2026, this fourth family included two pending U.S. provisional applications, and should any patents issue from applications claiming priority to these provisional patent applications, they would be expected to expire in 2046, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

With respect to our GB-7624 program, in addition to the TSLP and IL-13 combination and bispecific patent families in-licensed from Flagship that are described above, we own two patent families directed to antibodies that target IL-13 and associated compositions and methods. The first patent family is directed to compositions of matter and methods of treatment with IL-13 antibodies, including GB-7624. As of January 30, 2026, the first family included two pending PCT applications and patent applications currently pending in the United States and Taiwan. Should any patents issue from the patent applications in this family, they would be expected to expire in 2045, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The second patent family is directed to GB-7624 dosing regimens and, as of January 30, 2026, included four pending U.S. provisional applications. Should any patents issue from applications claiming priority to these provisional patent applications, they would be expected to expire in 2046, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

With respect to our GB-4362 program, we own two patent families directed to antibodies that target free MMAE and associated compositions and methods. The first patent family is directed to compositions of matter and methods of treatment with antibodies that target free MMAE, including GB-4362. As of January 30, 2026, this family includes one pending PCT application and one application currently pending in the United States. Should any patents issued from the patent applications in this family, they would be expected to expire in 2045, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The second family is directed to GB-4362 dosing regimens, and as of January 30, 2026, included two pending provisional applications. Should any patents issue from applications claiming priority to these provisional patent application, they would be expected to expire in 2046, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

With respect to our GB-5267 program, we own one patent family directed to antibodies that target MUC-16 and associated compositions and methods, including CAR-T compositions. As of January 30, 2026, this family included three pending U.S. provisional applications. Should any patents issue from applications claiming priority to these provisional patent applications in this family, they would be expected to expire in 2046, excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

We have a broad intellectual property estate directed to key aspects of our Generate Platform that is intended to provide multiple layers of protection. As of January 30, 2026, we owned four patent families and have exclusively in-licensed seven patent families from Flagship directed to various aspects of our machine learning platform, including programmable, AI-supported drug design and optimization using our proprietary generative algorithms. These families encompassed one issued U.S. patent; six patents issued in China, India, Israel and Japan; 10 non-provisional patent applications pending in the U.S.; two provisional patent applications pending in the U.S.; 29 patent applications pending in Canada, China, European Patent Office, Hong Kong, India, Israel, Japan and Republic of Korea; and three pending PCT applications. These patents and patent applications, if issued, are expected to expire between 2040 and 2044, in each case excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. In addition, as of January 30, 2026, we owned one pending U.S. application, one pending application in the European Patent Office, four pending PCT applications and one pending U.S. provisional application directed to technology related to our wet lab platform, including proprietary compositions, devices, assays and other methods which facilitate and support our high-throughput experimentation capabilities. Should any patents issue from patent applications claiming priority to these PCT applications they would be expected to expire between 2044 and 2046, in each case excluding any patent term adjustments or extensions that may be available and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended, and a given patent may only be extended once. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third-parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates or products, the methods of use or manufacture of those product candidates or products. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block potential competitors from practicing the claimed inventions of the issued patents.

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third-parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology. Our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or products that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our proprietary technology, product candidates or products. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

In addition to patent protection, we also rely on know-how and trade secret protection for our proprietary information to develop and maintain our proprietary position. However, trade secrets and know-how can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors and potential collaborators, third-parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our know-how, trade secrets, and other proprietary information.

In addition, we plan to rely on regulatory protection based on data exclusivities and market exclusivities. See "*Business—Government Regulation*" for additional information.

Further, we have and will continue to pursue trademark protection for our company name and brand. As of January 30, 2026, we owned three registered trademarks in the United States; six pending trademark applications in the United States; 39 registered trademarks in foreign jurisdictions including Argentina, Australia, Canada, China, European Union, Hong Kong, Japan, Mexico, Norway, Singapore, Switzerland and the United Kingdom; and 9 pending trademark applications in foreign jurisdictions including Australia, Brazil, Canada, India, and Israel.

License, Collaboration and Other Agreements

Collaboration and License Agreement with Amgen

On December 24, 2021, we entered into a Collaboration and License Agreement, as amended by the First Amendment, dated October 5, 2022, and the Second Amendment, dated December 12, 2023 (as amended from time to time, the "Amgen Collaboration Agreement"), with Amgen to identify biologic proteins and antibodies directed against specified targets. The collaboration initially covered five collaboration targets. Under the Amgen Collaboration Agreement, each of the collaboration programs is to be conducted under research plans with defined research terms. In addition, Amgen has the option to nominate up to five additional collaboration targets, at additional cost, the first of which was exercised in December 2023 related to the sixth target.

Under the Amgen Collaboration Agreement, each party is allocated certain research activities set forth in the research plans for the programs; however, we have primary responsibility. We must use commercially reasonable efforts to conduct research activities assigned to us under the applicable research plan. Amgen is also responsible for conducting the research assigned to it under the applicable research plans for the collaboration programs. Each party will conduct any research program activities allocated to it under the research plans at its own cost, except for certain additional research activities requested by Amgen for which Amgen will reimburse us. Amgen granted to us a non-exclusive license under certain Amgen intellectual property relating to or arising from the collaboration programs to conduct our research activities and other obligations under the Amgen Collaboration Agreement, along with a limited right to conduct certain research and development activities for our Generate Platform, and we granted to Amgen a non-exclusive, fully paid-up, royalty-free, non-sublicensable research license under certain of our intellectual property relating to or arising from the collaboration to conduct its research activities and perform its obligations under the Amgen Collaboration Agreement, on a target-by-target basis. We further granted Amgen an exclusive, worldwide, royalty-bearing, sublicensable license under certain of intellectual property relating to or arising from the collaboration to research, develop, manufacture, commercialize and otherwise exploit collaboration proteins and licensed products, on a target-by-target basis. After lead candidate selection for a collaboration target, Amgen has the sole right and responsibility to develop, manufacture and commercialize licensed products, including the obligation to use commercially reasonable efforts to develop, seek marketing approval for, and commercialize at least one licensed product per collaboration target.

On a collaboration target-by-collaboration target basis, during specified exclusivity periods and provided that Amgen is using commercially reasonable efforts to develop and commercialize a collaboration protein or licensed product for such collaboration target, we agreed not to research, develop, manufacture, commercialize or otherwise exploit competing products with certain specified criteria against the collaboration targets, or enable any third-party to do so, subject to specified exceptions. We have also granted Amgen a right of first negotiation in the event we seek to license rights to research, develop, manufacture or commercialize products comprising antibodies or biological proteins directed to a certain collaboration program target to third-parties.

As consideration for the collaboration, we received a $50.0 million upfront payment from Amgen. Additionally, the Amgen Collaboration Agreement contemplated an investment by Amgen of $25.0 million in equity, at the offering price, if we consummated certain future equity offerings. Amgen purchased 2,109,704 shares of our Series C preferred stock for $25.0 million on May 9, 2023. In connection with the Second Amendment, which added an additional collaboration target, we received an additional payment of $5.0 million. We are eligible to receive up to $370.0 million for each program upon the achievement of certain performance-based milestones, including $160.0 million in development and regulatory milestones and $210.0 million in commercial milestones per program. To date, we have received $5.0 million in milestone payments. No other milestones have been achieved to date. Amgen is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit up to a low tens percentage on worldwide net sales of any licensed product, subject to customary reductions and offsets. The royalty term will commence on the first commercial sale of a licensed product in a country until the latest of: (a) the tenth anniversary of the date of such first commercial sale of such licensed product in such country; (b) expiration of the last to expire valid claim within the relevant licensed or jointly-owned patents covering such licensed product in such country; (c) expiration of the last-to-expire valid claim within certain specified Amgen patent rights; and (d) expiration of regulatory exclusivity period for such licensed product in such country.

Unless earlier terminated, the Amgen Collaboration Agreement will continue on a licensed product-by-licensed product and country-by-country basis until all payment obligations expire. Upon expiry of the royalty term for a licensed product in a country, Amgen's license becomes fully paid-up for that product in that country. Amgen may terminate the Amgen Collaboration Agreement for convenience upon 30 days' prior written notice, in whole or per target. Each party has customary termination rights under the Amgen Collaboration Agreement, including for the other party's uncured material breach subject to specified cure periods or insolvency. We may also terminate the Amgen Collaboration Agreement in the event that Amgen directly or indirectly challenges in a legal or administrative proceeding the enforceability or validity of our licensed patents, subject to certain exceptions.

Collaboration and License Agreement with Novartis

On September 19, 2024, we entered into a Collaboration and License Agreement (the "Novartis Collaboration Agreement"), with Novartis, to discover, develop, manufacture and commercialize protein therapeutics using our Generate Platform The collaboration covers multiple collaboration targets, conducted under applicable research plans during defined research terms.

Under the Novartis Collaboration Agreement, each party is allocated certain research activities set forth in the research plans for the programs; however, we have primary responsibility. We must use commercially reasonable efforts in conducting the research activities assigned to us under the applicable research plan. Novartis is also responsible for conducting any research activities assigned to it under the applicable research plan. Each party will conduct any research program activities allocated to it under the research plans at its own cost. Novartis granted to us: (i) a non-exclusive research license under certain Novartis intellectual property solely to the extent necessary to conduct our research activities under the research plans and (ii) a non-exclusive, worldwide, fully paid-up and royalty free, perpetual, irrevocable, sublicensable license under certain Novartis know-how utilized or generated in the performance of a research plan and incorporated into our Generate Platform solely to develop, train, validate, test, improve, use and exploit the Generate Platform. We granted to Novartis: (i) a non-exclusive research license under certain of our intellectual property relating to or arising from the research programs to conduct its research activities; (ii) on a licensed program-by-licensed program basis, (a) an exclusive, worldwide, royalty-bearing, sublicensable license under our interest in certain jointly owned collaboration intellectual property and (b) a non-exclusive, sublicensable license under certain of our intellectual property relating to or arising from the licensed programs, in each case ((a)-(b)) to research, develop, manufacture, commercialize and otherwise exploit licensed compounds and licensed products directed against the collaboration target for such licensed program; and (iii) a non-exclusive, worldwide, fully paid-up and royalty free, perpetual, irrevocable, sublicensable (through multiple tiers) license under our solely owned collaboration intellectual property to practice Novartis's background intellectual property or any improvement, derivation, enhancement or other modification thereof. During specified exclusivity periods for each collaboration target, we will not research, develop, manufacture, commercialize or otherwise exploit certain products that compete against the collaboration targets, or enable any third-party to do so, subject to specified exceptions.

Following the research term for a licensed program, Novartis may elect to designate a licensed compound in such licensed program as candidate for further development, and Novartis will have the sole right and responsibility to develop, manufacture and commercialize licensed compounds and licensed products under such licensed program. For each licensed program, Novartis is obligated to use commercially reasonable efforts to develop and seek regulatory approval for at least one licensed product under such licensed program in the United States and at least three of five specified major European markets once a development candidate is declared.

As consideration for the collaboration, we received from Novartis a $50.0 million upfront payment. Novartis also purchased 1,265,822 shares of our Series C preferred stock for $15.0 million. We are eligible to receive up to $1.0 billion across all programs upon the achievement of certain performance-based milestones, including $130.0 million in development and regulatory milestones and $210.0 million in commercial milestones per research program. None of such milestones have been achieved to date. Novartis is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit to a low tens percentage on worldwide net sales of any licensed product, subject to specified reductions and offsets. The royalty term will commence on the first commercial sale of a licensed product in a country until the latest of: (a) the tenth anniversary of the date of such first commercial sale of such licensed product in such country; (b) expiration of the last to expire valid claim of within certain jointly and Novartis owned patent rights covering such licensed product in such country; and (c) the expiration of the last regulatory exclusivity period for such licensed product in such country.

Unless earlier terminated, the Novartis Collaboration Agreement will continue on a licensed product-by-licensed product and country-by-country basis until expiry of the royalty term for all licensed products worldwide. Upon expiry of the royalty term for a licensed product in a country, Novartis's license becomes fully paid-up and sublicensable for that licensed product in that country. Novartis may terminate the Novartis Collaboration Agreement for convenience upon 90 days' prior written notice in whole, per program or per country. Each party may terminate the Novartis Collaboration Agreement for the other party's uncured material breach, subject to specified notice and cure periods, or insolvency. We may terminate a licensed program after a development candidate declaration if Novartis ceases all bona fide research and development and commercialization for 12 consecutive months, subject to certain exceptions and cure periods.

License Agreement with Flagship

On August 30, 2021, we entered into an agreement (the "Flagship Agreement"), with Flagship, pursuant to which we (i) irrevocably and unconditionally assigned to Flagship all of our right, title and interest in and to certain foundational patent rights conceived prior to our launch, which is defined as the closing of our Series B financing, and our improvements to such patent rights that cannot be practiced without infringing the foregoing patent rights (such patent rights and improvements, the "Foundational IP"), and (ii) obtained an exclusive, worldwide, royalty-bearing, sublicensable, transferable license from Flagship under such Foundational IP to develop, manufacture and commercialize any product or process or component thereof in the licensed field of human therapeutics and vaccines that would, absent the license granted to us by Flagship, infringe at least one valid claim of the Foundational IP. Flagship retained a non-exclusive, worldwide, royalty-free, fully paid, sublicensable license to practice the Foundational IP within the licensed field (i) for non-commercial research and development purposes and (ii) to perform its duties under that certain managerial agreement between us and Flagship Pioneering, dated August 20, 2018 (the "Flagship Managerial Agreement"). In addition, Flagship irrevocably and unconditionally assigned to us all of its right, title and interest in and to any and all patent rights claiming any inventions conceived (i) solely by Flagship Management, or jointly by Flagship Pioneering and us, (ii) after our launch, and (iii) as a result of activities conducted pursuant to the Flagship Managerial Agreement, or other participation of Flagship Pioneering in our affairs, but excluding, in each case, patents that constitute Foundational IP. We utilize the rights granted to us by Flagship Pioneering under the Flagship Agreement in connection with certain aspects of the Generate Platform and GB-0895.

Pursuant to the Flagship Agreement, we are obligated to use commercially reasonable efforts to diligently exploit licensed products in the licensed field and maintain such efforts at all times during the term of the Flagship Agreement. To satisfy our diligence requirements, we are required to spend at least $1.0 million each year on development and commercialization activities with respect to licensed products during the term of the Flagship Agreement and at least $10.0 million on such activities within the first five years of the term, or August 30, 2026, which may include internal or external research and development costs. The research and development costs are expensed as incurred. Our only financial obligation to Flagship is to pay Flagship on a licensed product-by-licensed product and jurisdiction-by-jurisdiction basis, royalties equal to a low single-digit percentage on net sales of licensed products by us or our subsidiaries or sublicensees. The royalty term will commence on the first commercial sale of such licensed product in such jurisdiction until the expiration of the last valid claim of any Foundational IP covering such licensed product in such jurisdiction. To date, there have been no amounts paid or received by us under the Flagship Agreement.

Unless terminated earlier, the Flagship Agreement will expire on a licensed product-by-licensed product and jurisdiction-by-jurisdiction basis upon the expiration of the last-to-expire royalty term for such licensed product in such jurisdiction. Upon expiration of the royalty term with respect to a licensed product in any jurisdiction and payment in full of all amounts owed by us under the Flagship Agreement for such licensed product in such jurisdiction, the license granted to us will automatically convert into a non-exclusive, fully paid up license for such licensed product in such jurisdiction. We have the right to terminate the Flagship Agreement in its entirety for convenience upon 60 days' prior written notice to Flagship. Either party may terminate the Flagship Agreement upon a material breach by the other party that is not cured within 30 days after receiving written notice of such breach. Flagship may terminate the Flagship Agreement (i) upon 30 days' written notice if we cease to carry on our business with respect to the rights granted in the Flagship Agreement, (ii) upon written notice if we experience an event of bankruptcy or insolvency, or (iii) immediately upon written notice if we or our subsidiaries or sublicensees (provided that we do not timely terminate such sublicensee) challenge the validity, patentability, or enforceability of any Foundational IP or participate in any such challenge, subject to certain exceptions. The royalty term will commence on the first commercial sale of such licensed product in such jurisdiction (provided that we do not timely terminate such sublicensee) challenge the validity, patentability, or enforceability of any Foundational IP or participate in any such challenge, subject to certain exceptions. Flagship may also terminate the license granted to us under the Flagship Agreement with respect to the exploitation of licensed products in a specific sub-field within the licensed field if Flagship determines in its reasonable discretion that we have not used commercially reasonable efforts to develop or commercialize licensed products in such sub-field, subject to our right to retain the license if Flagship approves, and we carry out to Flagship's satisfaction, a written plan for development and commercialization of a licensed product within such sub-field.

Agreements with PMCo and PM LLC

On June 22, 2023, we entered into a collaboration agreement (the "Prior PMCo Agreement"), with PMCo, an affiliate of Flagship Pioneering and a wholly owned subsidiary of PM LLC, pursuant to which the parties agreed to collaborate on research and development activities with respect to the licensed products containing certain antibodies against TSLP and/or IL-4Rα and share research and development costs, with us bearing 65% and PMCo bearing 35% of all fully-burdened research costs and development expenses, which percentage commitments are subject to adjustment. In addition, concurrently with the Prior PMCo Agreement, we and PM LLC entered into a Drag-Along Agreement pursuant to which PM LLC agreed to, among other things, vote in favor of certain transactions with respect to PMCo.

On February 4, 2026, we entered into a stock purchase agreement (the "Stock Purchase Agreement") with PM LLC, pursuant to which we have agreed to purchase, and PM LLC has agreed to sell, all of the issued and outstanding equity interests in PMCo. In consideration for such sale, PMCo, PM LLC and we have agreed to terminate the Prior PMCo Agreement and the Drag-Along Agreement, and we have agreed to pay PM LLC a portion of our net sales, if any, arising from the sale of certain products covered by certain patents or containing certain know-how ("Generate Products") developed under the Prior PMCo Agreement. The closing of the Stock Purchase Agreement is scheduled to occur concurrently with the execution of the underwriting agreement for this offering.

From the closing of the Stock Purchase Agreement and for so long as we, our affiliates, or our sublicensees are developing or commercializing at least one Generate Product in at least one country, we agreed to use commercially reasonable efforts to develop and obtain regulatory approval for Generate Products in each of France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States (the "Major Markets"), and following receipt of regulatory approval in a country, to commercialize the applicable Generate Product in such country. If, prior to the 15th year anniversary of our receipt of regulatory approval for a Generate Product in the first Major Market, we discontinue development or commercialization of a Generate Product in a Major Market for a certain period, then such discontinuation would be a material breach of our diligence obligations in such Major Market. If we are in breach of our diligence obligations with respect to a Generate Product in a country, then PM LLC would have the right to acquire from us, at fair market value, the right to continue developing and commercializing such Generate Product in such country, and will no longer be obligated to make net sales payments as described below.

From the closing of the Stock Purchase Agreement until the fifth anniversary of our receipt of regulatory approval for a Generate Product in the first Major Market, subject to certain exceptions, we agree not to, directly or indirectly, develop or commercialize any product containing an antibody that binds to (i) only TSLP, (ii) only IL-4Rα, or (iii) both TSLP and IL-4Rα, but in each case no other protein. If we are acquired by a third party, the foregoing restriction will not apply to the existing or future arising products of our acquirer, so long as certain of our intellectual property and confidential information is not used in connection with the acquirer developing, manufacturing, commercializing or otherwise exploiting such products.

We will generally be obligated to make payments equal to a high-single digit percentage of net sales of Generate Products, including any Generate Product that contains GB-0895. However, if a Generate Product (i) does not contain GB-0895, (ii) binds to at least one of TSLP or IL-4Rα, and (iii) binds to other proteins in addition to TSLP or IL-4Rα, then the sales payment is reduced based on the composition of the product. On a country-by-country basis, our obligation to make such payments will continue so long as we sell such product in such country. Further, if we exclusively license our rights to exploit a Generate Product in one or more countries to a third party, and the royalties on net sales of such Generate Product to be paid by such third party are subject to certain specified reductions, then we may be allowed to further proportionally reduce the sales payment due to PM LLC, depending on the relative value of the future royalties due to us from such third party as compared to the total deal consideration.

Both PM LLC and we have the ability to trigger a buy-out of all future net sales payments under the Stock Purchase Agreement in certain instances, which would require us to make a single payment to PM LLC that is equivalent to the fair market value of the projected future net sales payments due to PM LLC based upon the projected future net sales of the applicable and then-existing Generate Products (the "Buy-Out Amount"). Both PM LLC and we have this right following our entering into an exclusive license to our rights to exploit a Generate Product in one or more countries with a third party (or transaction approximating an exclusive license). In addition, in the event we are acquired by a qualified acquirer, we have the right to trigger a buy-out of all future sales payments under the Stock Purchase Agreement in exchange for the Buy-Out Amount. Following payment of the Buy-Out Amount with respect to a Generate Product in a country, our diligence obligations and our obligations to make net sales payments with respect to the applicable Generate Products in the applicable countries shall immediately terminate, as do our exclusivity restrictions with respect to the protein targeted by such Generate Products in such countries.

The Stock Purchase Agreement may not be terminated.

Agreements with Lonza

On July 19, 2022, we entered into a Development and Manufacturing Services Agreement (the "DMSA") with Lonza Sales AG ("Lonza Sales") and Lonza AG (together with Lonza Sales, the "Lonza Entities") for the development and manufacture of biologic products. Under the DMSA, we will execute project plans authorizing Lonza Entities to provide development and manufacturing services with respect to certain of our products, and will pay for the services provided and batches delivered in accordance with the DMSA and project plan. Unless earlier terminated, the DMSA will expire when all development and manufacturing services are completed. Each party has customary termination rights under the DMSA, including for scientific or technical infeasibility, the other party's uncured material breach subject to specific cure period or insolvency.

Effective as of July 1, 2023, we also entered into a license agreement (the "Lonza Agreement") with Lonza Sales for a worldwide non-exclusive license under Lonza Sales' gene expression system and certain patent rights of or granted to Lonza and know-how to manufacture and commercialize certain products. We utilize the rights granted to us by Lonza Sales under the Lonza Agreement in connection with GB-0895. As consideration for the license agreement, we agreed to pay (i) up to 1,000,000 Swiss Francs and a low single-digit royalty of net sales if Lonza Sales manufactures the product or (ii) an annual payment in Swiss Francs in the mid-six-digits per sublicense and a low single-digit royalty of net sales if a third party manufactures the product. Royalty payments expire on a country-by-country basis until the later of: (i) the last valid claim in the sales or manufacture country and (ii) ten years from the first commercial sale in such country. The license agreement will continue in full force and effect in each country unless earlier terminated. Each party has customary termination rights under the license agreement, including for the other party's unremedied material breach subject to specific cure period or insolvency. We have the right to terminate the agreement with prior written notice.

Government Regulation

Regulation of Biological Products in the United States

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA"), and their implementing regulations. Biological products are also subject to other federal, state and local statutes and regulations. An applicant seeking approval to market and distribute a new biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies, with certain studies performed in accordance with the FDA's Good Laboratory Practices ("GLP") regulations, as applicable;
- manufacturing of the product candidate that the sponsor intends to use in human clinical trials along with required analytical and stability testing;

- submission to the FDA of an Investigational New Drug application ("IND") for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") representing each clinical trial site before a clinical trial may be initiated at each site;
- performance of adequate and well-controlled human clinical trials in accordance with current Good Clinical Practices ("GCP") and any additional nonclinical studies required to establish the safety and effectiveness of the product candidate for each proposed indication;
- preparation and submission to the FDA of a biologics license application ("BLA"), as applicable, requesting approval to market the product candidate for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product and proposed labeling;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third-parties, at which the product and/or components thereof, are produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the preclinical studies and clinical trial sites to assure compliance with GLP, as applicable, and GCP, and the integrity of clinical data in support of the BLA;
- payment of user fees under the Prescription Drug User Fee Act ("PDUFA"), unless exempted;
- obtaining FDA approval, or licensure, of the BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") and any post-approval studies or other post-marketing commitments required by the FDA.

The failure to comply with the applicable U.S. requirements at any time during the product development process, including preclinical testing, clinical testing, and the approval process, or the post-approval process, may subject an applicant to delays in development, regulatory review or approval and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, issuance of warning or untitled letters, adverse publicity, product recalls, marketing restrictions, product seizures, import detentions and refusals, total or partial suspension of production or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or the Department of Justice ("DOJ"), and other governmental entities, including state agencies.

Preclinical Studies and INDs

Before testing any product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. The conduct of certain preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information, analytical data, and plans for the proposed clinical studies, are submitted to the FDA as part of an IND application. An IND is a request for authorization from the FDA to administer an investigational product to humans. An IND will also include a clinical trial protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue after an IND is submitted.

An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product candidate or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the clinical trial on a partial or complete clinical hold. In that case, the IND sponsor and the FDA must resolve the clinical hold issues before the clinical trials can begin.

Clinical holds also may be imposed by the FDA after clinical trials have begun, including if there is concern for patient safety, as a result of new data, findings, or developments in clinical, preclinical and/or chemistry, manufacturing and controls, or where there is non-compliance with regulatory requirements. A separate submission to an existing IND must be made for each successive clinical trial conducted during development, and the FDA reviews such submissions before each clinical trial can begin.

Human Clinical Trials in Support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease or condition to be treated under the supervision of qualified investigators in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data.

Further, each clinical trial must be reviewed and approved by an IRB or ethics committee either centrally or individually at each institution at which the clinical trial will be conducted. The IRB or ethics committee will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects and the possible liability of the institution. The FDA, IRB, or ethics committee, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with GCP requirements or that the participants are being exposed to an unacceptable health risk.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board ("DSMB"), or data monitoring committee ("DMC"). This group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on certain available data from the trial to which only the DSMB/DMC has access.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials are initially conducted in a limited population of healthy subjects or patients to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.
- Phase 3 clinical trials typically proceed if one or more Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are generally undertaken within an expanded patient population to provide substantial evidence of clinical efficacy or purity and potency and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites to provide a basis for physician labeling and for submitting a BLA to seek regulatory approval for a biological product.

Historically, FDA approval has generally required evidence of effectiveness derived from two adequate and well-controlled clinical trials; however, in February 2026, the FDA publicly indicated that a single such trial will be the FDA's default standard moving forward for novel products, together with confirmatory evidence. The FDA retains broad discretion to determine the adequacy of the evidentiary package for any particular product candidate, and may require a second adequate and well-controlled clinical trial in some circumstances.

In some cases, the FDA may approve a BLA but require the sponsor to conduct additional clinical trials to further assess the product's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the approved indication and, where applicable, to confirm a clinical benefit for products approved under accelerated approval. The failure to exercise due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval of the applicable product.

