UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2025

Or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-41031

Bluejay Diagnostics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**47-3552922**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
360 Massachusetts Avenue, Suite 203, Acton, MA	**01720**
(Address of Principal Executive Offices)	(Zip Code)

(844) 327-7078
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	BJDX	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting stock held by non-affiliates as of June 30, 2025, was approximately $2,570,000 based on the closing price of the common stock of the registrant as reported on the Nasdaq Capital Market on such date. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant have been excluded from this computation. The determination

of affiliate status for this purpose is not necessarily a conclusive determination for other purposes. As of March 2, 2026, there were 972,215 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement relating to its Annual Meeting of Stockholders within 120 days of the fiscal year ended December 31, 2025. Portions of such definitive proxy statement are incorporated by reference in Part III of the Form 10-K to the extent described therein.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements in the "Business", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other sections of this Annual Report on Form 10-K (the "Form 10-K"). In some cases, you can identify these statements by forward-looking words such as "may," "might," "should," "would," "could," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or "continue," and the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to known and unknown risks, uncertainties and assumptions about us, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements.

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this Form 10-K may describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this Form 10-K to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this Form 10-K in the case of forward-looking statements contained in this Form 10-K.

You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward looking-statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

SPECIAL NOTE REGARDING COMPANY REFERENCES

In this Form 10-K, and unless the context otherwise requires, Bluejay Diagnostics, Inc. is referred to as the "Company," "we," "us" and "our".

SUMMARY OF RISK FACTORS

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, liquidity, results of operations and prospects. These risks are discussed more fully in Item 1A. Risk Factors. These risks include, but are not limited to, the following:

- We have incurred significant losses since our inception, do not currently generate any operating income, and will continue to incur losses as we work to obtain product approval, and thus we may never achieve or maintain profitability.

- We will require additional funding to finance our operations to continue as a going concern, which may not be available to us on acceptable terms, or at all, and our lack of cash resources could cause us to run out of cash resources in the near-term.

- Since the initial public offering of our common stock in November 2021, the market price of our common stock has fallen by more than 99.9%, and we expect to need additional funding amounts substantially greater than the current market capitalization of our common stock, which may result in future dilution that coincides with further declines in the trading price of our common stock beyond the substantial declines that have occurred in recent years.

- The number of shares of common stock underlying our outstanding warrants is several times greater than our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive the Black Scholes value of such warrants, which may reduce the consideration otherwise available for payment to holders of our common stock.

- Our common stock is currently listed for quotation on the Nasdaq Capital Market, but we may be unable to meet requirements for continued listing in the future, particularly if our common stock trades below $1.00 per share in the future. In addition, Nasdaq has recently proposed a new $5 million market value of listed securities requirement that we would not currently satisfy and therefore could cause our common stock be delisted by Nasdaq on an imminent basis, if approved by the SEC.

- Our license arrangements with Toray, which relate to the license of the core technology used in our Symphony Cartridges for Sanyoseiko Co., Ltd. (“Sanyoseiko”) to manufacture cartridges for Bluejay, are subject to risks that may threaten our viability or otherwise have a material adverse effect on us and our business, assets and its prospects.

- Certain processes related to manufacturing have been the cause of prior performance and reproducibility issues with our cartridge product and we do not expect to be able to test our clinical trial samples until such manufacturing issues have been confirmed to be resolved.

- Our Symphony platform, including its software and systems, may contain undetected errors, which could limit our ability to provide our products and diminish the attractiveness of our offerings.

- If we or our manufacturers fail to comply with the regulatory quality system regulations or any applicable equivalent regulations, our proposed operations could be interrupted, and our operating results would suffer.

- If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

- Significant raw material shortages, supplier capacity constraints, supplier disruptions, and sourcing issues may adversely impact or limit our products sales and or impact our product margins.