Information about applicable clinical trials must be submitted within specific timeframes to the National Institutes of Health ("NIH") for public dissemination on its ClinicalTrials.gov website. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical trial or to submit trial results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Under the Pediatric Research Equity Act, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP") within 60 days of an end-of-phase 2 meeting or as may be agreed between the sponsor and FDA. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor and the FDA must reach agreement on the PSP. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Compliance with cGMP Requirements

Concurrent with clinical trials, companies must finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of introduction of adventitious agents with the use of biological products, the PHSA emphasizes the importance of manufacturing controls. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Manufacturers and distributors of biological products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide certain information to the FDA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Noncompliance with such requirements can lead to adverse findings by the FDA during these inspections; in instances of significant or continued noncompliance, such adverse findings can serve as the basis for additional regulatory action by the FDA, including but not limited to warning letters, recalls, seizure, consent decrees, fines, and/or criminal penalties.

Review and Approval of a BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more specified indications. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Under federal law, the submissions of most BLAs are subject to an application user fee. The sponsor of an approved BLA is also subject to an annual program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether to accept it for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. If the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional or clarifying information within the last three months before the PDUFA goal date.

The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent for its intended use and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and may provide a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of preclinical and clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. The complete response letter may require additional clinical data and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the deficiencies identified by the FDA. The FDA will then re-review the application, taking into consideration the response, and determine whether the application meets the criteria for approval. The FDA will not approve an application until issues identified in any complete response letters have been addressed. Even if such data and information are submitted, the FDA may decide that the application does not satisfy the criteria for approval. Failure to respond to a complete response letter may be considered by the FDA as a request to withdraw the application.

Even if the FDA approves a new product, the approval may be limited to specific disease states, patient populations and dosages, and the indications for use may otherwise be limited. The FDA may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase 4 clinical trials, to further assess the product's efficacy and/or safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including a REMS, to help ensure that the benefits of the product outweigh the potential risks. A REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

FDA provides programs intended to facilitate and expedite development and review of new products that are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation ("Fast Track Designation"). These designations are not mutually exclusive, and a product candidate may qualify for one or more of these programs. While these programs are intended to expedite product development and approval, they do not alter the standards for FDA approval. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

The FDA may designate a product for Fast Track Designation if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For products with Fast Track Designation, sponsors may have more frequent interactions with the FDA, the product is potentially eligible for accelerated approval and priority review, if relevant criteria are met, and the FDA may initiate review of sections of a product's application before the application is submitted in full. The sponsor must provide, and the FDA must approve, a schedule for this type of "rolling review" process and the sponsor must pay applicable user fees; however, the FDA's review goal for a fast track application does not begin until the last section of the application is submitted. In addition, Fast Track Designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff managers in the review process; assigning a cross-disciplinary lead for the review team; and taking other steps to facilitate efficient clinical trial design. Breakthrough therapy designation may be rescinded if a product no longer meets the qualifying criteria.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is contingent on a sponsor's agreement to conduct, in a diligent manner, post-approval confirmatory studies to verify and describe the product's clinical benefit, and the FDA may require that such confirmatory trials be underway prior to granting accelerated approval. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of phase 4 or post-approval clinical trials. Failure to conduct required post-approval studies or confirm a clinical benefit in these studies, dissemination of false or misleading promotional materials, or other compliance concerns may lead the FDA to seek to withdraw accelerated approval on an expedited basis. All promotional materials for products approved under the accelerated approval pathway are subject to prior review by the FDA.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects 200,000 or more individuals in the United States and for which there is no reasonable expectation that development and production costs will be recovered from sales of the biological product for the disease or condition in the United States.

Orphan drug designation qualifies a sponsor for tax credits and the product for market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product but must be requested before submitting a BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. After FDA grants orphan designation, the product must then go through the same review and approval process as any other product.

A sponsor may request orphan drug designation of a previously unapproved product, or for a new orphan disease or condition for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same approved use or indication within such rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug, with respect to such use or indication. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file its own request for orphan designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for an indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the "same drug" as defined by the FDA, for the same approved use or indication within such rare disease or condition for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the approved use or indication within the rare disease or condition for which the product has been designated. The FDA may approve a different product for the same indication or use covered by the orphan exclusivity. The FDA cannot, however, approve the same product made by another manufacturer for the same approved use or indication within the relevant rare disease or condition during the market exclusivity period unless it has the consent of the sponsor, if the other manufacturer is able to demonstrate clinical superiority to the approved product with orphan drug exclusivity within the relevant approved use or indication, or if the sponsor is unable to provide sufficient quantities of the orphan drug relating to the approved use or indication or patients with the relevant rare disease or condition.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for an additional six months of marketing protection that attaches to the term of any existing regulatory exclusivity, including orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The

data do not need to show the product to be safe and effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted and extends whatever statutory or regulatory periods of exclusivity that cover the product by six months provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

U.S. Patent Term Extension

In the United States, a patent claiming a new biological product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. The extension period is typically one-half the time between the effective date of the IND and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Patent term extension cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office ("USPTO") reviews and approves the application for any patent term extension in consultation with the FDA.

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established a regulatory framework authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an already FDA-licensed biological product, called the "reference product." The FDA has issued multiple guidance documents outlining an approach to review and approval of biosimilars. Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a reference product. In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and that the biosimilar product and the reference product may be switched without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product, and the FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also established an exclusivity period for the first interchangeable biosimilar product to obtain approval. Interchangeable biological products may be substituted by pharmacies for the reference product, subject to state pharmacy law.

Post-Approval Regulation

If regulatory approval for a product or new indication for an existing product is obtained, the sponsor will be required to comply with all applicable post-approval regulatory requirements. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with advertising and promotional labeling requirements and record-keeping requirements. Manufacturers must register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort to maintain compliance with cGMP regulations and other regulatory requirements. There also are continuing, annual program fees for any marketed products.

The FDA may take enforcement action if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown issues with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product;
- fines, warning letters or holds on clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product licenses;
- product recall, seizure or detention, or refusal to permit the import or export of products;
- withdrawal of the product from the market and/or withdrawal of approval; or
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product;
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of biological products including, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Promotional claims about a product's safety or effectiveness are prohibited before it is approved. After approval, a product generally may be promoted for uses or patient populations consistent with the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe products for uses that are not approved by the FDA (sometimes called "off-label use") because the FDA does not regulate the practice of medicine. However, FDA regulations restrict manufacturers' communications about off-label uses. Promotional materials for approved biological products generally must be submitted to the FDA in conjunction with their first use.

If a company, including any representative of the company or anyone speaking on behalf of the company, is found to have promoted off-label uses, the company may become subject to adverse publicity and/or administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. Such enforcement could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes its products.

Combination Products

The FDA also regulates combination products. Specifically, under regulations issued by the FDA, a combination product may include:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and composed of drug and device products, device and biological products, biological and drug products or biological products, drug products and device products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product, the labeling of the other product would need

to be updated (*e.g.*, to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose); or

- an investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products, although it does not preclude consultations by the lead center with another FDA center. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a biologic-device combination product is attributable to the biologic product, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product. The FDA has established an Office of Combination Products to address issues regarding combination products and provide more certainty to the regulatory review process. This office is responsible for developing guidance and regulations to clarify the regulation of combination products, and for assigning the FDA center that will have primary jurisdiction for review of a combination product where the jurisdiction is unclear or in dispute.

Following approval of a combination product, each component of a combination product retains its regulatory status (as a biologic, drug or device, for example) and is generally subject to the requirements established by the FDA for that type of component. In addition, under FDA regulations, combination products are generally subject to the cGMP requirements applicable to each component within the combination. A combination product with a biologic primary mode of action and a device component such as a syringe generally would be reviewed and approved pursuant to the biologic approval process. In reviewing the BLA for such a combination product, however, FDA biologic reviewers consult with their counterparts in the device center to ensure that the device component of the combination product meets applicable requirements regarding safety, effectiveness, durability and performance. For example, syringes are generally regulated as Class 2 medical devices under FDA's classification regulations, requiring 510(k) clearance if marketing such devices as unfilled device-only products. If proposed for marketing as a prefilled biologic syringe or biologic-filled autoinjector, the device safety, effectiveness, durability and performance would be assessed in conjunction with the review of the biologic product.

Data Privacy and Security Laws

In the ordinary course of business, we collect, receive, or otherwise process personal data, including information we may collect about participants in our clinical trials. Accordingly, we are, or may be become, subject to numerous data privacy and security obligations, including global, federal, state, and local laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations related to privacy and data security.

Under the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the U.S. Department of Health and Human Services ("HHS"), has issued regulations to protect the privacy and security of protected health information ("PHI"), used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their regulations, also imposes certain obligations on the business associates of covered entities and their subcontractors that obtain PHI in providing services to or on behalf of covered entities. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal administrative, civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well.

Additionally, states, such as California, Virginia and Colorado have recently enacted the consumer privacy laws that grant rights to data subjects and place increased privacy and security obligations on entities handling personal data of consumers or households. While we are not currently subject to laws such as the California Consumer Privacy Act ("CCPA"), some observers note that the CCPA and similar

legislation could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

Because of the breadth of these laws and the narrowness of the statutory exceptions under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that we may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any applicable privacy or data security laws or regulations, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. While there are some exemptions for certain data processed in the context of clinical trials, developments in data privacy and security laws may further complicate compliance efforts. The impact these increasingly stringent laws and evolving regulatory frameworks related to personal data processing may have on us is more fully discussed in the section titled "*Risk Factors*" appearing elsewhere in this prospectus.

Additionally, to the extent we collect personal data from individuals outside of the United States, through clinical trials or otherwise, we are, or may become, subject to foreign data privacy and security laws, such as the European Union's General Data Protection Regulation 2016/679 ("EU GDPR") and other national data protection legislation in force in relevant EEA Member States, and the EU GDPR as it forms part UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"). Foreign privacy and data security laws impose significant and complex compliance obligations on entities that are subject to those laws, as more fully discussed in the section titled "*Risk Factors*" appearing elsewhere in this prospectus.

Regulation and Procedures Governing Approval of Medicinal Products Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. For example, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application ("MAA") and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Nonclinical Studies

Nonclinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Certain nonclinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice ("GLP"), as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, *e.g.*, radio-pharmaceutical precursors for radio-labeling purposes), which define a set of rules and criteria for a quality system for the organizational processes and conditions applicable to non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical Trial Approval

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. In April 2014, the European Union adopted the Clinical Trials Regulation (EU) No 536/2014 ("CTR"), which entered into application on January 31, 2022, repealing and replacing the Clinical Trials Directive 2001/20/EC. The CTR is directly applicable in all European Union Member States meaning no national implementing legislation in each European Union Member State is required. The CTR aims at harmonizing and streamlining the approval of clinical trials in the European Union, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the European Union on

the Clinical Trials Information System ("CTIS"). The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

While the EU Clinical Trials Directive required a separate clinical trial authorization application ("CTA"), to be submitted in each EU Member State in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision per Member State. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via CTIS. Once the CTA is approved, clinical trial development may proceed.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice ("GMP"). Other national and EU-wide regulatory requirements may also apply.

PRIME Designation in the European Union

The PRIority MEdicines ("PRIME"), scheme is intended to encourage product development in areas of unmet medical need and provides accelerated assessment under the European Union centralized procedure for marketing authorization of products representing substantial innovation. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the European Union or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of therapeutic candidates with PRIME designation, including but not limited to early and proactive regulatory dialogue with the European Medicines Agency ("EMA"), frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from the Committee for Medicinal Products for Human Use ("CHMP") are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan ("PIP"), covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or a deferral for one or more of the measures included in the PIP. The Paediatric Committee of the EMA ("PDCO"), may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases that only affect the elderly population. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, the so-called Paediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for six months' supplementary protection certificate extension. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. These pediatric rewards are subject to specific conditions and are not automatically available when data in compliance with the PIP are developed and submitted.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union Member States, as well as the countries of the EFTA Pillar of the European Economic Area (Norway, Iceland and Liechtenstein) ("EEA"). Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer, HIV, AIDS, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the European Union, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. Manufacturers must demonstrate the quality, safety and efficacy of their products to the EMA. The CHMP provides an opinion regarding the MAA. The European Commission grants or refuses a marketing authorization in light of the opinion delivered by the EMA.

Under the centralized procedure, the CHMP is responsible for conducting an initial assessment of a product. The maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation.

Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

National marketing authorizations, which are issued by the competent authorities of the Member States of the European Union and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the European Union, this national authorization can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

Regulatory Data Protection in the European Union

In the European Union, new chemical entities (including both small molecules and biological medicinal products) approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the European Union. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains a marketing authorization in the European Union for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan Designation and Exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, where either (i) such condition affects not more than five in ten thousand persons in the European Union at the time the application is made, or (ii) without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary

investment in its development. For either of these conditions, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such a method exists, that the product will be of significant benefit to those affected by that condition.

An orphan designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized marketing authorization. Marketing authorization for an orphan product leads to a ten-year period of market exclusivity being granted following marketing approval of the orphan medicinal product. During this market exclusivity period, the EMA, the European Commission or the European Union Member States may only grant a marketing authorization to a "similar medicinal product" for the same therapeutic indication as an authorized orphan product if: (i) a second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized orphan product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized orphan product cannot supply sufficient quantities of the orphan medicinal product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, including if the product is considered to be sufficiently profitable so as not to justify market exclusivity. Orphan designation must be requested before submitting an application for marketing authorization. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Patent Term Extensions in the European Union and Other Jurisdictions

The European Union also provides for patent term extension through supplementary protection certificates ("SPCs"). The rules and requirements for obtaining an SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a product from the date of its first marketing authorization in the European Union. In certain circumstances, the period of SPC protection may be extended for six additional months if pediatric exclusivity is obtained. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed indefinitely after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing EU Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing EU Member State (in the case of a national procedure) within three years after authorization, or which is not placed on the market for a consecutive period of three years at any time during its authorization, ceases to be valid.

Regulatory Requirements After Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product, and must adhere in strict compliance with the applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive (EU) 2017/1572, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint a qualified person responsible for pharmacovigilance ("QPPV"), who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

In addition, all new MAAs must include a risk management plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures may include post-authorization safety studies and additional monitoring obligations.

In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of European Union Member States and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the European Union.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under European Union directives, the details are governed by regulations in each Member State and can differ from one country to another.

The aforementioned European Union rules are applicable in the EFTA Pillar of the EEA (Iceland, Liechtenstein and Norway).

Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the European Union for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. The European Council, European Parliament and European Commission will enter into trilogue negotiations aimed at reaching a consensus on a final version of the legislation.

Brexit and the Regulatory Framework in the United Kingdom

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the UK is not generally subject to EU laws in respect of medicines. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK, however, new legislation such as the (EU) CTR is not applicable in the UK.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA") is the UK's standalone medicines and medical devices regulator. On January 1, 2025 a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes

and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which are derived from the CTD, as implemented into UK national law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 will take full effect from April 28, 2026, aims to create a streamlined, risk-proportionate system that accelerates approvals while maintaining robust safety standards. In addition, in October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. In order to use the centralized procedure to obtain a marketing authorization that will be valid throughout the EEA, companies must be established in the EEA. Therefore, after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized marketing authorizations. In order to obtain a UK marketing authorization to commercialize products in the UK, an applicant must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. In addition, since January 1, 2024, the MHRA introduced the International Recognition Procedure, or IRP, which enables the MHRA when reviewing certain types of MAAs to take into account the expertise and decision-making of trusted regulatory partners (*e.g.*, the medicines regulatory authorities in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the European Commission in the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust.

In the UK, the initial duration of a marketing authorization is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance to proceed with only one additional five-year renewal. Any authorization which is not followed by the actual placing of the medicine on the market in the UK within three years shall cease to be in force.

There is no pre-marketing authorization orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same as in the EU, but have been tailored for the market, *i.e.*, the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in the UK.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize GB-0895, GB-4362, GB-5267 and any potential future product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs.

Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Therefore, even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost- effectiveness of medical products and services and imposing controls to manage costs.

Further, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for GB-0895, GB-4362, GB-5267 and any potential future product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;

- the federal civil and criminal false claims laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (*e.g.*, public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Federal, state, and foreign enforcement bodies are continuing to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Violation of any of such laws or any other governmental regulations that apply can result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs, reputational harm, diminished profits and future earnings and individual imprisonment.

Healthcare Reform

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably.

For example, in the United States, in 2010 the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011 and subsequence legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers, which remain in effect through 2032 unless Congress takes additional action. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.
- Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting in 2025.
- The Inflation Reduction Act of 2022 (the "IRA") includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program if they have one or more orphan designations and are only approved for rare disease indications; otherwise, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.
- On July 4, 2025, President Trump signed the One Big Beautiful Bill Act, which imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the numbers of persons enrolled in Medicaid and reduce the services covered by Medicaid.

These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for GB-0895, GB-4362, GB-5267 and any potential future product candidates for which we may obtain regulatory approval or the frequency with which GB-0895, GB-4362, GB-5267 or any potential future product candidates is prescribed or used.

Additionally, there has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other

things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

In addition, the Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems, parallel distribution and parallel trade. It could also result from the application of external reference pricing mechanisms, which involve benchmarking or arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU member state could affect the price in other EU member states and, thus, have a negative impact on our financial results.

Health Technology Assessment ("HTA") of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to a medicinal product, as HTA bodies support national authorities in deciding on the use, price and reimbursement level of new health technologies. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects of obtaining reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 15, 2021, Regulation (EU) 2021/2282 on health technology assessment, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 12, 2025, with phased implementation based on the type of product, *i.e.*, oncology medicines and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other centrally authorized medicinal products from 2030. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and to provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It permits EU Member

States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing nonclinical (*e.g.*, economic, social, ethical) aspects of health technologies and for making national decisions on pricing and reimbursement.

Employees and Human Capital Resources

As of December 31, 2025, we had 312 full-time employees, of which 138 had M.D. or Ph.D. degrees. Within our workforce, 254 employees were engaged in research and development and 58 were engaged in business development, finance, legal and general management and administration as of December 31, 2025. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off.

Facilities

Our corporate headquarters is located in Somerville, Massachusetts, where we lease and occupy approximately 71,000 square feet of office and laboratory space at 101 South Street, Suite 900, Somerville, MA 02143. The current term of such lease expires in August 2031. We also lease approximately 75,000 square feet of office and laboratory space at 4 Corporate Drive, Andover, MA. The current term of such lease expires in December 2034.

We believe that our facilities are adequate for our current needs and for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space. We believe that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by us is required to determine both probability and the estimated amount. Our management is currently not aware of any legal matters that could have a material effect on our financial position, results of operations or cash flows.

MANAGEMENT

Executive Officers, Key Employees and Directors

The following table sets forth information regarding our executive officers, key employees and directors as of February 4, 2026.

Name	Age	Position
Executive Officers:		
Michael Nally, M.B.A.	50	Chief Executive Officer and Director
Gevorg Grigoryan, Ph.D.	45	Co-Founder and Chief Technology Officer
Beth Grous	58	Chief People Officer
Aarif Khakoo, M.D., M.B.A.	55	Chief Scientific Officer
Laurie Lee, M.D.	59	Chief Medical Officer
Sean Martin, J.D.	63	Chief Legal Officer and General Counsel
Jason Silvers, M.D., J.D.	54	President and Chief Financial Officer
Non-Employee Directors:		
Noubar B. Afeyan, Ph.D.[(1)(3)]	63	Chairperson of the Board
Frances Arnold, Ph.D.	69	Director
Stéphane Bancel, M.B.A.[(1)(3)]	53	Director
Marsha H. Fanucci, M.B.A.[(2)(3)]	72	Director
Jane Mendillo, M.B.A.[(2)]	67	Director
Paul Parker, M.B.A.[(2)]	62	Director
Nancy A. Simonian, M.D.[(1)]	65	Director
Rupert Vessey, B.M. B.Ch., D.Phil., FRCP	60	Director

(1) Member of the compensation committee.
(2) Member of the audit committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Michael Nally, M.B.A., has served as our Chief Executive Officer and as a member of our board of directors since March 2021, and served as our President from March 2021 to February 2026. Mr. Nally has also served as a CEO-Partner at Flagship Pioneering since March 2021. Previously, Mr. Nally served in multiple roles at Merck & Co., Inc. (NYSE: MRK) from August 2003 to March 2021, including most recently as executive vice president and chief marketing officer from January 2019 until March 2021. Additionally, Mr. Nally has served as a member of the board of directors for PPG Industries, Inc. (NYSE: PPG) ("PPG Industries") since February 2021. Mr. Nally holds an M.B.A. from Harvard Business School, a degree in accounting and finance from the London School of Economics and a B.A. in economics from Middlebury College. We believe that Mr. Nally's leadership and business expertise in the pharmaceutical industry provides him with the appropriate set of skills to serve as a member of our board of directors.

Dr. Jason Silvers, M.D., J.D., has served as our Chief Financial Officer since July 2022 and as our President since February 2026. Previously, Dr. Silvers served in multiple roles at Goldman Sachs & Co. ("Goldman Sachs") from August 2002 to June 2022, where he became a managing director in 2010 and partner in 2014. Most recently, he co-managed healthcare investment banking for Goldman Sachs in Europe, the Middle East and Africa. Dr. Silvers holds a J.D. from Yale Law School, an M.D. from the Johns Hopkins University School of Medicine and a B.S. in chemistry from Brown University. He also completed one year of a neurosurgical residency at Jackson Memorial Hospital and was awarded the Surgical Intern of the Year distinction.

Dr. Gevorg Grigoryan, Ph.D., is our co-founder and has served as our Chief Technology Officer since the founding of the company in 2018. He has also held various appointments at Dartmouth College since 2011 (tenured in 2017), where he conducted research and served on the faculty in the Departments of Computer Science, Biological Sciences, and Chemistry, focusing on uncovering the principles that link protein sequence, structure, and function. Dr. Grigoryan has authored over 50 peer-reviewed publications in leading journals including *Nature*, *Science*, and *PNAS* and has received recognition from the Alfred P. Sloan Foundation, National Institutes of Health, National Science Foundation, and the American Cancer Society. He holds a Ph.D. from the Massachusetts Institute of Technology and earned his B.S. in computer science and biochemistry from the University of Maryland, Baltimore County. Additionally, he completed postdoctoral training at the University of Pennsylvania.

Beth Grous has served as our Chief People Officer since April 2023. She has also served as a part-time venture advisor at SemperVirens Venture Capital since January 2019 and has served on the board of directors of the Tripadvisor Foundation since September 2015. Previously, Ms. Grous served as the senior vice president and chief people officer at Tripadvisor, Inc. (NASDAQ: TRIP) from September 2015 to March 2023. Prior to that role, she served as senior vice president of global human resources at Nuance Communications, Inc., as well as vice president and head of human resources at Sanofi S.A.'s Boston hub. She holds a B.A. in English from Cornell University.

Aarif Khakoo, M.D., M.B.A., has served as our Chief Scientific Officer since January 2026. He is also an adjunct clinical associate professor at the Stanford University School of Medicine, a role he has held since April 2011. Previously, Dr. Khakoo was chief scientific officer and head of research and development at Scribe Therapeutics, Inc. from December 2023 to January 2026. Prior to that role, he was chief medical officer and head of drug development at Calico Life Sciences LLC from February 2019 to July 2023. Earlier in his career, Dr. Khakoo served in senior research and development roles at Amgen Inc. Dr. Khakoo earned his M.D. from the Columbia University Vagelos College of Physicians and Surgeons, and his M.B.A. from Columbia Business School. He completed his residency in internal medicine at Johns Hopkins Bayview Medical Center, and a fellowship in cardiovascular medicine at the Johns Hopkins University School of Medicine.

Laurie Lee, M.D., has served as our Chief Medical Officer since September 2025. Previously, Dr. Lee served as vice president of research and development, transplant and immunology, at CSL Behring from April 2020 to September 2025. Prior to joining CSL Behring, Dr. Lee served in multiple roles at GlaxoSmithKline plc (GSK), including as vice president of research and development and medicine development leader. Dr. Lee is a board-certified physician in pediatrics, allergy and immunology. She earned her M.D. from the Ohio State University College of Medicine, and her B.S. in biology from the University of Notre Dame. Dr. Lee completed a residency at Columbus Children's Hospital and fellowship in allergy and immunology at Duke University Medical Center, where she subsequently joined the pediatrics faculty.

Sean Martin, J.D., has served as our Chief Legal Officer and General Counsel since April 2022. Previously, Mr. Martin served as general counsel and senior vice president at Baxter International Inc. (NYSE: BAX) from February 2017 to April 2022. Prior to that role, he was general counsel, senior vice president and secretary at Apollo Education Group, Inc. He also served as vice president for commercial law and corporate law at Amgen Inc. and vice president and deputy general counsel for litigation at Fresenius Medical Care North America. Earlier in his career, Mr. Martin was a law firm partner at Foley & Lardner LLP and served as an Assistant U.S. Attorney in Chicago for eight years, prosecuting federal criminal cases. Mr. Martin holds a J.D. from Harvard Law School and a B.A. in history from the University of Michigan.

Non-Executive Directors

Dr. Noubar B. Afeyan, Ph.D., is a co-founder and has served as the chairman of our board of directors since 2018. In 1999, Dr. Afeyan founded Flagship Pioneering and serves as its Chief Executive Officer. Flagship Pioneering is an institutional platform for the creation, development and capitalization of pioneering biotechnology companies, with over 100 ventures founded and about $14 billion in assets under its management. Dr. Afeyan is co-founder and has served as chairman of the board of Moderna, Inc. (NASDAQ: MRNA) ("Moderna") since 2012. He has previously served on the boards of numerous privately and publicly held companies, including Omega Therapeutics, Inc. (NASDAQ: OMGA) from July 2016 to August 2023 and Rubius Therapeutics, Inc. (NASDAQ: RUBY) from 2013 to November 2022. He received a Ph.D. in biochemical engineering from the Massachusetts Institute of Technology and a B.S. in chemical engineering from McGill University. Dr. Afeyan was previously a visiting lecturer of business administration at Harvard Business School and was previously a senior lecturer at MIT's Sloan School of Management where he taught courses on technology entrepreneurship, innovation and leadership. We believe that Dr. Afeyan's significant experience co-founding, leading, and investing in numerous biotechnology companies make him qualified to serve on our board of directors.

Dr. Frances H. Arnold, Ph.D., has served as a member of our board of directors since July 2019. Dr. Arnold manages a research group, is the Linus Pauling Professor of Chemical Engineering, Bioengineering and Biochemistry, and is the Director of the Donna and Benjamin M. Rosen Bioengineering Center, all at the California Institute of Technology. She joined the California Institute of Technology in 1986 and has served as a Visiting Associate, Assistant Professor, Professor, and Director. Her laboratory focuses on protein engineering by directed evolution, with applications in alternative energy, chemicals, and medicine. Dr. Arnold is the recipient of numerous honors, including the Nobel Prize in Chemistry, the Millennium Technology Prize, induction into the National Inventors Hall of Fame, Fellow of the National Academy of Inventors, the ENI Prize in Renewable and Nonconventional Energy, the U.S. National Medal of Technology and Innovation, and the Charles Stark Draper Prize of the U.S. National Academy of Engineering. Dr. Arnold has also served as a director of Alphabet Inc. (NASDAQ: GOOG) since October 2019 and Illumina, Inc. (NASDAQ: ILMN) since January 2016. Dr. Arnold holds a B.S. in mechanical and aerospace engineering from Princeton University and a Ph.D. in chemical engineering from the University of California, Berkeley. We believe that Dr. Arnold's pioneering expertise in protein engineering and directed evolution, combined with her experience advancing innovative technologies with applications in medicine, make her well qualified to serve as a member of our board of directors.

Stéphane Bancel, M.B.A., has served as a member of our board of directors since September 2019. Mr. Bancel has served as Moderna's chief executive officer since October 2011 and a venture partner at Flagship Pioneering since May 2013. Before joining Moderna, Mr. Bancel served for five years as CEO of the French diagnostics company bioMérieux SA. From July 2000 to March 2006, he served in various roles at Eli Lilly and Company, including as Managing Director, Belgium, and as Executive Director, Global Manufacturing Strategy and Supply Chain. Prior to Eli Lilly, Mr. Bancel served as Asia-Pacific Sales and Marketing Director for bioMérieux. Mr. Bancel has been a member of Moderna's board of directors since March 2011 and of Qiagen N.V.'s (NYSE: QGEN) board of directors from June 2013 to June 2021. Mr. Bancel was nominated Chevalier of the Legion d'honneur in 2022, the highest recognition in France, and was elected to the U.S. National Academy of Engineering in 2024. Mr. Bancel holds an M.B.A. from Harvard Business School, a Master of Science degree in chemical engineering from the University of Minnesota and Master of Engineering degree from École Centrale Paris. We believe that Mr. Bancel's extensive experience leading global life sciences organizations provides him with the appropriate set of skills to serve as a member of our board of directors.

Marsha H. Fanucci, M.B.A., has been a member of our board of directors since March 2025. Since 2009, Ms. Fanucci has been an independent consultant. From 2004 to 2009, she served as senior vice president and chief financial officer of Millennium Pharmaceuticals, Inc. ("Millennium"), which was subsequently acquired by Takeda Pharmaceuticals Company Limited (NYSE: TAK) ("Takeda"). She previously served in various other roles at Millennium, including as vice president, finance and corporate strategy and vice president, corporate development. Ms. Fanucci previously served as a director of Syros Pharmaceuticals, Inc. (NASDAQ: SYRS) from October 2015 to February 2025, Alnylam Pharmaceuticals, Inc. (NASDAQ: ALNY) from December 2010 to September 2023, Cyclerion Therapeutics, Inc. (NASDAQ: CYCN) from March 2019 to May 2023 and Forma Therapeutics Holdings, Inc. (NASDAQ: FMTX) from October 2014 to October 2022. Ms. Fanucci received her B.S. in pharmacy from West Virginia University and her M.B.A. from Northeastern University. We believe that Ms. Fanucci's experience as a biotechnology executive and expertise in corporate development, financial strategy and governance provide her with the appropriate set of skills to serve as a member of our board of directors.

Jane L. Mendillo, M.B.A., has served as a member of our board of directors since December 2022. Ms. Mendillo has spent over 30 years in the fields of endowment and investment management. As the CEO of the Harvard Management Company from 2008 to 2014, she managed Harvard University's approximately $37 billion global endowment and related assets across a wide range of public and private markets. Ms. Mendillo was previously the chief investment officer at Wellesley College for six years. Prior to that, she spent 15 years at the Harvard Management Company in various investment roles. Earlier in her career she was a management consultant at Bain & Co. and worked at the Yale Investment Office. Ms. Mendillo has also served as director of Lazard Inc. (NYSE: LAZ) from April 2016 to April 2025 and served as director of General Motors Co (NYSE: GM) from June 2016 to June 2022. She also serves as Trustee to the Old Mountain Private Trust Company, and Chair of the Investment Committee of Springboard Capital. Ms. Mendillo holds an M.B.A. from the Yale School of Management and a B.A. from Yale College. We believe that Ms. Mendillo's extensive investment management experience provide her with the appropriate set of skills to serve as a member of our board of directors.

Paul Parker, M.B.A., has served as a member of our board of directors since June 2025. Mr. Parker has also served as managing partner of capital solutions and value realization at Flagship Pioneering since September 2024. Previously, Mr. Parker held multiple leadership roles at Thermo Fisher Scientific Inc. (NYSE: TMO) from April 2020 to August 2024, most recently as senior vice president, head of strategy and corporate development, as well as at Goldman Sachs from August 2014 to February 2020, where he served as co-chairman of the Global Mergers and Acquisitions Group. Mr. Parker previously served as a member of the Board of The Clorox Company (NYSE: CLX) from November 2020 to November 2024. He earned an M.B.A. with distinction from Harvard Business School and a B.A. in international studies from the University of North Carolina at Chapel Hill. We believe that Mr. Parker's 35 years of experience in the banking, pharmaceutical and biotechnology industries, as well as in M&A, corporate strategy and organizational leadership, provide him with the appropriate set of skills to serve as a member of our board of directors.

Dr. Nancy A. Simonian, M.D., has served as a member of our board of directors since June 2024. She served as chief executive officer of Syros Pharmaceuticals, Inc. (NASDAQ: SYRS) ("Syros") from June 2012 to December 2023 and served as a member of the board of directors until February 2025. From 2001 to October 2011, Dr. Simonian was employed by Takeda and at Millennium, prior to its acquisition by Takeda, most recently as chief medical officer and senior vice president of clinical, medical and regulatory affairs. She currently is a member of the board of directors of Bayer AG (BAYRY), Alltrna, Inc., a private biotechnology company, and of the Damon Runyon Cancer Research Foundation. She previously served as a member of the board of directors of Seagen Inc. and Evelo Biosciences, Inc., each a publicly traded biotechnology company. Prior to joining the biotechnology industry, Dr. Simonian was on the faculty of Massachusetts General Hospital and Harvard Medical School as an assistant professor of neurology. She received a B.A. in biology from Princeton University and an M.D. from the University of Pennsylvania School of Medicine. We believe that Dr. Simonian's extensive experience as a physician-scientist, executive and board member provide her with the appropriate set of skills to serve as a member of our board of directors.

Dr. Rupert Vessey, B.M. B.Ch., D.Phil., FRCP, has served as a member of our board of directors since June 2024. Dr. Vessey joined Flagship Pioneering as Executive Partner and Chief Scientist in July 2023 after retiring from Bristol-Myers Squibb Company (NYSE: BMY) ("Bristol-Meyers Squibb"), where he had served as the President of Research and Early Development since 2019. Prior to joining Bristol-Myers Squibb, he was President of Global Research and Early Development at Celgene Corporation from 2015 to 2019. Before joining Celgene Corporation, Dr. Vessey held various research and development senior management positions during his 10-year tenure at Merck. Dr. Vessey has also served as a member of the board of directors of Bio-Techne Corp (NASDAQ: TECH) since July 2019. He graduated from the University of Oxford with degrees in physiological sciences (B.A., M.A.), clinical medicine (B.M., B.Ch.) and a Doctor of Philosophy (DPhil) in molecular immunology. We believe that Dr. Vessey's extensive experience guiding the expansion of therapeutics and bio-platforms provides him with the appropriate set of skills to serve as a member of our board of directors.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Composition of our Board of Directors

Our business and affairs are managed under the direction of the our board of directors, which currently consists of seven members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our amended and restated certificate of incorporation, as currently in effect (the "certificate of incorporation"), and agreements with our stockholders. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of director's priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier

of their resignation or removal. Our amended and restated certificate of incorporation, which will become effective promptly following the completion of this offering, and our amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Staggered Board of Directors

Our amended and restated certificate of incorporation, which will become effective promptly following the completion of this offering, and our amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, will permit our board of directors to establish the authorized number of directors from time to time by resolution. Each director serves until the expiration of the term for which such director was elected or appointed, or until such director's earlier death, resignation or removal. In accordance with our amended and restated certificate of incorporation, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Noubar B. Afeyan, Frances H. Arnold and Paul Parker and their terms will expire at our first annual meeting of stockholders following this offering, to be held in 2027;
- the Class II directors will be Stéphane Bancel, Jane L. Mendillo and Nancy A. Simonian and their terms will expire at our second annual meeting of stockholders following this offering, to be held in 2028; and
- the Class III directors will be Marsha H. Fanucci, Michael Nally and Rupert Vessey and their terms will expire at our third annual meeting of stockholders following this offering, to be held in 2029.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Director Independence

Under the listing standards, requirements and rules of The Nasdaq Stock Market LLC (the "Nasdaq Listing Rules"), independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of the members of our board of directors, except for Mr. Nally, have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules. Our board of directors has determined that Mr. Nally, by virtue of his position as our current Chief Executive Officer, is not independent under applicable rules and regulations of the Securities and Exchange Commission (the "SEC") and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in "*Certain Relationships and Related Person Transactions*."

Board of Directors Policies

In connection with this offering, we have adopted policies and procedures for director candidates for our nominating and corporate governance committee, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, and which provide that factors, such as a candidate's character, judgment, skills, education, expertise, and absence of conflicts of interest should be considered in determining director candidates. Our priority in selection of board members will be identification of members who will further the interests of our stockholders through their established records of professional accomplishment, their ability to contribute positively to the collaborative culture among board members, and their knowledge of our business and understanding of the competitive landscape in which we operate and adherence to high ethical standards.

Board of Directors Leadership Structure and Role in Risk Oversight

Dr. Afeyan is the current chair of our board of directors and Mr. Nally is our current Chief Executive Officer, hence the roles of chair of our board of directors and Chief Executive Officer are separated. We believe that separating these positions allows our Chief Executive Officer to focus on our day-to-day business, while allowing the chair of our board to lead our board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as chair of our board of directors, particularly as the board of directors' oversight responsibilities continue to grow. While our bylaws and corporate governance guidelines do not require that our board chair and Chief Executive Officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property as more fully discussed in "*Risk Factors*" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has adopted a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at *www.generatebiomedicines.com* upon the completion of this offering. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee consists of Marsha H. Fanucci, Jane L. Mendillo and Paul Parker, and the chair of our audit committee is Ms. Fanucci. Our board of directors has determined that each member of the audit committee can read and understand fundamental financial statements in accordance with applicable requirements, and that each of Ms. Fanucci and Ms. Mendillo is independent under Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. We intend to rely on the phase-in provisions of Nasdaq Listing Rule 5615, which permit companies listing in connection with their initial public offering to phase-in compliance with the heightened audit committee independence requirements. Specifically, we will be

required to have an audit committee of at least three directors that satisfy the heightened audit committee independence requirements within one year of listing. We intend to comply with such requirements within the allotted timeframe. Our board of directors has also determined that Ms. Fanucci and Ms. Mendillo are each an "audit committee financial expert" within the meaning of SEC regulations. In arriving at these determinations, our board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial statement audits, and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our consolidated financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- overseeing the preparation of our annual proxy statement, reviewing with management our consolidated financial statements to be included in our quarterly reports to be filed with the SEC and reviewing with management the "*Risk Factors*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" disclosures in our periodic reports filed with the SEC;
- oversee our risk management policies, procedures and practices, including those related to cybersecurity; and
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq Listing Rules.

Compensation Committee

Our compensation committee consists of Nancy A. Simonian, Stéphane Bancel and Paul Parker, and the chair of our compensation committee is Dr. Simonian. Our board of directors has determined that each member of the compensation committee is independent under the Nasdaq Listing Rules and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- annually reviewing and recommending to our board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and, based on such evaluation, recommending to our board of directors the cash compensation of our Chief Executive Officer;
- reviewing and approving the compensation arrangements with our other executive officers and certain other senior management;

- reviewing and recommending to our board of directors the compensation paid to our directors;
- administering our equity incentive plans and other benefit programs;
- overseeing and administering our compensation and similar plans; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

Our compensation committee will operate under a written charter, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq Listing Rules.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Noubar B. Afeyan, Stéphane Bancel and Marsha H. Fanucci, and the chair of our nominating and corporate governance committee will be Dr. Afeyan. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

The primary purpose of the nominating and corporate governance committee is to discharge the responsibilities of our board of directors with respect to our corporate governance functions and to identify, communicate with, evaluate and recommend candidates for our board of directors. Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

Our nominating and corporate governance committee will operate under a written charter, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq Listing Rules.

Code of Business Conduct and Ethics

In connection with this offering, we have adopted an amended and restated code of business conduct and ethics that applies to all our employees, officers and directors, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our code of business conduct and ethics will be posted on our website at *www.generatebiomedicines.com*. We intend to disclose on our website any future amendments of our code of business conduct and ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the code of business conduct and ethics. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. None of our officers currently serves, or has served during the last calendar year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Compensation Recovery

In connection with this offering, we have adopted a compensation recovery policy that applies to our officers, which became effective as of the effectiveness of the registration statement of which this prospectus forms a part. Under the Sarbanes-Oxley Act, in the event of misconduct that results in a financial restatement that would have reduced a previously paid incentive amount, we can recoup those improper payments from our Chief Executive Officer and Chief Financial Officer. The SEC also recently adopted rules which direct national stock exchanges to require listed companies to implement policies intended to recoup bonuses paid to executives if the company is found to have misstated its financial results.

Limitations on Liability and Indemnification

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation, which will become effective promptly following the completion of this offering, and amended and restated bylaws, which became effective upon the effectiveness of this registration statement, limit or eliminate the personal liability of officers and directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, an officer or director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, an officer or director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as an officer or director, except for liability for:

- any breach of the officer or director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for our directors, unlawful payments of dividends or unlawful stock repurchases, or redemptions as provided in Section 174 of the Delaware General Corporation Law (the "DGCL");
- for our officers, any derivative action by or in the right of the corporation;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter an officer or director's liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation that will become effective promptly following the completion of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws, which became effective upon the effectiveness of this registration statement, provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we entered into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification

provisions contained in the DGCL. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend or terminate a Rule 10b5-1 plan in some circumstances. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plans would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

EXECUTIVE COMPENSATION

The following discussion contains forward looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from the programs summarized in this discussion.

As an emerging growth company and a smaller reporting company, we have opted to comply with the executive compensation disclosure rules applicable to "emerging growth companies" and "smaller reporting companies," as such terms are defined in the rules promulgated under the Securities Act. The compensation provided to our named executive officers for the fiscal year ended December 31, 2025 ("Fiscal Year 2025") is detailed in the 2025 Summary Compensation Table and accompanying footnotes and narrative that follow.

Our named executive officers for Fiscal Year 2025 are:

- Michael Nally, M.B.A., our Chief Executive Officer;
- Gevorg Grigoryan, Ph.D., our Chief Technology Officer; and
- Jason Silvers, M.D., J.D., our Chief Financial Officer.

To date, the compensation of our named executive officers has consisted of a combination of base salary, cash incentive compensation, and long-term incentive compensation, as more fully described below. Our executive officers, like all full-time employees, are eligible to participate in our health, welfare, and retirement benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

2025 Summary Compensation Table

The following table shows the total compensation earned by, or paid to, our named executive officers for services rendered to us in all capacities during the fiscal years set forth in the table.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1][2]	Non-Equity Incentive Plan Compensation ($)[3]	All Other Compensation ($)[4]	Total ($)
Michael Nally, M.B.A.	2025	668,250	—	4,450,000	397,238	12,250	5,527,738
Chief Executive Officer	2024	628,250	—	4,222,501	401,321	11,725	5,264,297
Gevorg Grigoryan, Ph.D.	2025	490,233	—	1,557,500	235,532	12,250	2,295,515
Chief Technology Officer							
Jason Silvers, M.D., J.D.	2025	515,835	—	1,446,250	244,817	12,250	2,219,152
Chief Financial Officer	2024	490,500	—	1,412,015	266,112	12,075	2,180,702

(1) The amounts reported represent the aggregate grant date fair value of stock option awards granted to our named executive officers in the applicable fiscal year, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 ("FASB ASC Topic 718"), disregarding any estimates of forfeitures related to service-based vesting. For the performance-based options granted to Mr. Nally in 2024, the amount reported is based upon the probable outcome of the performance conditions. For these awards, we determined that as of the date of the grant it was not probable, as defined under applicable accounting guidance, that the applicable performance conditions would be achieved and, accordingly, the grant date fair value of such awards is $0. The value of these awards at the grant date assuming the maximum achievement of the performance conditions is $666,000. The assumptions used in calculating the grant date fair values of the option awards reported in this column are set forth in Note 4 of our consolidated financial statements for Fiscal Year 2025, included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these option awards and do not correspond to the actual economic value that may be received by our named executive officers upon the exercise of the option awards or any sale of the underlying securities.

(2) For Mr. Nally, the amount reported for 2024 also includes the incremental fair value attributable to the partial accelerated vesting of a performance-based stock option granted to Mr. Nally in 2021. The performance-based stock options granted to Mr. Nally in March 2024 were amended in December 2024 to clarify the vesting terms and to extend the end of the performance period from December 31, 2024 to December 31, 2025 but such amendment resulted in no incremental expense because achievement of the applicable performance conditions was deemed not probable on the modification date.
(3) The amounts reported represent annual bonuses earned for the applicable fiscal year based on achievement of corporate performance measures and individual performance, as described in more detail under the heading "*—2025 Cash Bonuses*" below.
(4) The amounts reported represent employer matching contributions made on behalf of our named executive officers under our 401(k) plan.

Narrative Disclosure to the 2025 Summary Compensation Table

2025 Base Salaries

The named executive officers each receive a base salary to compensate them for services rendered to us. Base salaries are intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors, and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience.

For Fiscal Year 2025, the base salaries for Mr. Nally, Dr. Grigoryan and Dr. Silvers were $675,000, $500,280 and $520,002, respectively.

2025 Cash Bonuses

For Fiscal Year 2025, each of the named executive officers was eligible to earn an annual cash bonus based on the achievement of certain corporate performance milestones and individual performance. Mr. Nally had a target annual bonus for Fiscal Year 2025 equal to 55% of his annual base salary, and Dr. Grigoryan and Dr. Silvers each had a target annual bonus for Fiscal Year 2025 equal to 40% of his respective annual base salary.

Each named executive officer's annual cash bonus for Fiscal Year 2025 was determined by reference to the achievement of pre-determined corporate performance goals related to our clinical programs, finance, and human resource management and, for named executive officers other than the Chief Executive Officer, individual performance. Following review and determinations of corporate and individual performance for Fiscal Year 2025, our board of directors determined that the corporate performance goals were achieved at 107% of target and that the individual performance goals for Dr. Grigoryan and Dr. Silvers were achieved at 110% of target. The annual cash bonus paid to each of our named executive officers for Fiscal Year 2025 is set forth in the "Non-Equity Incentive Plan Compensation" column of the "2025 Summary Compensation Table" above.

Equity Incentive Compensation

Although we do not yet have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe equity grants provide our executives with a strong link to our long-term performance, create an ownership culture, and help to align the interests of our executives and our stockholders. In addition, we believe equity grants promote executive retention because they incentivize our executive officers to remain in our service during the vesting period. During Fiscal Year 2025, we granted our named executive officers options to purchase our common stock that vest over four years. For additional information regarding outstanding equity awards held by our named executive officers as of December 31, 2025, see the "Outstanding Equity Awards at 2025 Fiscal Year End" table below.

401(k) Plan and Health and Welfare Benefits

We currently maintain a tax-qualified 401(k) retirement savings plan (the "401(k) Plan") for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) Plan on the same terms as other full-time employees. Our 401(k) Plan is intended to qualify for favorable tax treatment under Section 401(a) of the Code and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. We provide matching contributions under the 401(k) Plan equal to 100% of the first 1% of each employee's contributions and 50% of the next 5% contributed, up to a maximum of 3.5% of the employee's annual eligible compensation. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) Plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies. Other than the 401(k) plan, we do not provide any qualified or non-qualified retirement or deferred compensation benefits to our employees, including our named executive officers.

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including medical, dental, and vision benefits, short-term and long-term disability insurance, and basic life and AD&D insurance.

Employment Arrangements for Named Executive Officers

We initially entered into offer letters with each of our named executive officers in connection with their commencement of employment, which set forth the terms and conditions of their employment, including initial base salary, initial target annual bonus opportunity, initial equity awards, and eligibility to participate in our employee benefit plans generally offered to our employees. The material terms of the offer letters are summarized below.

In connection with this offering, we have adopted a severance plan that will cover our named executive officers, which became effective as of the effectiveness of the registration statement of which this prospectus is a part.

Current Offer Letters

Michael Nally, M.B.A.

On March 2, 2021, our stockholder, Flagship Pioneering, Inc. ("Flagship Pioneering"), entered into an offer letter with Mr. Nally (the "Nally Offer Letter"), for the position of CEO-Partner of Flagship Pioneering and Chief Executive Officer of Generate, which provided for Mr. Nally's at-will employment. Pursuant to the Nally Offer Letter, Mr. Nally was eligible to receive an annual base salary from Generate and an annual incentive bonus based on the achievement of specific objectives to be agreed to by Mr. Nally and our board of directors. Mr. Nally was also eligible to participate in Flagship Pioneering's employee benefit plans generally available to similarly situated employees, subject to the terms of those plans. Mr. Nally's employment with Flagship Pioneering terminated on December 31, 2024. Following the termination of the Nally Offer Letter, Mr. Nally is an employee of Generate on an at-will basis. His services as a CEO Partner of Flagship Pioneering pursuant to a consulting agreement terminated in connection with the effectiveness of this registration statement of which this prospectus is a part.

In addition, the Nally Offer Letter provided for initial equity awards and equity awards to be granted to Mr. Nally in connection with subsequent equity financings. For information regarding outstanding equity awards held by Mr. Nally as of December 31, 2025, see the "Outstanding Equity Awards at 2025 Fiscal Year End" table below.

Gevorg Grigoryan, Ph.D.

On September 11, 2018, we entered into an offer letter with Dr. Grigoryan (the "Grigoryan Offer Letter") for the position of Founding Chief Technology Officer, which provides for Dr. Grigoryan's at-will employment. Pursuant to the Grigoryan Offer Letter, Dr. Grigoryan is eligible to receive an annual base salary and an annual incentive bonus based on the company's and Dr. Grigoryan's performance. Dr. Grigoryan is also eligible to participate in the employee benefit plans generally available to similarly situated employees, subject to the terms of those plans.

In addition, the Grigoryan Offer Letter provides for an initial equity award that was granted to Dr. Grigoryan. For information regarding outstanding equity awards held by Dr. Grigoryan as of December 31, 2025, see the “Outstanding Equity Awards at 2025 Fiscal Year End” table below.

Jason Silvers, M.D., J.D.

On May 1, 2022, we entered into an offer letter with Dr. Silvers (the “Silvers Offer Letter”) for the position of Chief Financial Officer, which provides for Dr. Silvers' at-will employment. Pursuant to the Silvers Offer Letter, Dr. Silvers is eligible to receive an annual base salary and an annual incentive bonus based on the achievement of specific milestones to be mutually agreed. Dr. Silvers is also eligible to participate in the employee benefit plans generally available to similarly situated employees, subject to the terms of those plans.

In addition, the Silvers Offer Letter provides for an initial equity award that was granted to Dr. Silvers. For information regarding outstanding equity awards held by Dr. Silvers as of December 31, 2025, see the “Outstanding Equity Awards at 2025 Fiscal Year End” table below.

Severance Plan

In connection with this offering, we have adopted an Executive Severance Plan (the “Severance Plan”), which became effective as of the effectiveness of this registration statement of which this prospectus forms a part, in which the named executive officers and certain other employees are eligible to participate.

The Severance Plan provides that upon a (i) termination of a named executive officer’s employment by us for any reason other than due to “cause,” death or “disability” or (ii) a named executive officer’s resignation for “good reason” (each as defined in the Severance Plan), in each case outside of the period beginning three months prior to and ending on the one-year anniversary of a “change in control” (as defined in the Severance Plan) (such period, the “Change in Control Period”), each named executive officer will be entitled to receive, subject to the execution and delivery of an effective and irrevocable separation agreement containing, among other things, a general release of claims in our favor and continued compliance with all applicable continuing obligations: (A) continued payment of the named executive officer’s base salary for 12 months following termination (such period, the “Severance Period”); and (B) an amount equal to the employer portion of the monthly COBRA premium until the earliest of (x) the end of the Severance Period, (y) the date the named executive officer becomes eligible for group medical plan benefits under any other employer’s group medical plan or (z) the cessation of the named executive officer’s health continuation rights under COBRA.

The Severance Plan also provides that upon a (i) termination of a named executive officer’s employment by us other than for cause or due to death or disability or (ii) resignation by a named executive officer for good reason, in each case within the Change in Control Period, each named executive officer will be entitled to receive, in lieu of the payments and benefits above and subject to the execution and delivery of an effective and irrevocable separation agreement containing, among other things, a general release of claims in our favor and continued compliance with all applicable continuing obligations: (A) a lump sum amount equal to one times (or, in the case of the Chief Executive Officer, one and a half times) the sum of the named executive officer’s base salary and target annual bonus in effect immediately prior to the date of termination or immediately prior to the change in control, if higher; (B) an amount equal to the employer portion of the monthly COBRA premium until the earliest of (x) 12 months (or, in the case of the Chief Executive Officer, 18 months) following termination of employment, (y) the date the named executive officer becomes eligible for group medical plan benefits under any other employer’s group medical plan or (z) the cessation of the named executive officer’s health continuation rights under COBRA; and (C) accelerated vesting of all outstanding and unvested equity awards held by the named executive officer that are subject solely to time-based vesting.

Pursuant to Section 280G of the Code, we may not be eligible for a U.S. federal income tax deduction on the payments and benefits provided under the Severance Plan in connection with a change in control. These payments and benefits may also subject an eligible participant, including the named executive officers, to an excise tax under Section 4999 of the Code. If the payments or benefits payable in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to the eligible participant.

Outstanding Equity Awards at 2025 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2025.