- The regulatory clearance process which we may be required to navigate may be expensive, time-consuming, and uncertain and may prevent us from obtaining clearance for our planned products.
- Clinical data obtained in the future may not meet the required objectives, which could delay, limit or prevent any regulatory clearance.
- We may be unable to complete required clinical evaluations, or we may experience significant delays in completing such clinical evaluations, which could prevent or significantly delay our targeted product launch timeframe and impair our viability and business plan.
- We and our suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.
- We may be liable if the FDA or another regulatory agency concludes that we have engaged in the off-label promotion of our products.
- Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of any future products and to manufacture, market and distribute our products after clearance or approval is obtained.
- We depend on intellectual property licensed from Toray, and any dispute over the license would significantly harm our business.
- We will depend primarily on Toray to file, prosecute, maintain, defend and enforce intellectual property that we license from it and that is material to our business.
- We and Toray may be unable to protect or enforce the intellectual property rights licensed to us, which could impair our competitive position.
- We and/or Toray may be subject to claims alleging the violation of the intellectual property rights of others.
- We and Toray may be subject to claims challenging the invention of the intellectual property that we license from Toray.
- Our analytical validation, required for FDA clearance, may take longer than expected.
- The FDA could request additional data or testing after our submission for application, requiring additional costs and delaying approval.
- We face intense competition in the diagnostic testing market, particularly in the IL-6 space, and as a result we may be unable to effectively compete in our industry.
- Sales of substantial amounts of our securities in the public market could depress the market price of our common stock.
- Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have material adverse effect on our business and stock price. Our President and Chief Executive Officer, in addition to serving as principal executive officer, currently serves as our principal financial and accounting officer, and we have no employees devoted on a full-time basis to our finance, accounting, legal or compliance functions, which may substantially increase the likelihood that we will fail to successfully maintain effective internal controls over financial reporting, or effective disclosure controls and procedures.

PART I

ITEM 1. BUSINESS

Overview

Bluejay Diagnostics, Inc. ("Bluejay") is a medical diagnostics company focused on improving patient outcomes in critical care settings, with a focus on sepsis. We are working on developing rapid, near-patient tests using whole blood on our Symphony technology platform ("Symphony"), which consists of an analyzer and single-use protein detection cartridges. We do not yet have regulatory clearance for Symphony, and we will need to receive regulatory authorization from the U.S. Food and Drug Administration (the "FDA") before Symphony can be marketed as a diagnostic product in the United States. We have completed the pre-clinical development of the Symphony analyzer. During 2026, we transferred the knowledge, technology and process underlying the production of the Symphony cartridges from the original developer and outside supplier, Toray Industries, to a contract manufacturing facility with FDA certification run by Sanyoseiko. We are also working with Sanyoseiko to modify the manufacturing process of the Symphony cartridges to address certain technical issues to bring Symphony to a level consistent with necessary performance and quality requirements for regulatory submission. To achieve our plan, we expect to need to raise at least $20 million of further capital by the end of the 2027 fiscal year, which we hope to do in various tranches.

Our Symphony platform is a combination of Bluejay's intellectual property ("IP") and exclusively licensed and patented IP on the Symphony technology that we believe, if cleared, authorized, or approved by the FDA, could provide a solution to a significant market need in the United States. The Symphony device candidate is designed to produce laboratory-quality results in approximately 20 minutes in critical care settings, including Intensive Care Units ("ICUs") and Emergency Rooms ("ERs"), where rapid and reliable results are required.

Our first product candidate, the Symphony IL-6 test, is an immunoassay for the measurement of interleukin-6 (IL-6) to be used for the monitoring of disease progression in critical care settings. We are currently focused on pursuing the Symphony IL-6 test in the context of sepsis. IL-6 is a clinically established inflammatory biomarker, and is considered a 'first-responder' for assessment of severity of infection and inflammation across many disease indications, including sepsis. A current challenge of healthcare professionals is the excessive time and cost associated with determining a patient's level of severity at triage and we believe that our Symphony IL-6 test, if ultimately successful and approved, could have the ability to consistently monitor this critical care biomarker with rapid results.

We are currently enrolling patients in our SYMON-II pivotal clinical trial, which is designed to validate findings from our SYMON-I pilot study. The trial aims to assess the predictive performance of IL-6 levels in ICU patients for 28-day all-cause mortality. As of the date of this filing, we have enrolled approximately 583 hospital patients among a target of 750 patients, and we have collected, frozen and biobanked blood samples from the enrolled patients, while also obtaining all related patient data regarding their disease progression and outcomes. We expect to complete patient enrollment in the study in the summer of 2026. We are not yet testing the samples because we are simultaneously working with Sanyoseiko to manufacture the cartridges that will be used in the test, and these cartridges are still being manufactured and verified to ensure that they meet FDA requirements for submission and commercial production. Our goal is to produce and verify these cartridges during 2026 and be in position to analyze the blood samples using our Symphony IL-6 test in the third quarter of 2026, with a goal of being in position to submit a 510(k) regulatory application to the FDA in 2027 and an objective of achieving FDA clearance thereafter.

If we succeed with the foregoing plan, in the future we hope to develop additional tests for Symphony, including tests for myocardial infarction and congestive heart failure (cardiac biomarkers hsTNT and NT pro-BNP) as well as other tests using the Symphony platform.

In the future, we also hope to explore new products to support our biomarker detection program. Furthermore, we intend to explore strategic opportunities around our pending IP on clinical utilities of IL-6 and the specimen biobanks generated from our SYMON I and SYMON II clinical studies.

Our operations to date have been funded primarily through the proceeds of (i) our initial public offering (the "IPO") in November 2021, (ii) the registered direct offering of common stock and concurrent private placement of warrants that we completed in August 2023, (iii) the public offering of common stock and warrants that we completed in January 2024, (iv) the public offering of common stock and warrants that we completed in June 2024, (v) the warrant inducement and private placement transaction of common stock and warrants that we completed in April 2025 and (vi) the private placement of common stock and warrants that we completed in October 2025. Since inception, our operations have resulted in accumulated deficit of approximately $41.5 million, and for the fiscal year ended December 31, 2025, we incurred operating losses of approximately $6.8 million. As described above and elsewhere herein, we expect to need a material amount of additional funding to finance our operations during the next several years and ultimately commercialize our products, and we do not currently expect to have any sources of revenue during this period.

We were incorporated under the laws of Delaware on March 20, 2015. Our headquarters is located in Acton, Massachusetts.

Our Market

The Symphony platform is designed to address a subset of the global *in vitro* diagnostics devices ("IVDs") market, with a focus on targeting critical care markets where physicians must quickly determine patient acuity to identify optimal treatment regimens. We are currently focused on our initial biomarker test, Symphony IL-6 test, in the context of the evaluation of the risk of mortality due to sepsis. We hope in the future to also explore the potential for adding new biomarker tests to the Symphony platform to also be used in the context of cardio-metabolic diseases, cancer and other diseases that require rapid tests.

Our Business Model

We do not currently have any revenue-generating operations. Our goal is to become the first provider of rapid tests for critical care settings, including infectious, inflammatory and metabolic diseases, by leveraging the strengths of our Symphony platform. We intend to target our sales and marketing of Symphony to the largest critical care facilities in the United States. Our planned business model, which is contingent on us ultimately obtaining market clearance and commercializing our Symphony platform, includes the following:

- *Financing Model*. We intend to offer various financing options for the device itself. As such, our planned business model would not require customers to incur a significant capital outlay, assuming we are able to successfully offer such financial options.

- *Recurring Revenue*. We intend to sell single-use diagnostic test cartridges, thereby seeking to create a growing and recurring revenue stream, as adoption and utilization increase, and as we develop tests for additional indications. We intend that the sale of test cartridges would generate the majority of our revenue and gross profit.