		Option Awards[1]				
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Michael Nally, M.B.A.	3/22/2021	2,210,829	—	—	0.34	5/27/2031
	—	631,665	—	—	0.34	5/27/2031
	—	315,832	—	—	0.34	5/27/2031
	9/1/2023 [2]	322,169	250,576	—	7.19	12/3/2033
	1/3/2024 [2]	230,414	296,248	—	7.25	2/28/2034
	3/1/2025 [3]	—	658,327	—	9.15	2/20/2035
Gevorg Grigoryan, Ph.D.	3/22/2022 [2]	123,436	8,229	—	6.04	4/18/2032
	9/1/2023 [2]	74,061	57,604	—	7.19	12/3/2033
	3/1/2024 [2]	57,603	74,062	—	7.25	2/8/2034
	3/1/2025 [3]	—	230,414	—	9.15	2/20/2035
Jason Silvers, M.D., J.D.	7/25/2022 [3]	710,335	163,924	—	6.05	9/29/2032
	3/1/2024 [2]	115,207	148,124	—	7.25	2/8/2034
	3/1/2025 [3]	—	213,956	—	9.15	2/20/2035

(1) All option awards were granted under the 2019 Plan.

(2) This option award vests in 16 equal quarterly installments following the vesting commencement date, subject to the named executive officer's continued service relationship through the applicable vesting date.

(3) This option award vests over four years, with 25% of the shares vesting on the first anniversary of the vesting commencement date and the remaining 75% of the shares vesting in 12 equal quarterly installments thereafter, in each case subject to the named executive officer's continued service relationship through the applicable vesting date.

Employee Benefit and Equity Compensation Plans

2019 Equity Incentive Plan

The 2019 Plan was initially adopted by our board of directors and approved by our stockholders in July 2019 and was most recently amended in February 2025 to increase the number of shares reserved for issuance thereunder. Under the 2019 Plan, we have reserved for issuance an aggregate of 31,928,901 shares of our common stock. The number of shares reserved for issuance is subject to adjustment in the event of a dividend or other distribution, reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange, or other disposition of our assets, or sale or exchange of our securities, issuance of warrants or other rights to purchase our securities, or other similar corporate transaction or event. Our board of directors has determined not to make any further awards under the 2019 Plan following the closing of this offering, but all outstanding awards under the 2019 Plan will continue to be governed by the 2019 Plan. In connection with this offering, we have adopted a new incentive equity plan under which we will grant stock-based awards following this offering, as described below under "*—2026 Equity Incentive Plan*." The following summary describes the material terms of the 2019 Plan. This summary is not a complete description of all provisions of the 2019 Plan and is qualified in its entirety by reference to the 2019 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

The shares of common stock underlying any awards under our 2019 Plan that expire, lapse, or are terminated, surrendered, or cancelled without having been exercised in full, or are otherwise forfeited in whole or part, in any case in a manner that results in any shares not being issued or being so reacquired by us, the unused shares covered by such Award are currently added back to the shares of common stock available for issuance under our 2019 Plan (and, following the completion of this offering, will be added back to the shares of common stock available for issuance under the 2026 Plan). Further, shares of common stock delivered to us to satisfy the applicable exercise or purchase price of an award under the 2019 Plan and/or any applicable tax withholding obligation with respect to an award under the 2019 Plan are currently added back to the shares of common stock available for issuance under our 2019 Plan (and, following the completion of this offering, will be added back to the shares of common stock available for issuance under the 2026 Plan).

Our board of directors has acted as administrator of the 2019 Plan. The administrator has the authority to, among other things, select, from among the individuals eligible for awards, the individuals to whom awards will be granted, make any combination of awards to participants, determine the specific terms and conditions of each award, subject to the provisions of the 2019 Plan. Persons eligible to participate in our 2019 Plan are our employees, directors, and consultants, as selected from time to time by the administrator in its discretion.

The 2019 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and (2) options that do not so qualify. The option exercise price of each option is determined by the administrator but may not be less than 100% of the fair market value of the common stock on the date of grant or, in the case of an incentive stock option granted to a 10% owner, 110% of the fair market value of our common stock on the date of grant. The term of each option is fixed by the administrator and may not exceed ten years from the date of grant (or five years in the case of certain incentive stock option grants). The administrator determines at what time or times each option may be exercised.

The administrator of the 2019 Plan may award restricted shares of common stock, restricted stock units, and other awards based upon or payable in shares of common stock, subject to such conditions and restrictions as it determines.

In the event of certain corporate transactions and events, including a dividend or other distribution, reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange, or other disposition of our assets, or sale or exchange of our securities, issuance of warrants or other rights to purchase our securities, or other similar corporate transaction or event, the administrator of the 2019 Plan may make appropriate adjustments to the maximum number of shares reserved for issuance under the 2019 Plan, the number and kind of securities subject to outstanding awards under the 2019 Plan, the grant or exercise price of any outstanding awards under the 2019 Plan, and the terms and condition of any outstanding awards under the 2019 Plan.

The 2019 Plan provides that in the event of certain events affecting our capitalization (including a change in control) or any change in applicable laws or accounting principles, the plan administrator may take any one or a combination of actions with respect to awards under the 2019 Plan in order to prevent dilution or enlargement of benefits under the 2019 Plan, facilitate such corporate event, or give effect to such change in applicable law or accounting principle, including cancellation of awards in exchange for a payment of cash or other property, accelerating the vesting of awards, providing for the assumption, continuation, or substitution of awards by the successor or survivor corporation, if applicable, adjusting of the number and type of securities subject to awards and the terms and conditions of awards, replacing awards with other rights or property, or terminating awards.

The board of directors may amend or discontinue the 2019 Plan at any time, subject to stockholder approval where required by applicable law.

No awards may be granted under our 2019 Plan after the date that is ten years from the date our 2019 Plan was adopted by the board of directors. As described above, our board of directors has determined not to make any further awards under our 2019 Plan following the completion of this offering.

2026 Equity Incentive Plan

The 2026 Plan was adopted by our board of directors on February 19, 2026, was approved by our stockholders on February 20, 2026, and became effective as of the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. The 2026 Plan replaces the 2019 Plan. The 2026 Plan allows us to make stock-based and cash-based incentive awards to our officers, employees, directors, and consultants. The following summary describes the material terms of the 2026 Plan. This summary is not a complete description of all provisions of the 2026 Plan and is qualified in its entirety by reference to the 2026 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Authorized Shares. We have initially reserved 11,852,719 shares of our common stock for the issuance of awards under the 2026 Plan (the “Initial Limit”). The 2026 Plan provides that the number of shares reserved and available for issuance under the 2026 Plan will automatically increase on January 1, 2027 and each January thereafter during the term of the 2026 Plan, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by the compensation committee (the “Annual Increase”). The number of shares reserved for issuance under the 2026 Plan will be subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

The shares we issue under the 2026 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards under the 2019 Plan and the 2026 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2026 Plan. The maximum number of shares of common stock that may be issued pursuant to incentive stock options shall not exceed the Initial Limit, cumulatively increased on January 1, 2027 and on each January 1 thereafter by the lesser of the Annual Increase for such year or 11,852,000 shares of common stock.

Non-Employee Director Compensation Limit. The grant date fair value of all awards under the 2026 Plan and all other cash compensation paid by us to any non-employee director during any one calendar year for services as a non-employee director may not exceed $750,000; provided, however, that such amount shall be $1,000,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to our board of directors.

Plan Administration. The 2026 Plan is administered by our compensation committee. Our compensation committee has the full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award, and to determine the specific terms and conditions of each award, subject to the provisions of the 2026 Plan. The compensation committee is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent.

Eligibility. Persons eligible to participate in the 2026 Plan will be those employees, non-employee directors, and consultants selected from time to time by our compensation committee in its discretion.

Stock Options. The 2026 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option (i) is granted pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code, (ii) is granted to an individual who is not subject to United States income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant (or five years in the case of certain incentive stock options). Our compensation committee will determine at what time or times each option may be exercised.

Stock Appreciation Rights. Our compensation committee may award stock appreciation rights under the 2026 Plan subject to such conditions and restrictions as it determines. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of our common stock on the date of grant unless the stock appreciation right (i) is granted pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code, (ii) is granted to an individual who is not subject to United States income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Restricted Stock and Restricted Stock Units. Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it determines. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or other service relationship with us through a specified vesting period.

Unrestricted Stock Awards. Our compensation committee may grant shares of common stock that are free from any restrictions under the 2026 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Dividend Equivalent Rights. Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Cash-Based Awards. Our compensation committee may grant cash bonuses under the 2026 Plan to participants, subject to the achievement of certain performance goals.

Sale Event. The 2026 Plan provides that, upon the effectiveness of a "sale event" (as defined in the 2026 Plan), an acquirer or successor entity may assume, continue, or substitute outstanding awards under the 2026 Plan. To the extent that awards granted under the 2026 Plan are not assumed, continued, or substituted by the successor entity, the 2026 Plan and all awards granted under the 2026 Plan will terminate. In such case, except as may be otherwise provided in the relevant award agreement, all awards with time-based vesting, conditions, or restrictions will become fully vested and exercisable or nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and exercisable or nonforfeitable in connection with the sale event in the compensation committee's discretion or to the extent specified in the relevant award agreement. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise any options and stock appreciation rights (to the extent exercisable) within a specified time period, as determined by the compensation committee, prior to the sale event or (ii) we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights; provided, that any options or stock appreciation rights with exercise prices equal to or greater than such per share consideration will be cancelled for no consideration. In addition, we may make or provide for a payment, in cash or in kind, to the participants holding other awards in an amount equal to the per share consideration payable to stockholders in the sale event multiplied by the number of vested shares of common stock under such awards.

Amendment. Our board of directors may amend or discontinue the 2026 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may materially and adversely affect rights under an award without the holder's consent. Certain amendments to the 2026 Plan require the approval of our stockholders. The compensation committee is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent.

No awards may be granted under the 2026 Plan after the date that is ten years from the effective date of the 2026 Plan. No awards have been made under the 2026 Plan prior to the date hereof.

2026 Employee Stock Purchase Plan

The ESPP was adopted by our board of directors on February 19, 2026, was approved by our stockholders on February 20, 2026, and became effective as of the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. The ESPP has two components: a component intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code (the "423 Component"), and a component that is not intended to so qualify (the "Non-423 Component"). Except as otherwise provided, the Non-423 Component will be operated and administered in the same manner as the 423 Component, except where prohibited by law. The following summary describes the material terms of the ESPP. This summary is not a complete description of all provisions of the ESPP and is qualified in its entirety by reference to the ESPP, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Authorized Shares. The ESPP initially reserves and authorizes the issuance of up to a total of 1,481,589 shares of our common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2027 and each January 1 thereafter through January 1, 2036, by the least of (i) 1% of the outstanding number of shares of our common stock on the immediately preceding December 31, (ii) 2,963,178 shares of common stock, or (iii) such number of shares of common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

Eligibility. All individuals classified as employees on our payroll records or the payroll records of a "designated company" (as defined in the ESPP) as of the first day of the applicable offering period are eligible to participate in the ESPP, provided that the ESPP administrator may determine in advance of an offering that employees are eligible only if, as of the first day of the offering, they (a) are customarily employed by us or a designated company for more than 20 hours a week (or such greater amount determined by the ESPP administrator), (b) are customarily employed by us or a designated company for more than five months per calendar year, (c) have completed a minimum period of employment as determined by the ESPP administrator, provided such service requirement does not exceed two years of employment, and/or (d) they are not highly compensated employees. However, any employee who owns, or as a result of participation in the ESPP would own or hold, 5% or more of the total combined voting power or value of all classes of our stock will not be eligible to purchase shares of common stock under the ESPP.

Offerings. We may make one or more offerings each year to our employees to purchase shares of our common stock under the ESPP, each of which may consist of one or more purchase periods. Offerings will begin and end on the dates determined by the ESPP administrator, except that no offering will exceed 27 months in duration. Each eligible employee may elect to participate in any offering by submitting an enrollment form by the deadline established by the ESPP administrator.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions at a minimum of 1% and up to a maximum of 15% of such participant's eligible compensation during an offering period (or such other minimum and maximum as determined by the administrator in advance of an offering). Unless the participating employee has previously withdrawn from the offering, such participant's accumulated payroll deductions will be used to purchase shares of our common stock on the last day of each purchase period at a price equal to 85% of the fair market value of the shares on the first day or the last day of the purchase period, whichever is lower, provided that no more than the number of shares of common stock determined by dividing $25,000 by the fair market value of our common stock on the first day of such offering period (or such other maximum number of shares as may be established by the administrator) may be purchased by any one employee during any purchase period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of our common stock, valued at the start of the offering period, under the ESPP for each calendar year during which any option granted to the employee is outstanding at any time.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

Sale Event. In the case of and subject to the consummation of a "sale event" (as defined in the ESPP), the administrator of the ESPP, in its discretion, and on such terms and conditions as it deems appropriate, is authorized to take any one or more of the following actions under the ESPP or with respect to any right under the ESPP to facilitate such transactions or events: (i) provide for either (A) termination of any outstanding option in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such option had such option been currently exercisable or (B) the replacement of such outstanding option with other options or property selected by the administrator of the ESPP in its sole discretion; (ii) provide that the outstanding options under the ESPP shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for similar options covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices; (iii) make adjustments in the number and type of shares of common stock (or other securities or property) subject to outstanding options under the ESPP and/or in terms and conditions of outstanding options and options that may be granted in the future; (iv) provide that the offering with respect to which an option relates will be shortened by setting a new exercise date on which such offering period will end; and (v) provide that all outstanding options shall terminate without being exercised and all amounts in the accounts of participants shall be promptly refunded.

Amendment. The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of our common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

Senior Executive Cash Incentive Bonus Plan

On February 18, 2026, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan (the "Bonus Plan"), which became effective upon the effectiveness of the registration statement of which this prospectus forms a part. The Bonus Plan provides for cash bonus payments based upon company and individual performance targets established by our compensation committee. The performance targets will be related to financial or operational measures or objectives with respect to our company ("Corporate Performance Goals"), as well as individual performance objectives. The following summary describes the material terms of the Bonus Plan. This summary is not a complete description of all provisions of the Bonus Plan and is qualified in its entirety by reference to the Bonus Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Our compensation committee may select corporate performance goals from among the following: research and development, publication, clinical, and/or regulatory milestones; revenue; corporate revenue; earnings before interest, taxes, depreciation, and amortization; net income (loss) (either before or after interest, taxes, depreciation, and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions or strategic transactions, including licenses, collaborations, joint ventures or promotion arrangements; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention and recruiting, and other human resources matters; operating income; and/or net annual recurring revenue; or any other performance goal selected by the compensation committee, any of which may be (A) measured in absolute terms or as compared to any incremental increase, (B) measured in terms of growth, (C) as compared to results of a peer group, (D) measured against the market as a whole, compared to applicable market indices, and/or (E) measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate Performance Goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but not later than 74 days after the end of the year in which such performance period ends. Subject to any rights contained in any agreement between the executive officer and us, an executive officer shall be required to be employed by us on the bonus payment date to be eligible to receive a bonus payment under the Bonus Plan. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

Equity Grants to Employees (Including Named Executive Officers)

In connection with this offering, our board of directors approved grants to certain of our employees, including our named executive officers, of options to purchase an aggregate of 4,562,572 shares of our common stock (the “Employee IPO Grants”) under the 2026 Plan. The Employee IPO Grants to Mr. Nally, Dr. Grigoryan and Dr. Silvers include options to purchase 1,963,683, 196,368 and 274,493 shares of our common stock, respectively. The Employee IPO Grants were contingent on and subject to the effectiveness of the registration statement of which this prospectus forms a part. The Employee IPO Grants each have an exercise price per share equal to the initial public offering price of $16.00 per share and expire ten years from the date of grant. The Employee IPO Grants to the named executive officers will vest as follows: 844,595 shares underlying Mr. Nally’s grant, 196,368 shares underlying Dr. Grigoryan’s grant and 274,493 shares underlying Dr. Silvers’ grant will vest in 48 equal monthly installments following the February 19, 2026 vesting commencement date, subject to the named executive officer's continued service relationship through each applicable vesting date, and the remaining portion of the Employee IPO Grants to the named executive officers will vest over four years, with 50% vesting on each of the third and fourth anniversaries of the February 19, 2026 vesting commencement date, subject in each case to the named executive officer’s continued service relationship through the applicable vesting date.

Each of our non-employee directors will also receive equity grants in connection with this offering, as described in more detail below under “*Director Compensation—Equity Grants to Non-Employee Directors*.”

DIRECTOR COMPENSATION

2025 Director Compensation Table

The following table presents the compensation awarded to, earned by, or paid to each person who served as a non-employee member of the board of directors for their services to us during Fiscal Year 2024. During Fiscal Year 2025, Mr. Nally served as a member of our board of directors but received no additional compensation for his services as member of our board of directors. The compensation for Fiscal Year 2025 received by Mr. Nally as our Chief Executive Officer is presented in "*Executive Compensation—2025 Summary Compensation Table*" above.

Name	Fees Earned or Paid in Cash ($)[1]	Option Awards ($)[2] [3]	Total ($)
Noubar B. Afeyan, Ph.D.	—	221,500	221,500
Frances H. Arnold, Ph.D.	50,000	221,500	271,500
Stéphane Bancel, M.B.A.	—	221,500	221,500
Marsha H. Fanucci, M.B.A.[4]	—	886,000	886,000
Jane L. Mendillo, M.B.A.	—	221,500	221,500
Paul Parker, M.B.A.[5]		886,000	886,000
Gary P. Pisano, Ph.D.[6]	—	221,500	221,500
Nancy Simonian, M.D.	—	—	—
Rupert Vessey, B.M. B.Ch., D.Phil., FRCP	—	—	—

(1) The amounts reported represent the cash fees each director received for their services to our board of directors during Fiscal Year 2025.

(2) The amounts reported represent the aggregate grant date fair value of stock option awards granted to our directors in Fiscal Year 2025, computed in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures related to service-based vesting. The assumptions used in calculating the grant date fair values of the option awards reported in this column are set forth in Note 4 of our consolidated financial statements for Fiscal Year 2025, included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these option awards and do not correspond to the actual economic value that may be received by our directors upon the exercise of the option awards or any sale of the underlying securities.

(3) As of December 31, 2025, each non-employee director held options to purchase the aggregate number of shares of our common stock as set forth in the table below. As of December 31, 2025, none of the non-employee directors held any unvested stock awards.

(4) Ms. Fanucci joined the board of directors on March 11, 2025.

(5) Mr. Parker joined the board of directors on June 5, 2025.

(6) Dr. Pisano resigned from the board of directors on June 5, 2025, but continues to serve as an advisor.

Name	Shares Underlying Outstanding Option Awards at Fiscal Year-End
Noubar B. Afeyan, Ph.D.	65,832
Frances H. Arnold, Ph.D.	98,748
Stéphane Bancel, M.B.A.	98,748
Marsha H. Fanucci, M.B.A.	131,665
Paul Parker, M.B.A.	131,665
Gary P. Pisano, Ph.D.	362,079
Jane L. Mendillo, M.B.A.	164,581
Nancy A. Simonian, M.D.	131,665
Rupert Vessey, B.M. B.Ch., D.Phil., FRCP	131,665

Non-Employee Director Compensation Policy

In connection with this offering, we have adopted a non-employee director compensation policy which became effective upon the effectiveness of the registration statement of which this prospectus forms a part and is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below, which amounts will be payable quarterly in arrears and prorated for partial years of service:

Board of Directors	Annual Retainer
Members	$ 50,000
Additional retainer for non-executive chair	$ 35,000
Audit Committee:	
Members (other than chair)	$ 10,000
Retainer for chair	$ 20,000
Compensation Committee:	
Members (other than chair)	$ 7,500
Retainer for chair	$ 15,000
Nominating and Corporate Governance Committee:	
Members (other than chair)	$ 5,000
Retainer for chair	$ 10,000
Science and Technology Committee:	
Members (other than chair)	$ 7,500
Retainer for chair	$ 15,000

In addition, the non-employee director compensation policy provides that, upon initial election to our board of directors, each non-employee director will be granted an initial option award with a grant date fair value of $700,000 (the “Initial Award”). The Initial Award will vest in equal annual installments over three years following the grant date, subject to continued service through the applicable vesting date. Furthermore, on the date of each annual meeting of stockholders following the completion of this offering, each non-employee director who continues as a non-employee director following such meeting will be granted an annual option award with a value of $350,000 (the “Annual Award”). Each Annual Award will vest on the earlier of the first anniversary of the date of grant and our next annual meeting of stockholders.

All outstanding equity awards granted to non-employee directors will become fully vested and exercisable upon a “sale event” (as defined in the 2026 Plan).

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director for service as a non-employee director in a calendar year period will not exceed $750,000 (or $1,000,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to our board of directors).

We will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the board of directors and committees thereof.

Equity Grants to Non-Employee Directors

In connection with this offering, our board of directors approved grants to each of our non-employee directors of options to purchase 236,488 shares of common stock (the “Director IPO Grants”) under the 2026 Plan and the non-employee director compensation policy described above. The Director IPO Grants were contingent to and subject to effectiveness of the registration statement of which this prospectus forms a part. The Director IPO Grants each have an exercise price per share equal to the initial public offering price of $16.00 per share, expire ten years from the date of grant and vest in full upon the earlier of the first anniversary of the date of grant and the first annual meeting of stockholders following the date of grant, in each case subject to the applicable director’s continued service relationship through the vesting date. Consistent with the non-employee director compensation policy, the Director IPO Grants will become fully vested and exercisable upon a "sale event" (as defined in the 2026 Plan).

Certain of our employees will also receive equity grants in connection with this offering, as described in more detail above under “*Executive Compensation—Equity Grants to Employees (Including Named Executive Officers)*.”

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements, and indemnification arrangements discussed, when required, in the sections titled "*Management*," "*Director Compensation*" and "*Executive Compensation*" and the registration rights described in the section titled "*Description of Capital Stock—Registration Rights*," the following is a description of all transactions since January 1, 2023 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets at the year-end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% or more of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities or affiliated entities, had or will have a direct or indirect material interest.

Series C Preferred Stock Financing

Between May 9, 2023 and January 21, 2025, we issued and sold an aggregate of 33,704,613 shares of our Series C convertible preferred stock, par value $0.001 per share (the "Series C preferred stock"), at a purchase price of $11.85 per share, for an aggregate purchase price of approximately $399.4 million.

The outstanding shares of Series C preferred stock will convert into shares of common stock at a rate of one share of common stock for each 1.5190 shares of Series C preferred stock upon the completion of this offering. The following table summarizes the shares of our Series C preferred stock issued to our related parties:

Purchasers	Shares of Series C Preferred Stock	Total Purchase Price
Flagship Funds(1)	5,907,170	$ 69,999,965

(1) Consists of (i) 2,531,644 shares of Series C preferred stock held by Flagship Pioneering Fund VII, L.P., (ii) 1,265,822 shares of Series C preferred stock held by Flagship Pioneering Special Opportunities Fund II, L.P. and (iii) 2,109,704 shares of Series C preferred stock held by FPN II, L.P. The Flagship Funds beneficially own more than 5% of our outstanding shares of common stock. Noubar Afeyan, Ph.D., Paul Parker, M.B.A., and Rupert Vessey, B.M. B.Ch., D.Phil., FRCP, are members of our board of directors and affiliates of the Flagship Funds. In addition, Geoffrey A. von Maltzahn, Ph.D., and Gary P. Pisano, Ph.D., were members of our board of directors at the time of the Series C preferred stock financing and are affiliates of the Flagship Funds. Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section "*Principal Stockholders*."

Flagship Agreements

Agreements with PMCo and PM LLC

On June 22, 2023, we entered into a collaboration agreement (the "Prior PMCo Agreement") with PMCo, an affiliate of Flagship Pioneering and a wholly owned subsidiary of PM LLC, pursuant to which the parties agreed to collaborate on research and development activities and share certain research and development costs with respect to certain licensed products. In addition, concurrently with the Prior PMCo Agreement, we and PM LLC entered into a Drag-Along Agreement pursuant to which PM LLC agreed to, among other things, vote in favor or certain transactions. For the years ended December 31, 2025, 2024 and 2023, we allocated $19.3 million, $7.0 million and $3.2 million of shared research and development expenses to PMCo under the Prior PMCo Agreement.

On February 4, 2026, we entered into a stock purchase agreement (the "Stock Purchase Agreement") with PM LLC, pursuant to which we have agreed to purchase, and PM LLC has agreed to sell, all of the issued and outstanding equity interests in PMCo. In consideration for such sale, PMCo, PM LLC and we have agreed to terminate the Prior PMCo Agreement and the Drag-Along Agreement, and we have agreed to pay PM LLC a portion of our net sales, if any, arising from the sale of certain products covered by certain patents or containing certain know-how ("Generate Products") developed under the

Prior PMCo Agreement. The closing of the Stock Purchase Agreement is scheduled to occur concurrently with the execution of the underwriting agreement for this offering. For more information, see "*Business—License, Collaboration and Other Agreements—Agreements with PMCo and PM LLC*."

License Agreement with Flagship

In August 2021, we entered into an agreement (the "Flagship Agreement"), with Flagship Pioneering Innovations VI, LLC ("Flagship"), an affiliate of Flagship Pioneering, pursuant to which we (i) irrevocably and unconditionally assigned to Flagship all of our right, title and interest in and to certain foundational patent rights conceived prior to our launch, which is defined as the closing of our Series B financing, and our improvements to such patent rights that cannot be practiced without infringing the foregoing patent rights (such patent rights and improvements, the "Foundational IP"), and (ii) obtained an exclusive, worldwide, royalty-bearing, sublicensable, transferable license from Flagship under such Foundational IP to develop, manufacture and commercialize any product or process or component thereof in the licensed field of human therapeutics and vaccines that would, absent the license granted to us by Flagship, infringe at least one valid claim of the Foundational IP. We utilize the rights granted to us by Flagship Pioneering under the Flagship Agreement in connection with certain aspects of the Generate Platform and GB-0895. To date, there have been no amounts paid or received by us under the Flagship Agreement. For more information regarding the Flagship Agreement, see "*Business—License and Collaboration Agreements—License Agreement with Flagship*."

Managerial Agreement with Flagship Pioneering

In August 2018, we entered into a ten-year management service agreement (the "Flagship Managerial Agreement") with Flagship Pioneering to provide management services, including accounting, human resources, information technology, legal, and consultation. We also agreed to reimburse Flagship Pioneering for certain expenses, including insurance and benefits, partner and related fees, and software licenses, incurred on our behalf. For the years ended December 31, 2025, 2024 and 2023, we recognized expense related to Flagship Pioneering of $0.6 million, $1.0 million and $2.0 million, respectively, in management services fees and other reimbursements. The Flagship Managerial Agreement was terminated in connection with the effectiveness of the registration statement of which this prospectus forms a part.