- *Expand our Menu of Diagnostic Products*. Our goal would be for the average customer use of the Symphony platform to increase as overall adoption of the product occurs. If we are able to achieve market clearance in the context of sepsis and then expand our test menu to other diseases and/or conditions, we hope to be able to increase our annual revenue per customer through the resulting increase in utilization.

The Symphony Platform

The Symphony platform is a proprietary technology platform that is designed to provide rapid and accurate measurements of key diagnostic biomarkers found in blood in a manner that we believe is innovative in the market. Symphony is compact and is designed for the potential of it to be deployed in a manner that is more mobile than current laboratory diagnostic platforms on the market. Symphony incorporates a user-friendly interface where all sample preparation and reagents are integrated into the disposable Symphony cartridges. Symphony only requires a few drops of blood to provide a measurement in approximately 20 minutes.

The Symphony analyzer is developed and is designed to orchestrate sample processing (e.g. whole blood, plasma, serum, etc.), biomarker isolation, and immunoassay preparation using non-contact centrifugal force. All necessary reagents and components are integrated into the Symphony cartridges. Utilizing precision microchannel technology and high specificity antibodies, liquid samples are processed, and the biomarker is isolated within the Symphony cartridge. Intermitted centrifugation cycles enable complex fluid movements, allowing sequential reagent additions and independent reaction steps inside the Symphony cartridge. At the conclusion of the test, the Symphony analyzer measures the fluorescence signature correlating to a highly sensitive quantitation of the biomarker.

To perform a Symphony test, the test operator adds the sample (e.g. whole blood, plasma, serum, etc.) to the Symphony cartridge. After scanning the patient ID, the Symphony cartridge is inserted into the Symphony analyzer and the operator initiates the fully automated test. Each analyzer can run up to six cartridges simultaneously, either with six different patient samples or six different tests, providing quantitative measurements used for improved patient management and clinical decision-making.

Manufacturing

We plan to manufacture our analyzers through Sanyoseiko as a contract manufacturing organizations (“CMO”), and we have entered into a master supply and service agreement governing these matters with Sanyoseiko. Pursuant to statements of work that have begun providing to Sanyoseiko under these agreements, Sanyoseiko will provide end-to-end support for the Symphony platform, including supporting the manufacturing redevelopment process for analyzers and cartridges (with hardware, software, and design updates), managing raw material sourcing and vendor compliance, and serving as the Company’s contract manufacturing organization for analyzers, cartridges, and related components. In this capacity, Sanyoseiko will oversee fulfillment, kit assembly, labeling, packaging, shipping, and quality control of manufactured products, while also providing regulatory and quality management support, and equipment storage and maintenance.

Sanyoseiko had been selected as our CMO due to their core competencies in manufacturing and quality system recognized by the FDA. Sanyoseiko's facilities are located in Japan. We currently license the technology for the Symphony cartridges from Toray. Our license grants us exclusive global marketing, sales and manufacturing rights, with the exception of Japan. Bluejay holds the rights to manufacture the analyzers.

FDA Regulatory Strategy

The design, development, manufacture, testing and sale of our products in the U.S. are subject to regulation by numerous governmental authorities, principally the FDA, and corresponding state and local regulatory agencies. Generally, the products we develop must be cleared by the FDA before they are marketed in the United States. Before and after approval, authorization, or clearance in the United States, our products are subject to extensive regulation by the FDA, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, recordkeeping, market clearance, authorization or approval, labeling and promotion, import and export, marketing and sales, and distribution of medical devices.

Our current regulatory strategy is designed to support commercialization of Symphony in the United States if and when we receive marketing authorization from the FDA. In May 2023, we submitted a pre-submission application to the FDA presenting study designs to validate Symphony IL-6 for use with hospitalized sepsis patients. We participated in a pre-submission meeting with the FDA in August 2023, and at the meeting the FDA provided feedback on the study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Based on this feedback, we determined to proceed on this basis, which considers the FDA's feedback.