Shared Space Agreement with Cellarity

In July 2022, we entered into a shared space operating agreement, as amended in May 2024, with Cellarity, Inc. ("Cellarity"), an affiliate of Flagship Pioneering, to use a vivarium space, along with other companies affiliated with Flagship Pioneering. We pay Cellarity a monthly operating fee for using the vivarium and obtaining various services; the shared cost is variable depending on the actual usage. During the years ended December 31, 2025, 2024 and 2023, we recognized expense related to Cellarity of $0.4 million, $0.6 million and $0.7 million, respectively, reflecting upfront payments and monthly operating fees.

Employment Arrangements

We have entered into employment agreements with certain of our named executive officers, and granted stock options to our named executive officers and certain of our directors, as more fully described in "*Executive Compensation*" and "*Director Compensation*."

Agreements with our Stockholders

In connection with our preferred stock financings, we entered into an investor rights agreement, a right of first refusal and co-sale agreement, and voting agreement, in each case, with the purchasers of our preferred stock. Our amended and restated right of first refusal and co-sale agreement (the "ROFR Agreement") provides for rights of first refusal and co-sale and drag along rights in respect of sales by certain holders of our capital stock. Our amended and restated voting agreement, as amended (the "Voting Agreement"), contains provisions with respect to the election of our board of directors and its composition. The rights under each of the ROFR Agreement and Voting Agreement will terminate upon the closing of this offering.

Our amended and restated investors' rights agreement (the "Investor Rights Agreement") provides certain holders of our preferred stock with a participation right to purchase their pro rata share of new securities that we may propose to sell and issue, subject to certain exceptions. Such participation right will terminate upon the closing of this offering. The Investor Rights Agreement further provides certain holders of our capital stock with the right to demand that we file a registration statement, subject to certain limitations, and to request that their shares be covered by a registration statement that we are otherwise

filing. See the section titled "*Description of Capital Stock—Registration Rights*" appearing elsewhere in this prospectus, for additional information regarding such registration rights.

Indemnification Agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors and officers, and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board of directors. In addition, we have entered into indemnification agreements with each of our directors and executive officers, which require us to indemnify them. For more information regarding these agreements, see the section titled "*Management—Limitations on Liability and Indemnification*."

Directed Share Program

At our request, the underwriters have reserved up to 1,250,000 shares of common stock offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers, employees and certain other individuals identified by management. The directed share program will not limit the ability of our directors, officers and their family members, or holders of more than 5% of our capital stock, to purchase more than $120,000 in value of our common stock. We do not currently know the extent to which these related persons will participate in our directed share program, if at all, or the extent to which they will purchase more than $120,000 in value of our common stock. See the section titled "*Underwriting—Directed Share Program*."

Policies and Procedures for Transactions with Related Persons

Prior to the completion of this offering, we have adopted a written policy, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any series of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any series of our common stock or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related person's interest in the transaction.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of January 15, 2026 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Under these rules, beneficial ownership includes any shares of common stock as to which the individual or entity has sole or shared voting power or investment power. Unless otherwise indicated below, to our knowledge the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. We have deemed shares of common stock subject to options that are currently exercisable or exercisable within 60 days of January 15, 2026, to be outstanding and to be beneficially owned by the person holding the option for the purpose of computing the percentage ownership of that person but have not treated them as outstanding for the purpose of computing the percentage ownership of any other person.

Applicable percentage ownership before the offering is based on an aggregate of 102,451,049 shares of common stock deemed to be outstanding as of January 15, 2026, after giving effect to the automatic conversion of all outstanding shares of preferred stock into 69,333,244 shares of common stock upon the completion of this offering, and based on the initial public offering price of $16.00 per share.

The number of shares beneficially owned and applicable percentage ownership after the offering is based on 127,450,201 shares of common stock assumed to be outstanding immediately after the completion of this offering (including the sale of shares of common stock in this offering, but excluding any shares which may be purchased by any individual or entity named in the table in this offering, including through our directed share program, and assuming no exercise of the underwriters' option to purchase additional shares).

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Generate Biomedicines, Inc., 101 South Street, Suite 900, Somerville, MA 02143.

Name of Beneficial Owner	Before Offering		After Offering	
	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Shareholders:				
Entities affiliated with Flagship Funds(1)	57,985,617	56.60%	57,985,617	48.76%
Named Executive Officers and Directors:				
Michael Nally, M.B.A., *Chief Executive Officer and Director*(2)	6,813,361	6.40%	6,813,361	5.55%
Jason Silvers, M.D., J.D., *President and Chief Financial Officer*(3)	950,132	*	950,132	*
Gevorg Grigoryan, Ph.D., *Chief Technology Officer*(4)	989,137	*	989,137	*
Noubar B. Afeyan, Ph.D.(5)	58,010,304	56.61%	58,010,304	48.78%
Frances H. Arnold, Ph.D.(6)	514,319	*	514,319	*
Stéphane Bancel, M.B.A.(7)	1,234,364	1.20%	1,234,364	*
Marsha H. Fanucci, M.B.A.(8)	32,916	*	32,916	*
Jane L. Mendillo, M.B.A.(9)	115,207	*	115,207	*
Paul Parker, M.B.A.(10)	24,687	*	24,687	*
Nancy A. Simonian, M.D.(11)	57,604	*	57,604	*
Rupert Vessey, B.M. B.Ch., D.Phil., FRCP(12)	57,604	*	57,604	*
All executive officers and directors as a group (15 persons)(13)	70,219,989	64.12%	70,219,989	55.75%

*Represents beneficial ownership of less than 1%.

(1) Consists of (i) 25,016,458 shares of common stock held by Flagship VentureLabs VI LLC ("VentureLabs VI"), (ii) 12,168,390 shares of common stock issuable upon the conversion of Series A preferred stock held by Flagship Pioneering Fund VI, L.P. ("Flagship Fund VI"), (iii) 555,550 shares of common stock issuable upon the conversion of Series B preferred stock held by Flagship Fund VI, (iv) 1,944,427 shares of common stock issuable upon the conversion of Series B preferred stock held by Flagship Pioneering Special Opportunities Fund II, L.P. ("Flagship Opportunities Fund II"), (v) 833,325 shares of common stock issuable upon the conversion of Series C preferred stock held by Flagship Opportunities Fund II, (vi) 987,491 shares of common stock issuable upon the conversion of Series A preferred stock held by Nutritional Health LTP Fund, L.P. ("Nutritional LTP"), (vii) 11,202,248 shares of common stock issuable upon the conversion of Series A preferred stock held by Flagship Pioneering Fund VII, L.P. ("Flagship Fund VII"), (viii) 833,325 shares of common stock issuable upon the conversion of Series B preferred stock held by Flagship Fund VII, (ix) 1,666,651 shares of common stock issuable upon the conversion of Series C preferred stock held by Flagship Fund VII, (x) 1,388,876 shares of common stock issuable upon the conversion of Series B preferred stock held by FPN II, L.P. ("FPN II Fund" and together with VentureLabs VI, Flagship Fund VI, Flagship Opportunities Fund II, Flagship Fund VII, and Nutritional LTP, the "Flagship Funds"), (xi) 1,388,876 shares of common stock issuable upon the conversion of Series C preferred stock held by FPN II Fund. Flagship Fund VI is a member of VentureLabs VI. VentureLabs VI Manager LLC ("VentureLabs VI Manager") is the manager of VentureLabs VI. Flagship Pioneering, LLC ("Flagship Pioneering") is the manager of VentureLabs VI Manager. The General Partner of Flagship Fund VI is Flagship Pioneering Fund VI General Partner LLC ("Flagship VI GP"). The General Partner of Flagship Opportunities Fund II is Flagship Pioneering Special Opportunities Fund II General Partner LLC ("Flagship Opportunities Fund II GP"). The General Partner of Flagship Fund VII is Flagship Pioneering Fund VII General Partner LLC ("Flagship VII GP"). The general partner of FPN II Fund is FPN General Partner LLC ("FPN GP"). The general partner of Nutritional LTP is Nutritional Health LTP Fund General Partner LLC ("Nutritional LTP GP"). The manager of Flagship VI GP, Flagship Opportunities Fund II GP, Flagship VII GP, Nutritional LTP GP, and FPN GP is Flagship Pioneering (together with VentureLabs VI Manager, Flagship VII GP, Flagship VI GP, Flagship Opportunities Fund II GP and FPN GP, the "Flagship General Partners"). Noubar B. Afeyan, Ph.D., is the sole member and manager of the manager of Flagship Pioneering and may be deemed to have voting and investment control over all the shares held by the Flagship Funds. None of the Flagship General Partners nor Dr. Afeyan directly own any of the shares held by the Flagship Funds, and each of the Flagship General Partners and Dr. Afeyan disclaims beneficial ownership of such shares except to the extent of its or his pecuniary interest therein. The mailing address of the Flagship Funds is 55 Cambridge Parkway, Suite 800E, Cambridge, MA 02142.

(2) Consists of (i) 658,327 shares of common stock held by MTN 2024 GST Trust, (ii) 658,327 shares of common stock issuable upon the conversion of Series A preferred stock held by MTN 2024 GST Trust, (iii) 999,793 shares of common stock held by MTN 2024 GRAT, (iv) 552,707 shares of common stock, and (v) 3,944,207 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(3) Consists of 950,132 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(4) Consists of (i) 659,973 shares of common stock and (ii) 329,164 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(5) Consists of (i) 24,687 shares of common stock subject to options exercisable within 60 days of January 15, 2026 and (ii) the shares described in footnote (1) above.
(6) Consists of (i) 232,472 shares of common stock held by The Frances Arnold 2010 Irrevocable Trust, (ii) 232,472 shares of common stock and (iii) 49,375 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(7) Consists of (i) 724,160 shares of common stock issuable upon the conversion of Series A preferred stock held by OCHA LLC, (ii) 460,829 shares of common stock and (iii) 49,375 shares of common stock subject to options exercisable within 60 days of January 15, 2026. Mr. Bancel is the controlling unit holder and sole managing member of OCHA LLC.
(8) Consists of 32,916 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(9) Consists of 115,207 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(10) Consists of 24,687 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(11) Consists of 57,604 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(12) Consists of 57,604 shares of common stock subject to options exercisable within 60 days of January 15, 2026.
(13) Consists of (i) 28,813,035 shares of common stock, (ii) 25,740,619 shares of common stock issuable upon the conversion of Series A preferred stock, (iii) 4,722,181 shares of common stock issuable upon the conversion of Series B preferred stock, (iv) 3,888,855 shares of common stock issuable upon the conversion of Series C preferred stock and (v) 7,055,300 shares of common stock subject to options exercisable within 60 days of January 15, 2026.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation, which will become effective promptly following the completion of this offering, and the amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect on the completion of this offering.

Upon the filing of our amended and restated certificate of incorporation and the completion of this offering, our authorized capital stock will consist of 500,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share, all of which shares of preferred stock will be undesignated.

As of December 31, 2025, there were 33,116,957 shares of common stock outstanding and held of record by 130 stockholders. This amount assumes the conversion of all outstanding shares of our preferred stock into common stock, which will occur upon the completion of this offering.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Upon the completion of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Stock Options

As of December 31, 2025, 20,422,301 shares of common stock were issuable upon the exercise of outstanding stock options under the 2019 Plan, at a weighted-average exercise price of $5.91 per share; and 3,404,855 shares of our common stock were reserved for future issuance under the 2026 Plan, which became effective immediately preceding the date the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under the 2026 Plan, and any shares underlying outstanding stock awards granted under the 2019 Plan, that expire or are repurchased, forfeited, cancelled or withheld. For additional information regarding terms of our equity incentive plans, see the section titled "*Executive Compensation—Employee Benefit and Equity Compensation Plans*."

Registration Rights

Upon the completion of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, holders of 94,349,702 shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our preferred stock upon the completion of this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors' rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay all registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than four years after the completion of this offering.

Form S-1 Registration Rights

Upon the completion of this offering, certain holders of our common stock, including those issuable upon the conversion of shares of our preferred stock upon completion of this offering, will be entitled to certain demand registration rights. At any time beginning 180 days after the completion of this offering, the holders of a majority of registrable securities then outstanding may request that we register all or a portion of their shares on Form S-1 if the anticipated aggregate offering price of the shares offered would exceed $10 million. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 60 days following the effective date of the registration statement for this offering. We will not be required to effect more than two registrations pursuant to this provision of our amended and restated investors' rights agreement.

Piggyback Registration Rights

In connection with this offering, certain holders of our common stock, including those issuable upon the conversion of shares of our preferred stock upon completion of this offering, were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

Form S-3 Registration Rights

Upon the completion of this offering, certain holders of our common stock, including those issuable upon the conversion of shares of our preferred stock upon completion of this offering, will be entitled to certain Form S-3 registration rights. Holders of at least 30% of registrable securities then outstanding can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the anticipated aggregate offering price of the shares offered would exceed $5 million. We will not be required to effect more than two registrations on Form S-3 within any twelve-month period pursuant to this provision of our amended and restated investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Expiration of Registration Rights

The demand registration rights and short-form registration rights granted under the investor rights agreement will terminate on the earliest of (i) the closing of a "Deemed Liquidation Event," as such term is defined in our certificate of incorporation (as currently in effect), (ii) the fifth anniversary of the completion of this offering and (iii) such time after consummation of this offering as SEC Rule 144 or another similar exemption under the Securities Act is available for the sale of all of the securities subject to such registration rights without limitation during a three-month period without registration.

Anti-Takeover Effects of Our Certificate of Incorporation and Bylaws and Delaware Law

Our amended and restated certificate of incorporation will include, and amended and restated bylaws include, a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board of Directors Composition and Filling Vacancies

Our amended and restated certificate of incorporation will provide for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our amended and restated certificate of incorporation also will provide that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board of directors, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our amended and restated certificate of incorporation will provide that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our amended and restated bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our amended and restated certificate of incorporation will provide, and amended and restated bylaws provide, that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our amended and restated bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our amended and restated bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our amended and restated bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment to our amended and restated certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our amended and restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our amended and restated bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the amended and restated bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our amended and restated certificate of incorporation will provide for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our amended and restated certificate of incorporation will grant our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"). In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Choice of Forum

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our current or former directors, officers or other employees or stockholders to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws (including the interpretation, validity or enforceability thereof) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (iv) any action asserting a claim governed by the internal affairs doctrine.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, this choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction or the Securities Act. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our amended and restated bylaws provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Limitations on Liability and Indemnification

See the section titled "*Management—Limitations on Liability and Indemnification*" appearing elsewhere in this prospectus.

Exchange Listing

Our common stock has been approved for listing on Nasdaq under the symbol "GENB."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 150 Royall Street, Suite 101, Canton, MA 02021.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital. Although our common stock has been approved for listing on Nasdaq, we cannot assure you that there will be an active public market for our common stock.

Following the completion of this offering, based on our shares outstanding as of December 31, 2025, a total of 127,450,201 shares of common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options or warrants. Of the outstanding shares, all of the shares sold in this offering (other than any shares sold to our directors and officers pursuant to our directed share program, which are subject to lock-up agreements) will be freely tradable.

All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, summarized below.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately 1,274,502 shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock from us; or
- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 under the Securities Act ("Rule 701") generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under the 2019 Plan, the 2026 Plan and the ESPP. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-Up Arrangements

We, all of our directors and executive officers, and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us, which prevents them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock, including shares purchased by directors, officers or employees or current holders of our capital stock pursuant to our directed share program, for a period of not less than 180 days from the date of this prospectus without the prior written consent of Goldman Sachs & Co. LLC and Morgan Stanley & Co, LLC, subject to certain exceptions. See the section titled "*Underwriting*" appearing elsewhere in this prospectus for more information.

Registration Rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement of which this prospectus forms a part. See the section titled "*Description of Capital Stock—Registration Rights*" appearing elsewhere in this prospectus for more information.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS

The following discussion is a summary of material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is based on the Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), and judicial decisions, all as in effect on the date hereof. These authorities are subject to differing interpretations and may change, possibly with retroactive effect, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax, or the special tax accounting rules under Section 451(b) of the Code, and also does not address any U.S. federal non-income tax consequences, such as estate or gift tax consequences, or any tax consequences arising under any state, local or non-U.S. tax laws. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of such non-U.S. holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens, or long-term residents of the United States;
- partnerships or other entities or arrangements treated as pass-through or disregarded entities for U.S. federal income tax purposes (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, mutual funds, financial institutions, investment funds, insurance companies, brokers, dealers or traders in stock, securities, commodities or currencies;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or synthetic security or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of owning and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR NON-U.S. TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or any organization taxable as a corporation for U.S. federal income taxes that is not created or organized under the laws of the United States, any state thereof, or the District of Columbia; or
- a foreign trust or estate, the income of which is not subject to U.S. federal income tax on a net income basis.

Distributions on Our Common Stock

As described under "*Dividend Policy*," we do not currently anticipate declaring or paying, for the foreseeable future, any distributions on our capital stock. However, if we were to distribute cash or other property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will then constitute a return of capital and will first be applied against and reduce a holder's tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under "*—Gain on Disposition of Our Common Stock*" below.

Subject to the discussions below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our withholding agent with a timely and valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of the dividends and must be updated periodically. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and, if required by an applicable tax treaty, are attributable to such holder's permanent establishment or fixed base in the United States), such non-U.S. holder generally will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder generally must furnish a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. Holder's conduct of a trade or business within the United States to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected dividends, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other taxable disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation ("USRPHC") for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not "regularly traded" on an "established securities market" within the meaning of applicable Treasury Regulations, during the calendar year in which the sale or other disposition occurs.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

Determining whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our worldwide real property interests and our other trade or business assets. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we have not been, are not currently or will not in the future become a USRPHC. Even if we are treated as a USRPHC, gain realized by a non-U.S. holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the non-U.S. holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (a) the five-year period preceding the disposition or (b) the holder's holding period and (2) our common stock is "regularly traded" on an "established securities market," within the meaning of applicable U.S. Treasury Regulations. There can be no assurance that our common stock qualifies as regularly traded on an established securities market for purposes of the rules described above. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we have been, are or were to become a USRPHC.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of distributions on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or otherwise establishes an exemption, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Foreign Entities

Sections 1471 through 1474 of the Code, which are commonly referred to as FATCA, impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally imposes a U.S. federal withholding tax of 30% on certain payments made to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent a certification that it does not have any "substantial United States owners" or provides information identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our common stock. However, proposed regulations under FATCA provide for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of from property of a type that can produce U.S.-source dividends or interest. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA withholding does not apply to gross proceeds from sales or other dispositions of our common stock.

Prospective investors are encouraged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT AND PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC and Morgan Stanley & Co. LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	7,737,500
Morgan Stanley & Co. LLC	7,737,500
Piper Sandler & Co.	3,175,000
Guggenheim Securities, LLC	3,175,000
Cantor Fitzgerald & Co.	3,175,000
Total	25,000,000

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 3,750,000 shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days from the date of this prospectus. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase 3,750,000 additional shares.

Paid by Us	No Exercise	Full Exercise
Per Share	$ 1.04	$ 1.04
Total	$ 26,000,000	$ 29,900,000

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $0.624 per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to their receipt and acceptance of the shares being offered and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors and holders of substantially all of our shares of common stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC and Morgan Stanley & Co. LLC. See section titled "*Shares Eligible for Future Sale*" for a discussion of certain transfer restrictions.

The restrictions on transfers or other dispositions by our officers, directors and holders of common stock described in the immediately preceding paragraph do not apply to, subject to certain limitations, the following transfers: (i) as one or more *bona fide* gifts or charitable contributions, or for bona fide estate planning purposes, (ii) upon death by will, testamentary document or intestate succession, (iii) to any immediate family member of the transferor or any trust for the direct or indirect benefit of the transferor or any immediate family member of the transferor, (iv) to any corporation, partnership, limited liability company or other entity, in each case, all of the beneficial ownership interests of which are held by the transferor or any immediate family member(s) of the transferor, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i)-(iv), (vi) if the transferor is a corporation, partnership, limited liability company, trust or other business entity, to an affiliate of such entity or as part of a distribution, transfer or disposition solely to its stockholders, partners, members or other equityholders or to the estate of any such stockholders, partners, members or other equityholders, (vii) by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement, (viii) to us from an employee of ours upon death, disability or termination of employment, in each case, of such employee, (ix) acquired in the public offering of the securities offered by this prospectus (other than any issuer-directed shares of common stock purchased in the public offering of the securities offered by this prospectus by an officer or director of the company) or in open market transactions after the pricing of the public offering of the securities offered by this prospectus, (x) to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of common stock that are scheduled to expire or automatically vest during the restricted period, (xi) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, (xii) transfers or dispositions of shares of common stock or such other securities pursuant to a bona fide tender offer for shares of our capital stock, merger, consolidation or other similar transaction made to all holders of our securities involving a change of control (as defined in the agreement) of us that has been approved by our board of directors, or (xiii) the conversion of any convertible preferred stock into, or the exercise of any option or warrant for, shares of common stock.

The restrictions on transfers or other dispositions by us described above do not apply with respect to (i) the shares to be sold in this offering, (ii) shares of common stock or any securities convertible into, or exercisable for, shares of common stock issued by us upon exercise or settlement of options, warrants or restricted stock units outstanding as of the date of this prospectus and described in this prospectus, (iii) the grant of any shares of common stock or any securities convertible into, or exercisable for, shares of common stock (including, without limitation, options, warrants, restricted stock or restricted stock units) pursuant to employee equity-based compensation plans, incentive plans, stock plans, dividend reinvestment plans or other arrangements in place as of the date of this prospectus and described in this prospectus, (iv) the filing of a registration statement on Form S-8 in connection with the registration of securities issuable under any employee equity-based compensation plan, incentive plan, stock plan or dividend reinvestment plan adopted and approved by our board of directors prior to the date of this prospectus and described in this prospectus, or (v) shares of common stock or other securities issued in connection with any bona fide merger, joint venture, strategic alliance, commercial or other collaborative transaction, or the acquisition or license by the company of the business, property, technology or other assets of another individual or entity that is an unaffiliated third party of the company, or the assumption of an employee benefit plan in connection with such a merger or acquisition, provided that, in the case of clause (v), the aggregate number of shares of our common stock that we may sell or issue or agree to sell or issue may not exceed 5% of the total number of shares of our common stock issued and outstanding immediately following this offering, and each recipient of any such shares of our common stock issued pursuant to clause (v) during such period must execute and deliver to the representatives an agreement having substantially the same terms as those agreements governing the securities described above prior to, or concurrently with, such issuance or sale.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of the business potential and our earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

Our common stock has been approved for listing on Nasdaq under the symbol “GENB.”

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any “covered short position” by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the “covered short position,” the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such “naked” short position by purchasing shares in the open market. A “naked” short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, will be approximately $5,200,000. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to $60,000. In addition, the underwriters have agreed to reimburse us for certain expenses incurred in connection with the offering.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively traded securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Directed Share Program

At our request, the underwriters have reserved up to 5% of the shares of common stock to be issued by us and offered by this prospectus for sale, at the initial public offering price, to our directors, officers, employees and certain other individuals identified by management. The sales will be made at our direction by Morgan Stanley & Co. LLC and its affiliates through a directed share program. Any shares sold in the directed share program to our directors or officers who have entered into lock-up agreements described above will be subject to the provisions of such lock-up agreements. The number of shares of common stock available for sale to the general public will be reduced to the extent such persons purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area (each, a "Relevant Member State"), an offer to the public of any shares may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares may be made at any time under the following exemptions under the EU Prospectus Regulation:

a) to any legal entity which is a "qualified investor" as defined under the EU Prospectus Regulation;

b) to fewer than 150 natural or legal persons (other than "qualified investors" as defined under the EU Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

c) in any other circumstances falling within Article 1(4) of the EU Prospectus Regulation,

provided that no such offer of shares shall result in a requirement for us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or a supplemental prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, warranted and agreed to and with each of the representatives and us that it is a qualified investor within the meaning of Article 2 of the EU Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 1(4) of the EU Prospectus Regulation, each financial intermediary will also be deemed to have represented, warranted and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public, other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We and our affiliates, and the representatives and their affiliates, will rely upon the truth and accuracy of the foregoing representations, warranties and agreements. Notwithstanding the above, a person who is not a "qualified investor" and who has notified the representatives of such fact in writing may, with the prior consent of the representatives, be permitted to acquire shares in the offer.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "EU Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom except that the shares may be offered to the public in the United Kingdom at any time:

a) where the offer is conditional on the admission of the shares to trading on the London Stock Exchange plc's main market (in reliance on the exception in paragraph 6(a) of Schedule 1 of the POATR);

b) to any qualified investor as defined under paragraph 15 of Schedule 1 of the POATR;

c) to fewer than 150 persons (other than qualified investors as defined under paragraph 15 of Schedule 1 of the POATR), subject to obtaining the prior consent of the underwriters for any such offer; or

d) in any other circumstances falling within Part 1 of Schedule 1 of the POATR.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication to any person which presents sufficient information on: (a) the shares to be offered; and (b) the terms on which they are to be offered, to enable an investor to decide to buy or subscribe for the shares and the expression "POATR" means the Public Offers and Admissions to Trading Regulations 2024.

Canada

The shares may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) ("Securities and Futures Ordinance"), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the "Corporations Act");
- has not been, and will not be, lodged with the Australian Securities and Investments Commission ("ASIC"), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act ("Exempt Investors").

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares of our common stock under this prospectus will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares of our common stock you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares of our common stock to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for six months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32").

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for six months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended) (the "FIEA"). The shares may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Brazil

THE OFFER AND SALE OF THE SHARES HAVE NOT BEEN AND WILL NOT BE REGISTERED WITH THE BRAZILIAN SECURITIES COMMISSION (COMISSÃO DE VALORES MOBILIÁRIOS, OR "CVM") AND, THEREFORE, WILL NOT BE CARRIED OUT BY ANY MEANS THAT WOULD CONSTITUTE A PUBLIC OFFERING IN BRAZIL UNDER CVM RESOLUTION NO 160, DATED 13 JULY 2022, AS AMENDED OR UNAUTHORIZED DISTRIBUTION UNDER BRAZILIAN LAWS AND REGULATIONS. THE SHARES MAY ONLY BE OFFERED TO BRAZILIAN PROFESSIONAL INVESTORS (AS DEFINED BY APPLICABLE CVM REGULATION), WHO MAY ONLY ACQUIRE THE SHARES THROUGH A NON-BRAZILIAN ACCOUNT, WITH SETTLEMENT OUTSIDE BRAZIL IN NON-BRAZILIAN CURRENCY. THE TRADING OF THESE SHARES ON REGULATED SECURITIES MARKETS IN BRAZIL IS PROHIBITED.

Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the "FSCMA"), and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the "FETL"). Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

LEGAL MATTERS

The validity of the shares of our common stock being offered in this prospectus will be passed upon for us by Goodwin Procter LLP. Certain partners of Goodwin Procter LLP and of Latham & Watkins LLP have a beneficial interest in an aggregate of less than 1% of our securities. Latham & Watkins LLP is representing the underwriters in this offering.

EXPERTS

The consolidated financial statements of Generate Biomedicines Inc. at December 31, 2025 and 2024, and for each of the two years ended December 31, 2025, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-1 (File Number 333-293204) under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

We currently do not file periodic reports with the SEC. On the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the website of the SEC referred to above.

We also maintain a website at *www.generatebiomedicines.com*. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference. Upon completion of this offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendment to those reported filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Generate Biomedicines, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Generate Biomedicines, Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, convertible preferred stock, and non-controlling interest and stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2022.

Boston, Massachusetts

February 4, 2026 except for Note 21(b), as to which the date is February 23, 2026

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2024	**2025**
Assets		
Current assets:		
Cash and cash equivalents	$ 176,269	$ 121,650
Marketable securities	217,358	99,848
Restricted cash and cash equivalents (VIE)	1,427	339
Accounts receivable	308	—
Prepaid expenses and other current assets	12,129	12,528
Total current assets	407,491	234,365
Property and equipment, net	37,692	29,151
Operating lease right-of-use assets	63,376	59,860
Other assets	9,700	6,806
Total assets	$ 518,259	330,182
Liabilities, convertible preferred stock, non-controlling interest and stockholders' deficit		
Current liabilities:		
Accounts payable[(1)]	$ 5,667	3,837
Accrued expenses and other current liabilities	21,771	42,164
Deferred revenue – current	42,425	21,194
Current portion of finance lease liabilities	8,932	4,311
Operating lease liability, current	7,785	10,697
Current portion of restricted stock repurchase liability	46	—
Total current liabilities	86,626	82,203
Non-current liabilities:		
Warrant to purchase convertible preferred stock	1,092	1,205
Finance lease liabilities, net of current portion	6,447	2,908
Deferred revenue – non-current	15,174	4,511
Operating lease liability – non-current	53,808	50,610
Other long term liabilities	349	116
Total liabilities	163,496	141,553
Commitments and contingencies (Note 15)		
Convertible preferred stock	789,853	811,826
Non-controlling interest	(571)	(7,232)
Stockholders' deficit:		
Common stock, $0.001 par value; 195,956,735 and 200,456,735 shares authorized as of December 31, 2024 and 2025, respectively; 32,829,805 and 33,116,957 shares issued as of December 31, 2024 and 2025, respectively; 32,691,628 and 33,116,957 shares outstanding as of December 31, 2024 and 2025, respectively	33	33
Additional paid-in capital	38,469	60,189
Accumulated other comprehensive income	118	106
Accumulated deficit	(473,139)	(676,293)
Total stockholders' deficit	(434,519)	(615,965)
Total liabilities, convertible preferred stock, non-controlling interests and stockholders' deficit	$ 518,259	$ 330,182

(1) Includes related party amounts of $0.3 million for the year ended December 31, 2024, and $0.2 million for the year ended December 31, 2025. See Note 17 for details of related party amounts.

The accompanying notes are an integral part of these consolidated financial statements.

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2024	**2025**
Collaboration revenue	$ 20,459	$ 31,893
Operating expenses:		
Research and development[1]	175,311	224,698
General and administrative[2]	42,087	42,260
Total operating expenses	217,398	266,958
Loss from operations	(196,939)	(235,065)
Other income (expense), net		
Change in fair value of preferred stock warrant liability	(154)	(113)
Interest expense	(2,118)	(1,136)
Interest income	18,118	13,661
Foreign currency exchange loss	(79)	(149)
Total other income (expense), net	15,767	12,263
Loss before provision for income tax	(181,172)	(222,802)
Provision for Income taxes	(212)	(163)
Net loss	(181,384)	(222,965)
Net loss attributable to non-controlling interests	(7,613)	(19,811)
Net loss attributable to Generate Biomedicines, Inc. stockholders	(173,771)	(203,154)
Convertible preferred stock accrued dividends	(40,006)	(46,369)
Net loss attributable to Generate Biomedicines, Inc. common stockholders	$ (213,777)	$ (249,523)
Net loss per share, basic and diluted	$ (6.66)	$ (7.57)
Weighted average common shares outstanding, basic and diluted	32,084,572	32,974,656
Comprehensive loss:		
Net loss	(181,384)	(222,965)
Unrealized gain (loss) on marketable securities	69	(12)
Comprehensive loss	$ (181,315)	$ (222,977)
Comprehensive loss attributable to non-controlling interest	(7,613)	(19,811)
Comprehensive loss attributable to Generate Biomedicines, Inc. stockholders	$ (173,702)	$ (203,166)

(1) Includes related party amounts of $0.6 million for the year ended December 31, 2024, and $0.4 million for the year ended December 31, 2025. See Note 17 for details of related party amounts.
(2) Includes related party amounts of $1.0 million for the year ended December 31, 2024, and $0.6 million for the year ended December 31, 2025. See Note 17 for details of related party amounts.

The accompanying notes are an integral part of these consolidated financial statements.

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK, NON-CONTROLLING INTEREST AND STOCKHOLDERS' DEFICIT
(in thousands, except share data)

	Convertible Preferred Stock		Non-Controlling Interest	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount		Shares	Amount				
Balance at December 31, 2023	95,321,482	$ 693,548	$ 2,042	31,593,872	$ 32	$ 17,693	$ 49	$ (299,368)	$ (281,594)
Issuance of series C convertible preferred stock (net of issuance costs of $145)	8,139,234	96,305	—	—	—	—	—	—	—
Contributions from non-controlling interests	—	—	5,000	—	—	—	—	—	—
Exercise of stock options	—	—	—	545,050	—	1,127	—	—	1,127
Stock-based compensation	—	—	—	—	—	19,465	—	—	19,465
Vesting of restricted stock	—	—	—	552,706	1	184	—	—	185
Unrealized gain on marketable securities	—	—	—	—	—	—	69	—	69
Net loss attributable to Generate Biomedicines, Inc. stockholders	—	—	(7,613)	—	—	—	—	(173,771)	(173,771)
Balance at December 31, 2024	103,460,716	$ 789,853	$ (571)	32,691,628	$ 33	$ 38,469	$ 118	$ (473,139)	$ (434,519)
Issuance of series C convertible preferred stock (net of issuance costs of $28)	1,856,539	21,973	—	—	—	—	—	—	—
Contributions from non-controlling interests	—	—	13,150	—	—	—	—	—	—
Exercise of stock options	—	—		287,152	—	1,097	—	—	1,097
Stock-based compensation	—	—	—	—	—	20,577	—	—	20,577
Vesting of restricted stock	—	—	—	138,177	—	46	—	—	46
Unrealized loss on marketable securities	—	—	—	—	—	—	(12)	—	(12)
Net loss attributable to Generate Biomedicines, Inc. stockholders	—	—	(19,811)	—	—	—	—	(203,154)	(203,154)
Balance at December 31, 2025	105,317,255	$ 811,826	$ (7,232)	33,116,957	$ 33	$ 60,189	$ 106	$ (676,293)	$ (615,965)

The accompanying notes are an integral part of these consolidated financial statements.

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2024	2025
Operating activities		
Net loss	$ (181,384)	$ (222,965)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of property and equipment	(10)	(64)
Amortization and accretion on marketable securities	(5,448)	(2,783)
Non-cash stock-based compensation	19,465	20,577
Non-cash lease expense	6,006	5,941
Depreciation and amortization	15,349	13,178
Changes in fair value of preferred stock warrant liability	154	113
Changes in operating assets and liabilities:		
Accounts receivable	(213)	308
Prepaid expenses and other current assets	(5,378)	(166)
Other assets	(3,499)	4,835
Accounts payable	3,499	(2,130)
Operating lease liabilities	(5,550)	(2,710)
Other long term liabilities	349	(233)
Accrued expenses and other liabilities	4,369	17,374
Deferred revenue	34,541	(31,894)
Net cash used in operating activities	(117,750)	(200,619)
Investing activities		
Proceeds from disposal of property and equipment	10	—
Purchase of marketable securities	(282,979)	(164,731)
Purchases of property and equipment	(3,447)	(3,514)
Proceeds from sales and maturities of marketable securities	228,691	285,012
Net cash used in investing activities	(57,725)	116,767
Financing activities		
Proceeds from issuance of convertible preferred stock, net of issuance costs	96,324	21,973
Contributions from non-controlling interests	5,000	13,150
Proceeds from exercise of stock options	1,127	1,097
Payments on finance lease obligations	(11,124)	(8,161)
Net cash provided by financing activities	91,327	28,059
Net decrease in cash, cash equivalents and restricted cash	(84,148)	(55,793)
Cash, cash equivalents and restricted cash at the beginning of period	265,979	181,831
Cash, cash equivalents and restricted cash at end of period	$ 181,831	$ 126,038
Cash and cash equivalents, end of period	176,269	121,650
Restricted cash and cash equivalents (VIE)	1,427	339
Long-term restricted cash	4,135	4,049
Cash, cash equivalents and restricted cash at end of period	$ 181,831	$ 126,038
Supplemental disclosure of noncash investing and financing information:		
Purchase of property and equipment included in the accounts payable and accrued liabilities	$ 555	1,847
Offering costs included in accrued expense	$ 19	2,027
Vesting of restricted stock	$ 185	46

The accompanying notes are an integral part of these consolidated financial statements.

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Nature of Business – Generate Biomedicines, Inc. (the "Company") is a clinical-stage generative biology company pioneering the AI revolution in biotechnology and drug design and development. The Company's vision is to program biology to generate optimal therapeutics for the greatest impact on human health. Central to its vision is the Generate Platform, designed to be a therapeutic area and protein modality agnostic system integrating computational innovation with scalable biohardware to address therapeutic challenges beyond the reach of traditional technologies. The Company has built its Generate Platform to be a tight and fully-integrated loop (design–build–test–learn) to create proprietary, therapeutically relevant data and differentiated molecular solutions for the biological challenges we aim to address.

Since inception, the Company has devoted substantially all of its resources to drug discovery, the development of the Generate Platform and the advancement of GB-0895 and its other programs and product candidates, along with multiple preclinical programs in immunology and oncology. In addition to its research and development efforts, the Company has invested in establishing and protecting its intellectual property portfolio, raising capital and obtaining financing, organizing and staffing the company, and providing general and administrative support for these operations. It does not have any products approved for sale.

Risks and Uncertainties – The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for its drug candidates, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to manufacture its development candidates and products.

The Company is also subject to additional risks, including the need to obtain additional financing to support its ongoing research and development of its product candidates. Product candidates currently under development will require significant additional research and development efforts, including extensive clinical development and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Liquidity and Managements Plan – As of December 31, 2025, the Company had cash, cash equivalents and marketable securities of $221.5 million. The Company has incurred recurring losses since its inception, including a net loss of $181.4 million, of which $7.6 million was attributable to a non-controlling interest and $223.0 million, of which $19.8 million was attributable to a non-controlling interest for the years ended December 31, 2024 and 2025, respectively. As of December 31, 2025, the Company had an accumulated deficit of $676.3 million. Based on the Company's current capital resources, which consists of its cash, cash equivalents and marketable securities on hand at December 31, 2025, it will not have sufficient cash on hand to support current operations for at least twelve months from the date of issuance of these consolidated financial statements. This condition raises substantial doubt about the Company's ability to continue as a going concern.

The Company plans to address this condition by pursuing additional funding through one or more of the following: public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. The Company may not be able to obtain funding on acceptable terms, or at all. The terms of any future financing may adversely affect the holdings or the rights of the Company's current stockholders.

If the Company is unable to obtain funding, it could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or it may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all or that any proceeds would be sufficient to support the Company's operating plans for at least the next twelve months from the date of issuance of these financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation – The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation – The accompanying consolidated financial statements reflect the consolidated operations of the Company, including its wholly owned subsidiary, Generate Biomedicines Securities Corporation, and variable interest entities where the Company is the primary beneficiary, specifically Pioneering Medicines 02, Inc. ("PMCo"). All intercompany accounts and transactions have been eliminated.

At the inception of a transaction, the Company identifies each entity involved in such transaction for which control is achieved by the Company through means other than voting rights (each a "variable interest entity" or "VIE") and determines if the Company is the primary beneficiary of such entity's operations. A VIE is broadly defined as an entity where either (i) the equity investors as a group, if any, do not have a controlling financial interest, or (ii) the equity investment at risk is insufficient to finance that entity's activities without additional subordinated financial support. The Company consolidates investments in a VIE when the Company is determined to be the primary beneficiary. ASC Topic 810, *Consolidations* ("ASC 810"), requires the Company to perform a qualitative approach to determining whether or not a VIE will need to be consolidated. This evaluation is based on the Company's ability to direct and influence the activities of a VIE that most significantly impact that entity's economic performance, whether the Company has the power to direct those activities, and if the Company's obligation to absorb losses or receive benefits from the VIE could potentially be significant to the VIE.

For consolidated entities with ownership interest or economic rights held by third-parties, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations equal to the percentage of common stock ownership interest retained in the respective operations by the non-controlling parties. The Company presents non-controlling interests as a component of shareholders' equity or mezzanine equity on its consolidated balance sheets based on the redemption rights of the equity interest. The Company records the non-controlling interests' share of loss based on the percentage of ownership interest retained by the respective non-controlling interest holders.

Use of Estimates – The preparation of the consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. The Company bases its estimates and assumptions on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, which include but are not limited to accrued research and development expenses, the valuation of common stock and warrants to purchase convertible preferred stock, stock based compensation expense and the incremental borrowing rate for operating and finance lease right-of-use assets, and income taxes. Actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

Cash and Cash Equivalents – Cash and cash equivalents are short-term, highly liquid investments with original maturities of three months or less at the date of purchase. Investments qualifying as cash equivalents primarily consist of money market funds.

Restricted Cash – As of December 31, 2024 and 2025, restricted cash consisted of $4.1 million and $4.0 million, respectively, used to secure the letters of credit for the benefit of the landlords in connection with the Company's lease agreements (Note 14). These amounts are classified as other assets in the Company's consolidated balance sheet.

Restricted Cash and Cash Equivalents (VIE) – As of December 31, 2024 and 2025, restricted cash and cash equivalents consisted of $1.4 million and $0.3 million, respectively. The Company records the cash and cash equivalents of PMCo as restricted cash because the Company does not have control over the cash and cash equivalents and the cash and cash equivalents of PMCo can only be used to settle PMCo obligations. See Note 18.

Marketable Securities – Marketable securities consist of term deposits and government securities with original maturities greater than 90 days. Investments are classified at the time of purchase, based on management's intent and ability to sell the marketable securities before maturity. All of the Company's marketable security investments are classified as available-for-sale securities and are recorded as current assets on the Company's consolidated balance sheets because they are considered available to support current operations of the Company and are reported at fair market value using quoted prices in active markets for similar securities. At each balance sheet date, the Company reassess its marketable securities classification through examining its intent and ability to sell its marketable securities. The Company presents credit losses, if applicable, as an allowance rather than as a reduction in the amortized cost of the available-for-sale securities.

Marketable securities are considered impaired when a decline in fair value is judged to be other-than-temporary. The Company consults with its investment managers and considers available quantitative and qualitative evidence in evaluating potential impairment of its marketable securities on a quarterly basis. If the cost of an individual investment exceeds its fair value, the Company evaluates, among other factors, general market conditions, the duration and extent to which the fair value is less than cost and its intent and ability to hold the investment. Once a decline in fair value is determined to be other-than-temporary, an impairment charge will be recorded to other income (expense), net in the consolidated statements of operations and comprehensive loss. No allowance for credit losses was established as of December 31, 2024 and 2025.

Unrealized gains and losses on the Company's available-for-sale securities are recorded in other comprehensive income or loss in the consolidated statements of operations and comprehensive loss. Purchase premiums and discounts are amortized to interest income over the terms of the related securities. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included as other income (expense), net within the consolidated statements of operations and comprehensive loss.

Concentrations of Credit Risk – Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash. The Company places its cash in a financial institution that management believes to be of high credit quality and, consequently, the Company does not believe it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Bank accounts in the United States are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. As of December 31, 2024 and 2025, predominantly all of the Company's primary operating cash accounts significantly exceeded the FDIC limits.

Accounts Receivable – The Company's receivables primarily relate to amounts reimbursable under its collaboration agreements. Accounts receivable have standard payment terms that generally require payment within thirty (30) days. The Company maintains an allowance for credit losses to provide for the estimated amounts of receivables that will not be collected over the estimated life of the assets. To date, the Company has not incurred any credit losses, and the Company did not have an allowance for credit losses as of December 31, 2024 and 2025.

Property and Equipment – Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets. Construction-in-process reflects amounts incurred for property, equipment or improvements that have not been placed in service. Estimated useful lives by major asset category are as follows:

	Estimated Useful Life
Lab equipment	3-5 years
Finance lease right-of-use assets	5 years
Computers and software	3 years
Furniture and fixtures	5-7 years
Leasehold improvements	Shorter of useful life or remaining lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the consolidated statement of operations and comprehensive loss. Expenditures for repairs and maintenance are charged to expenses as incurred.

Impairment of Long-Lived Assets – Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If this comparison indicates that there is an impairment, the amount of the impairment is calculated as the difference between the carrying value and the fair value. The Company has not recorded any impairment charges in the periods presented.

Deferred Offering Costs – The Company capitalizes certain legal, professional, accounting, and other third-party fees that are incurred prior to consummation of and directly associated with a financings as deferred offering costs until such financings are consummated. After the consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholders' deficit as a reduction of additional paid-in capital. Should the in-process equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. There were no deferred offering costs as of December 31, 2024. As of December 31, 2025, the Company recorded deferred offering costs of $2.0 million related to the Company's proposed initial public offering.

Revenue Recognition – The Company recognizes revenue from contracts with customers in accordance with ASC Topic 606 *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In order to achieve this core principle, the Company applies the following five steps when recording revenue: (1) identify the contract, or contracts, with the customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when, or as, performance obligations are satisfied.

At contract inception, the Company assesses the goods or services promised within each contract, whether each promised good or service is distinct, and determines those that are performance obligations. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own and whether the required expertise is readily available. In addition, the Company considers whether the customer can benefit from a promise for its intended purpose without the receipt of the remaining promises, whether the value of the promise is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises, and whether it is separately identifiable from the remaining promises. The Company allocates the transaction price to the identified performance obligations based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated cost. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied.

As part of the accounting for arrangements under ASC 606, the Company must use significant judgment to determine: (a) the performance obligations based on the determination under step (2) above; and (b) the transaction price under step (3) above. The Company also uses judgment to determine whether milestones or other variable consideration, except for royalties and sales-based milestones where such payments principally relate to a license of intellectual property, should be included in the transaction price. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment. The transaction price is allocated to each performance obligation based on the relative standalone selling price of each performance obligation in the contract. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. The Company recognizes revenue related to each service based performance obligation over time using the costs incurred input method, such that revenue is recognized based on the Company's efforts or inputs to the satisfaction of a performance obligation. Through this method, the Company applies a cost-to-cost method and compares the actual costs incurred to date with the current estimate of total costs to complete ("ETCs") to measure the satisfaction of each performance obligation and recognize revenue as research activities progress and costs are incurred. Throughout each service period, the Company monitors its ETCs to determine if an adjustment is needed to ensure that revenue is recognized proportionally for costs incurred to date relative to the total costs expected to be incurred for the total performance obligation. As there are changes in facts and circumstances that impact management's ETCs with respect to ongoing and prospective research activities, the ETCs are updated accordingly, and a cumulative catch-up is recorded.

Customer Options – The Company's arrangements may provide a customer with the right to certain optional purchases, such as the right to license a target either at the inception of the arrangement or within a pre-defined option period. Under these agreements, fees may be due to the Company at the inception of the arrangement as an upfront fee or payment or upon the exercise of an option to acquire a license. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount.

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Collaborative arrangements – The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first evaluates whether any of the elements of the collaboration are within the scope of other ASC guidance, including ASC 606, and follows the relevant provisions of that guidance for that element. The Company accounts for components of collaborative arrangements that are outside the scope of other guidance by analogy to the authoritative accounting literature or, if there is no appropriate analogy, by using a reasonable, rational and consistently applied accounting policy election. Payments or reimbursements that are the result of a collaborative relationship instead of a vendor-customer relationship are recorded as an increase to collaboration revenue or reduction in research and development expense, depending on the nature of the activity.

Research and Development Costs – Research and development costs are comprised of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs and laboratory supplies, depreciation, manufacturing expenses and external costs of outside vendors engaged to conduct planned clinical development, preclinical development, manufacturing and manufacturing process development and other research support activities. Research and development costs are expensed as incurred. Research and development costs that are paid in advance of performance (if any) are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Research Contract Costs and Accruals – The Company has entered into various research and development-related contracts with research institutions and other third-party companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs and receives updated estimates of costs and amounts owed on a monthly basis from its third-party service providers. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted cost estimates from its third-party service providers. Estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation – The Company accounts for all stock-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value. The Company grants equity awards under its stock-based compensation plan, which may include stock options and restricted common stock. The measurement date for employee and non-employee awards is the date of grant. For the equity awards that vest based on a service condition, stock-based compensation costs are recognized as expense over the requisite service period, which is the vesting period, on a straight-line basis. For equity awards with performance conditions, the Company recognizes stock-based compensation expense when the achievement of a performance-based milestone is probable, and is recognized based on the accelerated attribution model. Stock-based compensation expense is classified in the accompanying consolidated statement of operations and comprehensive loss based on the function to which the related services are provided. The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

The fair value of each share option is estimated on the date of grant using the Black-Scholes option-pricing model (the "Black-Scholes OPM"). See Note 12 for the Company's assumptions used in connection with share options granted during the periods covered by these consolidated financial statements. Assumptions used in the Black-Scholes OPM include the following:

Expected volatility – As a private company, the Company lacks company-specific historical and implied volatility information for its common stock. Therefore, it estimates its expected share volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price.

Expected term – The Company uses the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to the lack of historical exercise data and the plain nature of its stock-based awards. If vesting is subject to a performance condition, the expected term is based on the expected period to vest and the contractual term.

Risk-free interest rate – The risk-free interest rate is determined by reference to the United States ("U.S.") Treasury yield curve in effect at the time of grant of the award for time periods that are approximately equal to the expected term of the award.

Expected dividend – Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on its common stock and does not expect to pay any cash dividends in the foreseeable future.

Fair value of common stock – The grant date fair value of restricted common stock is calculated based on the grant date fair value of the underlying common stock less any purchase price. The fair value of the common stock is also used as an input to the Black-Scholes OPM to value stock options. The Company's board of directors (the "Board") determines the fair value of the Company's common stock, with input from management, considering the Company's most recently available third-party valuations of common stock, as well as additional factors which may have changed since the date of the most recent valuation through the date of grant. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Leases – Pursuant to ASC Topic 842, *Leases*("ASC 842"), at the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. At the lease commencement date, when control of the underlying asset is transferred from the lessor to the Company, the Company classifies a lease as either an operating or finance lease and recognizes a right-of-use ("ROU") asset and a current and non-current lease liability as applicable, in the consolidated balance sheet if the lease has a term greater than one year. As permitted under ASC 842, the Company has made an accounting policy election, for all classes of underlying assets, to not recognize ROU assets and lease liabilities for leases having a term of twelve months or less. When it determines the lease term, the Company considers the committed lease term and any options available in the lease agreement. The Company's lease terms may include options to extend the lease, or the option to purchase the asset, only when it is reasonably certain that the Company will exercise that option.

At the lease commencement date, operating and finance lease liabilities, and their corresponding ROU assets are recorded at the present value of future lease payments over the expected remaining lease term using the discount rate implicit in the lease, if it is readily determinable, or the Company's incremental borrowing rate. Certain adjustments to the ROU asset may be required for items such as lease prepayments, incentives received or initial direct costs. The Company's incremental borrowing rate reflects the fixed rate at which the Company could borrow the amount of the lease payments in the same currency on a collateralized basis, for a similar term in a similar economic environment. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. For finance leases, amortization expense and interest expense are recognized separately in the consolidated statements of operations, with amortization expense recognized on a straight-line basis and interest expense recognized using the effective interest method.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components include costs that do not provide a right to use a leased asset but instead provide a service, such as common area maintenance charges or clinical research manufacturing services. The Company has elected to combine the lease and non-lease components together as a single lease component for all leases with the exception of embedded leases in clinical research service arrangements, for which the Company separates lease and non-lease components. Variable costs associated with the lease, such as reimbursement of real estate taxes and utilities, are not included in the measurement of right-to-use assets and lease liabilities but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

Income Taxes – The Company accounts for income taxes under the asset and liability method pursuant to ASC Topic 740, *Accounting for Income Taxes* ("ASC 740"), which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse or settled. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent of management's judgement that these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company also accounts for uncertain tax positions pursuant to ASC 740-10, which prescribes a two-step process in which (1) it is more likely than not that the tax position will be sustained on the basis of the technical merits of the position, and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the benefit recognized is the largest amount that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. As of December 31, 2024 and 2025, the Company had not identified any significant uncertain tax positions. In addition, the Company recognizes interest and penalties related to unrecognized tax benefits in the provision for income taxes in the accompanying statement of operations. As of December 31, 2024 and 2025, the Company had not recorded any accrued interest or penalties related to uncertain tax positions in the consolidated balance sheet.

Fair Value Measurements – Certain assets and liabilities are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- **Level 1** – Quoted prices in active markets for identical assets or liabilities
- **Level 2** – Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly

- **Level 3** – Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability

The Company's cash equivalents, marketable securities and preferred stock warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). The carrying values of the Company's other financial instruments, including accounts payable and accrued expenses, certain prepaid expenses and other current assets and other current liabilities approximate their fair values due to the short-term nature of these liabilities.

Convertible Preferred Stock – The Company records convertible preferred stock at fair value upon issuance, net of any issuance costs. The Company's convertible preferred stock are subject to a dividend when and if declared by the Board. The Company's Series B convertible preferred stock, par value $0.001 per share (the "Series B convertible preferred stock"), and Series C convertible preferred stock, par value $0.001 per share (the "Series C convertible preferred stock"), are entitled to receive cumulative dividends. Since inception, no dividend has been declared by the Board. The Company's convertible preferred stock is classified outside of stockholders' deficit on the consolidated balance sheet because the holders of such shares have redemption rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company. No accretion has been recognized as the contingent events that could give rise to redemption are not deemed probable.

Net Loss per Share – The Company follows the two-class method when computing net loss per share attributable to Generate Biomedicines, Inc. common stockholders as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires earnings for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all losses for the period had been distributed. During periods of loss, there is no allocation required under the two-class method since the participating securities do not have a contractual obligation to fund the losses of the Company.

The Company calculates basic net loss per share by dividing the net loss attributable to Generate Biomedicines, Inc. common stockholders by the weighted average number of common shares outstanding for the period. In the period presented, the Company included cumulative dividends on Series B and Series C convertible preferred stock in its calculation of net loss attributable to Generate Biomedicines, Inc. common stockholders. Diluted net loss per share attributable to Generate Biomedicines, Inc. common stockholders is computed by dividing the net loss attributable to Generate Biomedicines, Inc. common stockholders by the weighted average number of common shares outstanding for the period, including the effect of potentially dilutive common shares. For purpose of this calculation, outstanding options to purchase shares of common stock, unvested restricted common stock, shares of convertible preferred stock and warrants to purchase shares of convertible preferred stock are considered potentially dilutive common shares. The Company has generated a net loss in the period presented, therefore, basic and diluted net loss per share attributable to Generate Biomedicines, Inc. common stockholders is the same, as the potentially dilutive securities would be anti-dilutive.

Warrant Liability – Freestanding warrants related to shares that are contingently redeemable are classified as a liability on the Company's consolidated balance sheet. The warrants are initially recorded at fair value on the date of grant and are subsequently remeasured to fair value at each balance sheet date. Changes in fair value of these warrants are recognized as a component of other income (expense), net in the Company's consolidated statement of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants, or when the warrants become indexed to the Company's own stock. The Company classifies the liabilities as noncurrent as the settlement of the warrants is not expected within the next twelve months.

Comprehensive Loss – Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders and non-controlling interests. The Company's comprehensive net loss equals the reported net loss for all periods presented.

Emerging Growth Company Status – The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards.

Recently Adopted Accounting Pronouncements – In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures* (Topic 740). This ASU requires disclosure of disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The standard is effective for annual periods beginning after December 15, 2024, and may be applied prospectively or retrospectively. The Company adopted ASU No. 2023-09 on a retrospective basis during the year ended December 31, 2025, and the adoption did not have a material impact on its results of operations. These disclosures are included in Note 14, "Income Taxes."

Recently Issued Accounting Pronouncements Not Yet Adopted – In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): *Disaggregation of Income Statement Expenses*. This update requires that at each interim and annual reporting period public entities disclose (1) the amounts of purchases of inventory, employee compensation, depreciation, amortization, and depletion in commonly presented expense captions; (2) certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; (3) a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively; (4) the total amount of selling expenses and; (5) in annual reporting periods, the definition of selling expenses. In January 2025, the FASB issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Clarifying the Effective Date. This update clarifies that ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance on its financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software* (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This update removes all references to prescriptive and sequential software development stages throughout Subtopic 350-40. The update requires an entity to start capitalizing software costs when management has authorized and committed to funding the software project, and it is probable that the project will be completed and the software will be used to perform the function intended. The update further specifies that the disclosures in Subtopic 360-10 are required for all capitalized internal-use software costs. This update is effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted. The guidance can be applied using a prospective transition approach, a modified transition approach that is based on the status of the project and whether software costs were capitalized before the date of adoption, or a retrospective transition approach. The Company is currently evaluating the impact of adopting this guidance on its financial statements.

3. CASH EQUIVALENTS AND MARKETABLE SECURITIES

The following tables summarize the amortized cost and fair value of the Company's cash equivalents and marketable securities (in thousands):

	December 31, 2024			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 77,070	$ —	$ —	$ 77,070
	$ 77,070	$ —	$ —	$ 77,070
Marketable securities:				
Government securities	$ 157,240	$ 119	$ (1)	$ 157,358
Term deposits	60,000	—	—	60,000
	$ 217,240	$ 119	$ (1)	$ 217,358

	December 31, 2025			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 92,788	$ —	$ —	$ 92,788
	$ 92,788	$ —	$ —	$ 92,788
Marketable securities:				
Government securities	$ 99,742	$ 106	$ —	$ 99,848
	$ 99,742	$ 106	$ —	$ 99,848

The Company did not record a provision for credit losses on any marketable securities for the years ended December 31, 2024 and 2025. No securities held by the Company were delinquent on contractual payments as of December 31, 2024 and 2025, nor were any securities placed on non-accrual status for the year then ended. Interest on investments is recognized as interest income in the consolidated statements of operations and comprehensive loss. All marketable securities held as of December 31, 2024 and 2025 had remaining contractual maturities of less than one year.

Information pertaining to marketable securities with gross unrealized losses as of December 31, 2024, for which the Company did not recognize a provision for credit losses under the current expected credit loss methodology, aggregated by investment category and length of time that individual securities had been in a continuous loss position, is as follows (in thousands):

	December 31, 2024 – Less than 12 Months		
	# of Holdings	Gross Unrealized Loss	Fair Value
Government Securities	3	$ (1)	$ 12,213
	3	$ (1)	$ 12,213

As of December 31, 2025, the Company did not hold any securities with gross unrealized losses.

4. FAIR VALUE MEASUREMENTS

The following table sets forth by level, within the fair value hierarchy, the assets and liabilities carried at fair value on a recurring basis (in thousands):

	Fair Value Measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 77,070	$ —	$ —	$ 77,070
	$ 77,070	$ —	$ —	$ 77,070
Marketable securities:				
Government securities	$ —	$ 157,358	$ —	$ 157,358
Term deposits	—	60,000	—	60,000
	$ —	$ 217,358	$ —	$ 217,358
Liabilities:				
Warrant to purchase convertible preferred stock	$ —	$ —	$ 1,092	$ 1,092
	$ —	$ —	1,092	$ 1,092

	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 92,788	$ —	$ —	$ 92,788
	$ 92,788	$ —	$ —	$ 92,788
Marketable securities:				
Government securities	$ —	$ 99,848	$ —	$ 99,848
	$ —	$ 99,848	$ —	$ 99,848
Liabilities:				
Warrant to purchase convertible preferred stock	$ —	$ —	$ 1,205	$ 1,205
	$ —	$ —	$ 1,205	$ 1,205

Valuation of the Warrant to Purchase Convertible Preferred Stock

The fair value of the preferred stock warrant liabilities was determined using the Black-Scholes OPM with the assumptions as disclosed in Note 8. These assumptions include significant judgments, including the fair value of the underlying preferred stock. An increase or decrease in the estimated fair value will result in increases or decreases in the fair value of the warrant liability and such changes could be material.

The following table presents a roll-forward of the aggregate fair values of the Company's liabilities for which fair value is determined by Level 3 inputs (in thousands):

	Warrant to Purchase Preferred Stock
Balance as of December 31, 2023	$ 938
Change in fair value	154
Balance as of December 31, 2024	1,092
Change in fair value	113
Balance as of December 31, 2025	$ 1,205

There were no transfers among Level 1, Level 2, or Level 3 categories in the period presented.

Financial Instruments Not Recorded at Fair Value – The carrying value of accounts receivable, accounts payable and accrued expenses that are reported on the consolidated balance sheet approximate their fair value because of the relatively short period of time between origination and expected realization or settlement.

5. COLLABORATION AGREEMENTS

Agreement with Novartis Pharma AG ("Novartis")

On September 19, 2024, the Company entered into a Collaboration and License Agreement with Novartis (the "Novartis Collaboration Agreement") to discover, develop, manufacture and commercialize protein therapeutics using the Generate Platform. The collaboration covers multiple collaboration targets, conducted under applicable research plans during defined research terms. As consideration for the collaboration, the Company received a $50.0 million upfront payment. Novartis also purchased 1,265,822 shares of our Series C convertible preferred stock for $15.0 million. The Company is eligible to receive up to $1.0 billion across all programs upon the achievement of certain performance-based milestones, inclusive of $130.0 million in development and regulatory milestones and $210.0 million in commercial milestones associated with each research program. Novartis is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit to a low tens percentage on worldwide net sales of any licensed product, subject to specified reductions and offsets.

The Company concluded that the per share purchase price, paid by Novartis, was equal to the per share fair value of Series C convertible preferred stock. As such, there is no impact to the transaction price related to the investment in Series C convertible preferred stock by Novartis.

The Company concluded that the arrangement contemplated by the Novartis Collaboration Agreement represents a contract with a customer within the scope of ASC 606. The Company determined that for each research program, the research services and related research license granted under the Novartis Collaboration Agreement are not distinct and should be a combined performance obligation. The transaction price at inception was $50.0 million, representing the nonrefundable upfront fee. All contingent payments represent variable consideration that are constrained at inception as the achievement of the milestones underlying such contingent payments is based on either the Company or Novartis's ability to execute under the respective research program plans which is not certain at contact inception. The Company allocated the transaction price to each of the distinct research program performance obligations on a relative stand-alone selling price basis.

The Company recognizes revenue related to each distinct performance obligation over time using the costs incurred input method, such that revenue is recognized based on the Company's efforts or inputs to the satisfaction of a performance obligation.

The Company allocated the $50.0 million transaction price equally to the performance obligations based on the relative selling price.

The Company recognized $2.3 million and $25.1 million of revenue under the Novartis Collaboration Agreement during the years ended December 31, 2024 and 2025, respectively. The remaining transaction price of $22.6 million is expected to be recognized by the Company as revenue through 2027. As of December 31, 2025, all contingent payments were constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

Agreement with Amgen Inc. ("Amgen")

On December 24, 2021, the Company entered into a Collaboration and License Agreement, as amended by the First Amendment dated October 5, 2022 and the Second Amendment dated December 12, 2023 (as amended from time to time, the "Amgen Collaboration Agreement"), with Amgen to identify biologic proteins and antibodies directed against specified targets. The Amgen Collaboration Agreement initially covered five collaboration targets. In addition, Amgen has the option to nominate up to five additional collaboration targets, at additional cost, the first of which was exercised in December 2023 related to the sixth target. As consideration for the collaboration, the Company received a $50.0 million upfront payment. In connection with the Second Amendment, which added an additional collaboration target, the Company received an additional payment of $5.0 million. The Company is eligible to receive up to $370.0 million for each program upon the achievement of certain milestones, including $160.0 million in development and regulatory milestones and $210.0 million in commercial milestones per program. Amgen is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit up to a low tens percentage on worldwide net sales of any licensed product, subject to customary reductions and offsets. Additionally, the Amgen Collaboration Agreement included an investment by Amgen of $25.0 million in equity, at the offering price, if the Company consummated certain future equity offerings. Amgen purchased 2,109,704 shares of the Company's Series C convertible preferred stock for approximately $25.0 million on May 9, 2023.

The per share purchase price that would be paid by Amgen, if the Company were to engage in a future equity offering, is equal to the per share fair value of the Company's other investors at the time, therefore would not impact the transaction price under the Amgen Collaboration Agreement.

The Company assessed this arrangement in accordance with ASC 606 and concluded that Amgen is a customer. The Company determined that the research activities and the exclusive license granted under the Amgen Collaboration Agreement are not individually distinct and should be combined for each target program, and each target program was considered as a distinct performance obligation. Therefore, the transaction price was allocated to each target program on a relative stand-alone selling price basis.

In connection with the modification in 2023, the Company allocated the transaction price to the performance obligations on a relative selling price basis as follows: (i) $9.2 million to the first target program; (ii) $10.4 million to the second target program; (iii) $9.2 million to the third target program; (iv) $9.0 million to the fourth target program; (v) $9.5 million to the fifth target program and (vi) $7.7 million to the sixth target program.

The Company recognizes revenue related to each performance obligation over time using the costs incurred input method, such that revenue is recognized based on the Company's efforts or inputs to the satisfaction of a performance obligation.

During the year ended December 31, 2024, a development milestone related to an initial collaboration target was achieved which triggered a $5.0 million milestone payment to the Company. The $5.0 million milestone payment was fully recognized during the year ended December 31, 2024 as this variable consideration was allocated to a distinct performance obligation and the Company had completed its related performance obligation related to the collaboration target. All other milestones and royalties were constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

On July 21, 2025, the Company and Amgen executed an amendment to the Amgen Collaboration Agreement that effectively eliminated the remaining service obligation related to a collaboration target. The Company determined the amendment represented a modification of the arrangement under ASC 606 and that the remaining fixed transaction price at the modification date of $4.3 million should be re-allocated to the remaining performance obligations based on their updated standalone selling prices. Accordingly, the Company recorded a cumulative adjustment to revenue of approximately $1.3 million on the partially satisfied remaining performance obligations, as the remaining services to be performed under each of the performance obligations are not distinct from the services prior to the modification.

The Company recognized $18.2 million and $6.7 million of revenue during the years ended December 31, 2024 and 2025, respectively. The remaining transaction price of $3.1 million is expected to be recognized as revenue through 2026.

Agreement with The University of Texas M.D. Anderson Cancer Center

In April 2023, the Company entered into a co-development and commercialization collaboration agreement with The University of Texas M.D. Anderson Cancer Center ("MD Anderson") to discover and develop protein therapeutics for up to five oncology targets. Under the agreement, the Company and MD Anderson agreed to share research and development expenses as well as profits generated through commercialization of jointly developed products. The arrangement is considered a collaboration agreement under ASC 808 and the Company recognizes costs as incurred and reimbursements as a reduction of research and development expense. During the year ended December 31, 2024, MD Anderson reimbursed $0.2 million that was recognized as a reduction to research and development by the Company. As of December 31, 2025, the Company had a net reimbursement payable to MD Anderson of $0.1 million.

Agreement with Roswell Park Comprehensive Cancer Center ("Roswell Park")

In October 2023, the Company entered into a collaboration agreement with Roswell Park to discover and develop chimeric antigen receptors T-cell therapies and armoring technologies for up to three oncology targets. Under the agreement, the Company and Roswell Park agreed to share research and development expenses as well as profits generated through commercialization of jointly developed products. The arrangement is considered a collaboration agreement under ASC 808 and the Company recognizes costs as incurred and reimbursements as a reduction of research and development expense. During the year ended December 31, 2024, no reimbursement was received from Roswell Park. During the year ended December 31, 2025, the Company reimbursed Roswell Park $1.1 million, which was recorded as research and development expense.

6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	Year Ended December 31,	
	2024	2025
Finance lease right of use assets	$ 42,747	$ 20,722
Lab equipment	14,125	37,384
Computers and software	3,457	3,513
Furniture and fixtures	2,023	2,023
Leasehold improvements	9,626	9,661
Construction in process	886	4,105
Total property and equipment	72,864	77,408
Less accumulated depreciation	(35,172)	(48,257)
Property and equipment, net	37,692	29,151

The Company leases equipment under agreements which are classified as finance lease liabilities in the accompanying consolidated balance sheet. The equipment and obligations related to the leases are recorded at the present value of the minimum lease payments. Depreciation is computed on a straight-line basis over the shorter of the estimated useful lives of the assets or remaining lease term. Depreciation expense related to leased equipment totaled $8.5 million and $5.9 million for the years ended December 31, 2024 and 2025.

Depreciation and amortization expense for the years ended December 31, 2024 and 2025 was $15.3 million and $13.2 million, respectively, including the depreciation expense related to the leased equipment.

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following (in thousands):

	Year Ended December 31,	
	2024	2025
Compensation and benefit	$ 13,305	$ 13,798
Research and development	5,621	23,414
Legal and professional	413	2,324
Other current liabilities	2,432	2,628
Total accrued expenses and other current liabilities	$ 21,771	$ 42,164

8. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to Generate Biomedicines, Inc. common stockholders by the weighted average number of shares of the Company's common stock outstanding during the period. Diluted net loss per share is computed similarly to basic net loss per share except that it also includes potential common shares only if they are dilutive. When participating securities exist, earnings or losses are allocated between common and participating securities under the two-class method before calculating earnings per share. For the period presented, basic and diluted net loss per share are the same as any potential common shares would be anti-dilutive and the participating securities do not share in losses of the Company.

The following securities are common stock equivalents, but were excluded in the computation of diluted net loss per common stock because to do so would have been anti-dilutive:

	Year Ended December 31,	
	2024	2025
Series A convertible preferred stock	26,398,943	26,398,943
Series B convertible preferred stock	20,745,628	20,745,628
Series C convertible preferred stock	20,966,463	22,188,673
Warrant to purchase Series A convertible preferred stock	98,749	98,749
Restricted common stock	138,177	—
Stock options outstanding	19,102,595	20,422,301
Total	87,450,555	89,854,334

9. WARRANT LIABILITY

On July 10, 2020, the Company issued a warrant to purchase up to 150,000 shares of Series A convertible preferred stock with an exercise price of $1.00 per share (the "Warrant"). The Warrant has an original term to maturity of 10 years, expiring on July 10, 2030.

The assumptions that the Company used to determine the fair value of the Warrant are as follows:

	Year Ended December 31,	
	2024	2025
Expected term (years)	1.5	0.9
Expected volatility	97.8%	86.8%
Risk-free interest rate	4.2%	3.6%
Expected dividend yield	0.0%	0.0%
Fair value of Series A convertible preferred stock per share	$ 8.15	$ 9.29

As of December 31, 2025, the Warrant remained outstanding.

10. CONVERTIBLE PREFERRED STOCK

Series A Convertible Preferred Stock – Prior to January 1, 2024, the Company entered into the Series A Preferred Stock Purchase Agreement. As part of the initial closing and subsequent closings, 40,100,000 shares of Series A convertible preferred stock were issued at $1.00 per share for cash proceeds of $40.2 million. Issuance costs associated with the Series A convertible preferred stock were less than $0.1 million.

Series B Convertible Preferred Stock – Prior to January 1, 2024, the Company entered into the Series B Preferred Stock Purchase Agreement. As part of the initial closing and subsequent closings, 31,512,642 shares of Series B convertible preferred stock were issued at $11.85 per share for cash proceeds of $373.5 million. Issuance costs associated with the Series B convertible preferred stock closings were $0.3 million.

Series C Convertible Preferred Stock – Prior to January 1, 2024, the Company entered into the Series C Preferred Stock Purchase Agreement. As part of the initial closing and subsequent closings, 23,708,840 shares of Series C convertible preferred stock were issued at $11.85 per share for cash proceeds of $281.0 million. Issuance costs associated with the Series C convertible preferred stock closings for 2023 were $0.6 million.

On October 9, 2024 and three additional dates, the last occurring on December 20, 2024, the Company sold and issued to one or more purchasers at additional closings, on the same terms and conditions as the initial closing, an aggregate of 8,139,234 additional shares of Series C convertible preferred stock for $11.85 per share and cash proceeds of $96.5 million. Issuance costs associated with the Series C convertible preferred stock closings for 2024 were $0.1 million.

On January 21, 2025, the Company sold and issued to one or more purchasers at an additional closing, on the same terms and conditions as the previous closing, an aggregate of 1,856,539 additional shares of Series C convertible preferred stock for $11.85 per share and cash proceeds of $22.0 million. Issuance costs associated with the Series C convertible preferred stock closings for 2025 were less than $0.1 million.

As of each balance sheet date, convertible preferred stock consisted of the following (dollars in thousands):

	December 31, 2024				
	Preferred Stock Authorized	Issued and Outstanding	Carrying Value	Liquidation Preference	Issuable Upon Conversion
Series A convertible preferred stock	40,250,000	40,100,000	$ 40,053	$ 40,100	26,398,943
Series B convertible preferred stock	31,512,642	31,512,642	373,133	447,175	20,745,628
Series C convertible preferred stock	42,194,093	31,848,074	376,667	404,752	20,966,463
	113,956,735	103,460,716	$ 789,853	$ 892,027	68,111,034

	December 31, 2025				
	Preferred Stock Authorized	Issued and Outstanding	Carrying Value	Liquidation Preference	Issuable Upon Conversion
Series A convertible preferred stock	40,250,000	40,100,000	$ 40,053	$ 40,100	26,398,943
Series B convertible preferred stock	31,512,642	31,512,642	373,133	469,660	20,745,628
Series C convertible preferred stock	42,194,093	33,704,613	398,640	450,689	22,188,673
	113,956,735	105,317,255	$ 811,826	$ 960,449	69,333,244

The Series A, Series B and Series C convertible preferred stock (collectively, the “Preferred Stock”) have the following rights and privileges:

Dividends – The holders of the Series A convertible preferred stock are entitled to receive noncumulative dividends when and if declared by the Board. The holders of Series B and Series C convertible preferred stock are entitled to received cumulative dividends that accrued at an annual rate of $0.711 per share. Dividends are payable only when and if declared by the Board. The Company cannot declare, pay, or set aside any dividends on shares of any class of common stock, unless the holders of the Preferred Stock first receive dividends on each outstanding share of Preferred Stock in the amount equal to the greater of (i) the accrued dividends unpaid as of such date and (ii) the amount that would be due had all Preferred Stock been converted to common stock immediately prior to the dividend. Since inception and through December 31, 2025, no dividends had been declared by the Board.

Liquidation – In the event of any liquidation, dissolution or winding-up of the Company, which would include the sale of the Company, the Preferred Stock is senior to common stock. The stockholders holding shares of Preferred Stock would be entitled to preferential payment in the amount per share equal to the greater of (i) (a) for Series A convertible preferred stock, the respective original issue price and declared dividends unpaid thereon and (b) for Series B and the Series C convertible preferred stock, the original issue price plus any accrued but unpaid dividends and any declared but unpaid dividends or (ii) the amount that would be due had all Preferred Stock been converted to common stock immediately prior to the deemed liquidation event.

Voting – The stockholders holding shares of Preferred Stock are entitled to the number of votes equal to the number of shares of common stock into which the shares of Preferred Stock held by each holder are then convertible.

Conversion – Each share of Preferred Stock is convertible at any time at the option of the holder. The number of shares into which the Preferred Stock converts is equal to the original issuance price of such series of Preferred Stock divided by the respective series' conversion price. The conversion price is $1.52, $18.00 and $18.00 per share for the Series A, Series B and Series C convertible preferred stock, respectively, and may be adjusted for certain dilutive events. Conversion to common stock shall be mandatory upon the closing of an initial public offering resulting in gross proceeds of at least $50.0 million or upon the decision of the holders of at least a majority of the outstanding shares of Preferred Stock.

11. COMMON STOCK

As of December 31, 2025, the Company had authorized 200,456,735 shares of common stock. The voting, dividend and liquidation rights of the holders of the Company's common stock is subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock as set forth above.

As of December 31, 2025, the Company had reserved 93,259,189 shares for the conversion of outstanding shares of Preferred Stock, the exercise of outstanding stock options, the vesting of restricted common stock, the number of shares remaining available for grant under the Company's 2019 Equity Incentive Plan (see Note 12) and the exercise of the outstanding Warrant (see Note 9).

	December 31,	
	2024	**2025**
Series A convertible preferred stock outstanding	26,398,943	26,398,943
Series B convertible preferred stock outstanding	20,745,628	20,745,628
Series C convertible preferred stock outstanding	20,966,463	22,188,673
Stock options outstanding under the 2019 Plan	19,102,595	20,422,301
Shares reserved for future issuance under the 2019 Plan	2,050,125	3,404,855
Shares reserved for exercise of outstanding Warrant	98,749	98,749
Shares reserved for vesting of restricted common stock	138,177	—
Total shares of common stock reserved for issuance	89,500,680	93,259,189

12. STOCK-BASED COMPENSATION

2019 Equity Incentive Plan

During 2019, the Company adopted the 2019 Equity Incentive Plan, as amended (the "2019 Plan"). The 2019 Plan provided for the issuance of up to 31,928,901 shares of common stock as of December 31, 2025, to employees, officers, directors, consultants, and advisors in the form of non-qualified and incentive stock options, restricted stock awards, and other stock-based awards. Options typically vest over four years and have a maximum term of 10 years. As of December 31, 2025, there were 3,404,855 shares of common stock available for issuance under the 2019 Plan.

Stock Option Valuation

The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant. The fair value of the common stock has been determined by the Board at each measurement date based on the results obtained from independent third-party appraisals.

The Company utilized the Black-Scholes OPM to estimate the fair value of stock options awarded to employees, officers, directors, consultants and advisors. The Black-Scholes OPM requires several key assumptions. The assumptions that the Company used to determine the grant-date fair value of options granted to employees, non-employees and directors were as follows, presented on a weighted-average basis:

	Year Ended December 31,	
	2024	2025
Expected term (in years)	6.0	6.1
Expected volatility	84.8%	84.2%
Risk-free interest rate	4.1%	4.2%
Expected dividend yield	—	—
Fair value of underlying common stock	$ 7.34	$ 9.17

As of December 31, 2024 and December 31, 2025, there was $38.9 million and $42.8 million of unrecognized compensation expense, respectively, related to unvested time-based stock options that will be recognized over a weighted-average remaining term of 2.6 years and 2.4 years, respectively. As of December 31, 2024 and December 2025, there was $0.7 million of unrecognized compensation expense related to unvested stock options for which the performance condition was not deemed probable.

Prior to January 1, 2024, the Company issued stock options covering shares 631,665 of common stock subject to the performance condition of entering into one or more strategic transactions pursuant to which the Company has the right to receive, in the aggregate, at least $200.0 million in specified payments. During the year ended December 31, 2022, the vesting of stock options covering 157,916 shares of stock with this performance condition was accelerated following the signing of the Amgen Collaboration Agreement in recognition of performance that did not otherwise achieve the performance condition. During the year ended December 31, 2024, the vesting of stock options covering 157,916 shares of common stock with this performance condition was accelerated following the signing of the Novartis Collaboration Agreement in recognition of performance that did not otherwise achieve the performance condition. The balance of 315,833 shares of common stock underlying these stock options remains outstanding. No stock-based compensation expense has been recorded on the remaining unvested stock options as the performance conditions are not deemed probable of occurrence.

During the year ended December 31, 2024, the Company issued stock options covering 65,832 shares of common stock subject to the performance condition of entering into one or more strategic transactions pursuant to which the Company has the right to receive, in the aggregate, at least $50.0 million in specified payments. Additionally, the Company issued stock options covering 65,832 shares of common stock subject to the performance condition of entering into one or more strategic transactions pursuant to which the Company has the right to receive, in the aggregate, at least $100.0 million in specified payments. Any unvested shares underlying both stock option grants will lapse and be forfeited as of January 1, 2025. In December 2024, both of these option grants were modified to extend their vesting period to January 1, 2026 and to exclude the Novartis Collaboration Agreement from counting in the guaranteed payments used to determine if the performance criteria are met. During the years ended December 31, 2024 and December 31, 2025, no shares of common stock underlying these options vested.

The following table summarizes the option activity under the 2019 Plan:

	Options	Weighted Average Exercise Price per Unit	Weighted Average Remaining Life (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	17,696,443	$ 4.75	8.5	$ 44,334
Granted	4,137,855	7.34		
Exercised	(545,050)	2.70		
Forfeited/Expired	(2,186,678)	6.14		
Outstanding at December 31, 2024	19,102,570	$ 5.21	7.8	$ 75,404
Granted	4,798,689	9.18		
Exercised	(287,152)	3.82		
Forfeited/Expired	(3,191,806)	6.82		
Outstanding at December 31, 2025	20,422,301	$ 5.91	7.3	$ 119,395
Exercisable at December 31, 2025	11,846,991	$ 4.48	6.5	$ 86,168

During the years ended December 31, 2024 and December 31, 2025, the Company granted stock options to purchase an aggregate of 4,137,855 shares and 4,798,689 shares, at weighted average grant date fair values per option share of $5.41 and $6.88, respectively.

The aggregate intrinsic value of options exercised during the year ended December 31, 2024 and December 31, 2025 was $2.9 million and $1.7 million, respectively. The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

Restricted Common Stock

During the year ended December 31, 2021, the Company issued 2,210,829 shares of restricted common stock to certain directors, executive officers and founders, subject to a time-based service condition. No restricted common stock was issued during the year ended December 31, 2024 or 2025.

The grantees paid their respective subscription price on the grant date, which was the fair value of the common stock. The consideration received was recorded as a restricted stock repurchase liability. The relevant consideration paid will be transferred into common stock par value and additional paid in capital once the restricted common stock vested. As of December 31, 2024, the outstanding balance of the restricted stock repurchase liability was less than $0.1 million and was fully vested during the year ended December 31, 2025.

The following table summarizes the Company's restricted common stock activity for the years ended December 31, 2024 and 2025:

	Number of Restricted Stock
Issued and unvested as of December 31, 2023	690,885
Vested	(552,708)
Issued and unvested as of December 31, 2024	138,177
Vested	(138,177)
Issued and unvested as of December 31, 2025	—

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statement of operations and comprehensive loss:

	Year Ended December 31,	
	2024	2025
Research and development	$ 9,114	$ 10,157
General and administrative	10,351	10,420
	$ 19,465	$ 20,577

13. LICENSE AGREEMENT

Agreement with Immune Biosolutions, Inc. ("IBIO")

In June 2023, the Company entered into a License Agreement with IBIO, pursuant to which the Company licensed certain technologies in the intravenous, intramuscular and subcutaneous delivery field in exchange for a license of certain technologies in the inhaled field, in each case, related to the development of a SARS-CoV-2-specific antibody (the "IBIO License Agreement"). Pursuant to the IBIO License Agreement, the Company paid IBIO an upfront license fee of $0.1 million and each of the parties thereto have agreed to pay each other a low single digit royalty based on net sales of licensed products. No research and development expense was recognized during the years ended December 31, 2024 and 2025.

14. INCOME TAXES

The Company recorded $0.2 million of a tax provision for each of the years ended December 31, 2024 and 2025.

	Year Ended December 31,	
(in thousands)	2024	2025
Current expense (benefit)		
Federal	$ —	$ —
State	212	163
Foreign	—	—
Total current expense (benefit)	212	163
Total income tax expense (benefit)	$ 212	$ 163

The Company retrospectively applied ASU 2023-09. A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows (in thousands):

	Year Ended December 31, 2024		Year Ended December 31, 2025	
	Amount	Rate	Amount	Rate
U.S. federal statutory tax rate	$ (36,447)	21.00%	$ (42,696)	21.00%
State and local income taxes, net of federal income tax effect	167	(0.10)%	129	(0.06)%
Tax credits - research and development tax credits	(7,020)	4.04%	(8,299)	4.08%
Changes in valuation allowances	41,410	23.86%	48,435	(23.82)%
Nontaxable or nondeductible items				
Stock Compensation	1,247	(0.72)%	1,530	(0.75)%
Meals and entertainment	139	(0.08)%	119	(0.06)%
Other	311	(0.18)%	174	(0.09)%
Other	405	(0.23)%	771	(0.38)%
Total tax expense	$ 212	(0.12)%	$ 163	(0.08)%

The Company's effective tax rate differs from the federal statutory rate primarily due to the tax expense impact of nondeductible equity compensation and other permanent differences, tax credits, state taxes and valuation allowance.

In 2024 and 2025, state and local income taxes in Massachusetts comprised the majority of the state and local income taxes, net of federal income tax effect category.

A summary of income taxes paid, net of refunds received is as follows (in thousands):

	Year Ended December 31,	
	2024	2025
U.S. federal	$ —	$ —
U.S. state and local:		
Massachusetts	$ 212	$ 163
Total taxes paid, net of refunds received	$ 212	$ 163

The net deferred income tax asset balance related to the following (in thousands):

	Year Ended December 31,	
	2024	2025
Deferred Tax Assets:		
Deferred revenue	$ 3,061	$ 7,262
Lease liability	16,420	16,306
Net operating loss carryforwards	37,948	87,816
Tax credits	24,461	35,513
Accruals and other	8,461	10,884
Amortization	199	177
Section 174 R&D costs	75,931	66,614
Deferred tax assets before valuation and allowance	166,481	224,572
Valuation allowance	(147,889)	(207,770)
Net total deferred tax assets	18,592	16,802
Deferred Tax Liabilities:		
Right of use asset	(16,896)	(15,921)
Depreciation	(1,696)	(881)
Total deferred tax liabilities	(18,592)	(16,802)
Net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2025, the Company had a federal net operating loss ("NOL") carryforward of approximately $331.8 million, all of which was available to offset future income tax liabilities indefinitely. As of December 31, 2025, the Company had state NOL carryforwards of approximately $287.6 million. The Company also had U.S. federal research and development tax credit carryforwards of $24.9 million available to offset future U.S. federal income taxes, which expire at various times through 2040. As of December 31, 2025, the Company had state tax credit carryforwards of $13.4 million which expire at various times through 2040.

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("IRC"), a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. The Company conducted an ownership analysis under IRC Section 382 as of January 31, 2025, and determined the Company experienced an ownership change event on September 2, 2021 that would limit the Company's utilization of its NOLs and tax credits. The Company maintains a valuation allowance against deferred tax assets that are not expected to be realized, including those limited by Section 382.

The Tax Cuts and Jobs Act of 2017 ("TCJA") requires taxpayers to capitalize and amortize research and development expenditures, resulting in capitalized costs to date of $375.2 million and $411.1 million as of December 31, 2024 and 2025, respectively. We will amortize these costs for tax purposes over five years for research and development performed in the U.S. and over 15 years for research and development performed outside the U.S.

The One Big Beautiful Bill Act ("OBBBA"), passed July 4, 2025, permanently suspends the Section 174 requirement to capitalize and amortize domestic research & development expenditures paid or incurred. For tax years beginning after December 31, 2024, companies can elect to currently expense R&D amounts incurred in the U.S.. In addition, all taxpayers are permitted to make an election to accelerate the deductions for unamortized domestic R&D expenses that were capitalized after December 31, 2021 and before January 1, 2025 over a one or two-year period, beginning with the taxpayer's first tax year beginning after December 31, 2024 or allow these capitalized expenses to amortize over their remaining lives. The Company plans to amortized the remaining domestic R&D expenses which have been previously capitalized. In addition, the Company will currently expense domestic R&D costs beginning in the 2025 tax year and continue to capitalize foreign R&D costs over fifteen years.

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a valuation allowance against its deferred tax assets at December 31, 2024 and 2025, respectively, because the Company's management has determined that it is more likely than not that these assets will not be fully realized. The increase in the valuation allowance of $53.7 million in 2024 and $59.9 million in 2025 primarily relates to the net loss incurred by the Company and capitalized research and development costs.

A reconciliation of the valuation allowance is as follows (in thousands):

	Year Ended December 31,	
	2024	2025
Balance at beginning of year	$ 94,228	$ 147,889
Net charges to expense	53,661	59,881
Balance at end of year	$ 147,889	$ 207,770

The Company accounts for uncertainty in income taxes under the provisions of ASC 740 which defines the thresholds for recognizing the benefits of tax return positions in the financial statements as "more likely than not" to be sustained by the taxing authority. The tax benefit is measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. As of December 31, 2024 and 2025, the Company had recorded no unrecognized tax benefits.

The Company's policy is to recognize both interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of December 31, 2024 and 2025, there were no interest or penalties associated with unrecognized tax benefits.

The Company files income tax returns in the United States and various states. The Company has been notified by the IRS of their intention to audit the federal income tax return for the year ended December 31, 2023.

The tax years 2022 through present remain open to examination by major taxing jurisdictions to which the Company is subject to, which are primarily in the United States.

15. LEASES

Operating Leases

In June 2021, the Company entered into a lease agreement for office space at a building located in Somerville, MA. The lease commenced May 11, 2022 and is set to expire June 30, 2032. The Company is entitled to two options to extend the lease term for five years each. The option to extend the lease term is not reflected in the right-of-use asset and lease liability as it is not reasonably certain of being exercised. Under the terms of the lease, the Company provided a security deposit of approximately $2.9 million to the landlord, in the form of a letter of credit, which is classified as restricted cash within other assets on the consolidated balance sheet.

In October 2021, the Company entered into a lease agreement for office and laboratory space at a building located in Andover, MA. The lease commenced November 1, 2021 and is set to expire October 31, 2026. Under the terms of the lease, the Company provided a security deposit of approximately $0.8 million to the landlord, in the form of a letter of credit, which is classified as restricted cash within other assets on the consolidated balance sheet. On December 30, 2024, the Company entered into the First Amendment to the Lease Agreement (the "First Amendment") to extend the term of the Lease Agreement through December 31, 2034. The First Amendment provides an early termination option allowing the Company to terminate the Lease Agreement on or after December 31, 2031.

Finance Leases

In 2023, the Company entered into finance lease agreements for the purchase of lab equipment with a fair value of $10.3 million. The leases are payable over 36 to 60 months with an upfront payment $0.9 million. No additional finance lease agreement was entered into in 2024 or 2025.

The following table summarizes the Company's costs included in consolidated statement of operations and comprehensive loss related to operating leases and finance leases the Company has entered into through December 31, 2024 and 2025:

	Year Ended December 31,	
	2024	**2025**
Finance lease cost		
Amortization of right-of-use assets	$ 8,519	$ 5,938
Interest on lease liabilities	2,117	1,136
Operating lease cost	10,146	12,015
Variable lease cost	6,044	5,415
Short-term lease cost	14	43
Total lease cost	$ 26,840	$ 24,547
Other information		
Operating cash flows used for finance leases	$ 2,117	$ 1,136
Financing cash flows used for finance leases	$ 11,124	$ 8,161
Operating cash flows used for operating leases	$ 9,691	$ 8,784
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 18,648	$ 2,425
Right-of-use assets obtained in exchange for new finance lease liabilities	$ —	$ —
Weighted-average remaining lease term – finance leases	2.95 years	2.13 years
Weighted-average remaining lease term – operating leases	8.52 years	7.42 years
Weighted-average discount rate – finance leases	10.85%	11.37%
Weighted-average discount rate – operating leases	9.81%	9.81%

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at December 31, 2025, the following table summarizes the Company's maturities of lease liabilities as of December 31, 2025 (in thousands):

	Finance Lease	Operating Lease
2026	$ 4,525	$ 11,298
2027	3,278	11,621
2028	150	11,297
2029	—	11,281
2030		11,603
Thereafter	—	30,131
Total lease payments	$ 7,953	$ 87,231
Less: imputed interest	(734)	(25,924)
Present value of lease liabilities	$ 7,219	$ 61,307

16. COMMITMENTS AND CONTINGENCIES

Legal Proceedings – The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

17. RELATED-PARTY TRANSACTIONS

In August 2018, the Company entered into a ten-year management service agreement with Flagship Pioneering, Inc. ("Flagship Pioneering") to provide management services, including accounting, human resources, information technology, legal, and consultation. The Company also agreed to reimburse Flagship Pioneering for certain expenses, including insurance and benefits, partner and related fees, software licenses, supplies, and administration consulting services incurred on the Company's behalf. The Company recorded general and administrative expense totaling $1.0 million and $0.6 million related to these services for the years ended December 31, 2024 and 2025, respectively. As of December 31, 2024 and 2025, the Company owed $0.2 million and $0.1 million, respectively, to Flagship.

In July 2022, the Company entered into a Vivarium Shared Space Operating Agreement, as amended in May 2024, with Cellarity, Inc. ("Cellarity"), an affiliated with Flagship, to use a vivarium space, along with other companies affiliated with Flagship. The Company pays Cellarity a monthly operating fee for using the vivarium and obtaining various services; the shared cost is variable depending on the actual usage. The Company recognized less than $0.6 million and $0.4 million of expense paid to Cellarity during the years ended December 31, 2024 and 2025, respectively. As of December 31, 2024 and 2025, the Company had $0.1 million at each date outstanding in accounts payable to Cellarity, respectively.

In August 2021, the Company entered into an agreement (the "Flagship Agreement"), with Flagship Pioneering Innovations VI, LLC ("Flagship"), pursuant to which it (i) irrevocably and unconditionally assigned to Flagship all of the Company's right, title and interest in and to certain foundational patent rights conceived prior to the Company's launch, which is defined as the closing of its Series B financing, and its improvements to such patent rights that cannot be practiced without infringing the foregoing patent rights (such patent rights and improvements, the "Foundational IP"), and (ii) obtained an exclusive, worldwide, royalty-bearing, sublicensable, transferable license from Flagship under such Foundational IP to develop, manufacture and commercialize any product or process or component thereof in the licensed field of human therapeutics and vaccines that would, absent the license granted to the Company by Flagship, infringe at least one valid claim of the Foundational IP. Pursuant to the Flagship Agreement, the Company is obligated to use commercially reasonable efforts to diligently exploit licensed products in the licensed field and maintain such efforts during the term of the Flagship Agreement. To satisfy the due diligence requirements, the Company must spend at least $1.0 million each year on its own development and commercialization activities with respect to licensed products during the term of the Flagship Agreement and at least $10.0 million on such activities until August 2026, which may include internal or external research and development costs. The research and development costs are expensed as incurred. The Company's only financial obligation to Flagship is to pay Flagship, on a licensed product-by-licensed product and jurisdiction-by-jurisdiction basis, royalties equal to a low single-digit percentage on net sales of licensed products by the Company or its sublicensees until the expiration of the last valid claim of any Foundational IP covering such licensed product in such jurisdiction. To date, there have been no amounts paid or received by the Company under the Flagship Agreement.

In June 2023, the Company entered into a Collaboration Agreement with Pioneering Medicines 02, Inc., a company newly formed and controlled by Flagship Labs VII, LLC and Flagship Pioneering Fund VII, L.P., each of which are affiliated with Flagship Pioneering. See Note 18.

18. VARIABLE INTEREST ENTITIES

On June 22, 2023, the Company entered into a collaboration agreement (the “Prior PMCo Agreement”), with Pioneering Medicines 02, Inc. (“PMCo”), an affiliate of Flagship Pioneering, pursuant to which PMCo was granted an exclusive, worldwide, royalty-free, sublicensable license under certain of the Company’s patent rights and know-how to develop, manufacture and commercialize licensed products containing certain antibodies against TSLP and/or IL-4Rα, including GB-0895, in all fields. During the period from the effective date until June 2030, neither the Company nor any of its affiliates are permitted to develop or commercialize, nor collaborate with, enable or otherwise authorize, license or grant any right to any third-party to develop or commercialize, any antibody that (i) binds to TSLP, (ii) binds to both TSLP and IL-4Rα (but no other target), or (iii) binds to IL-4Rα (and no other target, including TSLP) in the territory. Subject to the license to PMCo, as between the parties, the Company will solely own and retain all right, title and interest in and to all technology, know-how and materials conceived, discovered, developed or otherwise made by or on behalf of PMCo or any of its affiliates or sublicensees in the course of performing activities under or in connection with the Prior PMCo Agreement, and any patents or patent applications claiming any of the developed know-how.

Under the terms of the Prior PMCo Agreement, the Company and PMCo will collaborate on research and development activities with respect to the licensed products and will share research and development costs, with the Company bearing 65% and PMCo bearing 35% of all fully-burdened research costs and development expenses, which percentage commitments are subject to adjustment if the Company or PMCo fail to pay or wish to reduce our respective percentage commitments prior to the consummation of a business combination of PMCo or a license transaction of all commercial rights for all licensed products. In addition, the Company is entitled to 70% and PMCo is entitled to 30% of the proceeds of a business combination of PMCo or an exclusive license transaction with a third-party; provided, however, that the failure by any party to bear their agreed portion of the fully-burdened research costs and development expenses shall result in an automatic *pro rata* adjustment of such party’s interest in any such proceeds and that such failure shall not automatically be deemed to constitute a breach of the Prior PMCo Agreement.

Subject to the terms and conditions of the Prior PMCo Agreement, the Company is obligated to use commercially reasonable efforts to develop licensed products in the licensed field in the territory, including by the way of directing PMCo under the Prior PMCo Agreement, and upon receipt of regulatory approval for a licensed product in a country, PMCo will be obligated to use commercially reasonable efforts to commercialize such licensed product in such country.

Following the first achievement of a specified regulatory milestone, and prior to a business combination of PMCo or a license transaction of all commercial rights for all licensed products, (i) the Company has the right to acquire all of the securities of PMCo for a price equal to a low tens percentage of the fair market value of such securities on terms and conditions to be negotiated between the Company and PMCo, and if the Company does not exercise such right, the Company has the right to initiate a business combination of PMCo or an exclusive license transaction with a third party; and (ii) PMCo has the right to have us acquire all of the securities of PMCo in exchange for royalties equal to a mid-to-high single-digit percentage on net sales of licensed products on a country-by-country and licensed product-by-licensed product basis until the later of (a) the expiration of the last to valid claim of any patent right controlled by us or PMCo covering the use or sale of such licensed product in such country, (b) expiration of regulatory exclusivity for such product in such country, and ten years following the first commercial sale of such licensed product in such country (such transactions in (i) and (ii), collectively, the “Subject Transactions”). Concurrently with the Prior PMCo Agreement, the Company, PMCo and Pioneering Medicines 02, LLC (“PM LLC”), the sole stockholder of PMCo, entered into a drag-along agreement (the "Drag-Along Agreement"), pursuant to which PM LLC agreed to, among other things, vote in favor of a Subject Transaction.

The Company consolidated PMCo, which is deemed to be VIE and of which the Company is the primary beneficiary based on a combination of the decision-making power over the activities that most significantly impact the economic performance of PMCo and an obligation to absorb losses or receive benefits from PMCo. These decisions and significant activities include, but are not limited to, research and development activities under the research plan and the development plan and other operational and strategic matters. The terms of the agreements governing PMCo prohibit the Company from using the assets of PMCo to satisfy the obligations of other entities.

The Prior PMCo Agreement is being treated as an asset acquisition as PMCo's assets transferred do not meet the definition of a business. Prior to the acquisition, PMCo's majority stockholder was the same as the Company's majority stockholder and there was common ownership and control, including common members of the Board. As such, the Company accounted for the asset acquisition as a transaction between entities under common control. The Company initially measured and recognized the assets and liabilities transferred at their carrying amounts in the accounts of PMCo at the date of transfer. Accordingly, the Company recognized non-controlling interest ("NCI") based on the net assets held by PMCo. As a result of PMCo's preferred stock being redeemable upon a deemed liquidation event and its put right, the NCI in PMCo is presented in mezzanine equity.

The net assets acquired on June 30, 2023, included cash totaling $0.6 million and liabilities totaling $2.1 million, comprised primarily of accounts payable and accrued liabilities.

The following table below presents the assets and liabilities (excluding intercompany balances that were eliminated in consolidation) as of December 31, 2024 and 2025 (in thousands):

	Year Ended December 31,	
	2024	2025
Assets		
Current Assets:		
Restricted cash and cash equivalents (VIE)	$ 1,427	$ 339
Prepaid expenses and other current assets	—	100
Total current assets	1,427	439
Total assets	$ 1,427	$ 439
Liabilities		
Current liabilities		
Accrued expenses and other current liabilities	$ 86	$ 90
Total current liabilities	86	90
Total liabilities	$ 86	$ 90

The Company has recorded PMCo's cash and cash equivalents as "Restricted cash and cash equivalents (VIE)" because (i) the Company does not have any interest in or control over PMCo's cash and cash equivalents and (ii) the Company's agreements with PMCo do not provide for PMCo's cash and cash equivalents to be used for the development of the assets that the Company licensed from PMCo. Assets recorded as a result of consolidating PMCo's financial condition into the Company's balance sheets do not represent additional assets that could be used to satisfy claims against the Company's general assets.

The net losses attributable to non-controlling interest holders is the loss absorbed by the holders of the ownership interest of PMCo, which consist primarily of research and development costs that were reimbursed by PMCo under the Prior PMCo Agreement and amounted to $7.6 million and $19.8 million during the years ended December 31, 2024 and 2025, respectively.

19. DEFINED CONTRIBUTION PLAN

The Company has established a defined contribution 401(k) Savings Plan (the "Generate 401(k) Plan") which allows eligible employees to contribute from 1% to 90% of their compensation, subject to certain statutory limitations. The Generate 401(k) Plan permits discretionary matching contributions by the Company to participant accounts. During each of the years ended December 31, 2024 and 2025, the Company paid, in the form of cash, matching contributions to participant accounts of approximately $1.9 million.

20. SEGMENT INFORMATION

The Company has one operating segment. The Company's operating segment is engaged in the field of generative biology by using machine learning for drug discovery and development through the programming of novel protein therapeutics. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of assessing performance and allocating resources based on net loss attributable to Generate Biomedicines, Inc. stockholders that also is reported on the consolidated statement of operations as consolidated net loss to Generate Biomedicines, Inc. stockholders. This financial metric is used by the chief operating decision maker ("CODM") to make key operating decisions such as the allocation of capital between program expenses, early-stage discovery expenses, and general and administrative expense, including headcount and facilities decisions. The operating segment's revenue is derived from multiple collaboration agreements from which the segment licenses certain development or product candidates and performs research and development services. The measure of segment assets is reported on the balance sheet as total consolidated assets. All of the Company's long-lived assets are held in the United States. The following table presents selected financial information about the Company's single operating segment for the years ended December 31, 2024 and 2025 (amounts in thousands):

	Year Ended December 31,	
	2024	2025
Revenue:		
Collaboration revenue	$ 20,459	$ 31,893
Operating Expenses[(a)]:		
Research and development personnel-related (excluding stock-based compensation)	65,292	74,554
External research and development costs – GB-0895	17,443	43,530
External – discovery related costs and other	68,459	83,392
General and administrative personnel-related (excluding stock-based compensation)	17,515	17,668
External – General and administrative	13,875	14,068
Stock-based compensation expense	19,465	20,577
Depreciation expense	15,349	13,178
Other segment expenses[(b)]	233	253
Interest income	(18,118)	(13,661)
Interest expense	2,118	1,136
Provision for income taxes	212	163
Consolidated net loss	$ 181,384	$ 222,965
Net loss attributable to non-controlling interests	7,613	19,811
Consolidated net loss attributable to Generate Biomedicines, Inc. stockholders	$ 173,771	$ 203,154

(a) The significant expense categories and amounts align with the segment-level information that is regularly provided to the CODM.
(b) Other segment expenses include change in fair value of preferred stock warrant liability and foreign currency exchange loss.

21. SUBSEQUENT EVENTS

(a) On February 4, 2026, the Company entered into a stock purchase agreement ("Stock Purchase Agreement") with PM LLC, pursuant to which the Company has agreed to purchase, and PM LLC has agreed to sell, all of the issued and outstanding equity interests in PMCo. In consideration for such sale, PMCo, PM LLC and the Company have agreed to terminate the Prior PMCo Agreement and the Drag-Along Agreement, and the Company has agreed to pay PM LLC a portion of the net sales, if any, arising from the sale of certain products covered by certain patents or containing certain know-how ("Generate Products") developed under the Prior PMCo Agreement. The closing of the Stock Purchase Agreement is scheduled to occur concurrently with the execution of the underwriting agreement for the Company's initial public offering.

The Company will generally be obligated to make net sales payments equal to a high-single digit percentage of net sales of Generate Products, including any Generate Product that contains GB-0895. However, if a Generate Product (i) does not contain GB-0895, (ii) binds to at least one of TSLP or IL-4Rα, and (iii) binds to other proteins in addition to TSLP or IL-4Rα, then the sales payment is reduced based on the composition of the product. Further, if we exclusively license our rights to exploit a Generate Product in one or more countries to a third party, and the royalties on net sales of such Generate Product to be paid by such third party are subject to certain specified reductions, then we may be allowed to further proportionally reduce the sales payment due to PM LLC, depending on the relative value of the future royalties due to us from such third party as compared to the total deal consideration.

Both PM LLC and the Company have the ability to trigger a buy-out of all future net sales payments under the Stock Purchase Agreement in certain instances, which would require the Company to make a single payment to PM LLC that is equivalent to the fair market value of the projected future net sales payments due to PM LLC based upon the projected future net sales of the applicable and then-existing Generate Products (the "Buy-Out Amount"). Both PM LLC and the Company have this right following the Company entering into an exclusive license to the Company's rights to exploit a Generate Product in one or more countries with a third party (or transaction approximating an exclusive license). In addition, in the event the Company is acquired by a qualified acquirer, the Company has the right to trigger a buy-out of all future sales payments under the Stock Purchase Agreement in exchange for the Buy-Out Amount. Following payment of the Buy-Out Amount with respect to a Generate Product in a country, the Company's diligence obligations and the Company's obligations to make net sales payments with respect to the applicable Generate Products in the applicable countries shall immediately terminate, as do the Company's exclusivity restrictions with respect to the protein targeted by such Generate Products in such countries.

The transaction represents the acquisition of a non-controlling interest in a consolidated subsidiary. The Company will account for the acquisition of the non-controlling interest as an equity transaction with no gain or loss recognized in net income (loss). The consideration payable by the Company is contingent upon the successful commercialization of licensed products. The contingent consideration will be recognized when the contingency is resolved and the consideration is paid or becomes payable.

As a result of the acquisition of the non-controlling interest, the Company will no longer allocate losses to the non-controlling interest. The net loss allocated to the non-controlling interest, which was $7.6 million and $19.8 million during the years ended December 31, 2024 and 2025, respectively, primarily represented amounts that PMCo had paid to the Company under the cost sharing arrangement.

(b) On February 20, 2026, the Company effected a 1-for-1.5190 stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 10). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

25,000,000 Shares

Generate:Biomedicines

Common Stock

Prospectus

Goldman Sachs & Co. LLC **Morgan Stanley**

Piper Sandler **Guggenheim Securities** **Cantor**

Until March 23, 2026 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

February 26, 2026