In the second quarter of 2024, we completed a multicenter SYmphony IL-6 MONitoring Sepsis ("SYMON") clinical study investigating the role of interleukin-6 (IL-6) in patients diagnosed with sepsis and septic shock. This prospective study assessed the performance of IL-6 upon initial presentation to the intensive care unit (ICU). A primary endpoint of the SYMON-I pilot clinical study (registered clinical trial number NCT06181604) suggested that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU may predict patient mortality out to 28 days. Furthermore, a secondary endpoint of the SYMON-I study suggested that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU is a predictor of patient mortality during their hospitalization. Other secondary endpoints suggested that lactate and Sequential Organ Failure Assessment (SOFA), standard clinical tests used for sepsis and septic shock patients, were not predictors of patient mortality out to 28 days. We believe that the findings underscore the potential importance of IL-6 as a predictor and provide new insights into the potential pathways for improving sepsis outcomes.

Using the data analysis from the SYMON-I pilot clinical study, we initiated the SYMON-II pivotal clinical study in the third quarter of 2024. The SYMON II clinical study has three components: (1) collection, freezing, and biobanking of patient samples, (2) measuring IL-6 concentrations in the biobanked samples near the end of patient enrollment or after the patient enrollment has completed, and (3) analysis of the IL-6 data with the patient outcomes to see if the established IL-6 cutoff value has been validated for 28-day all-cause mortality. Patient enrollment started during the fourth quarter of 2024. As of the date of this filing, we have enrolled approximately 583 hospital patients among a target of 750 patients, and we have collected, frozen and biobanked blood samples from the enrolled patients, while also obtaining all related patient data regarding their disease progression and outcomes. We expect to complete patient enrollment in the study in the summer of 2026. Our goal is to use the Symphony IL-6 test to complete the testing in the SYMON-II clinical trial. We are not yet testing the samples because we are simultaneously working with Sanyoseiko to manufacture the cartridges that will be used in the test, and these cartridges are still being manufactured and verified to ensure that they meet FDA requirements for submission and commercial production. Our goal is to produce and verify these cartridges during 2026.

If we are able to complete the SYMON-II clinical study and the results are positive, we intend to use the data generated from SYMON-II to support a 510(k) application to the FDA. This application is currently expected to be based on the following intended use: "Symphony IL-6 is intended for use to determine the IL-6 concentration as an aid in assessing the cumulative 28-day risk of all-cause mortality in conjunction with other laboratory findings and clinical assessments for patients diagnosed with sepsis or septic shock in the ICU." We also plan to present the SYMON-I and SYMON-II results at future national scientific meetings and publish them in peer-reviewed journals, subject to future completion of the SYMON-II study and the results being positive. Subject to achieving needed funding and successfully addressing the manufacturing process challenges with our cartridges that are described above, our plan is to begin testing of samples we are collecting as part of our SYMON-II clinical trial by the end of 2026, with a goal of being in position to submit a 510(k) regulatory application to the FDA in 2027, and an objective of achieving FDA clearance thereafter.

Our ability to engage in and complete the activities needed for an FDA submission will be contingent upon us addressing the various challenges described herein, including possessing and/or raising sufficient capital, remaining a going concern, and producing product capable of supporting our product requirements and meeting analytical validation and clinical validation.

Sales and Marketing

Until such time as Symphony products may be authorized by the FDA, our sales and marketing efforts are intended to focus on brand awareness and market education to potential customers, emphasizing the value of monitoring a critical care patient's IL-6 levels to improve decision making and patient outcomes. If the device is cleared by the FDA, we intend to target sales to ERs and ICUs at United States hospitals, as well as to long-term acute care facilities. We hope to establish a market presence by selling Symphony devices and tests both directly and through various distribution channels to maximize sales volume and market penetration. In addition to our hope to sell Symphony for eventual use in the patient care market, we are also evaluating sales of Symphony devices for "research use only" purposes.

License Agreement

We depend on Toray's intellectual property to develop the Symphony cartridges upon which the Symphony platform relies. On October 6, 2020, we entered into a License and Supply Agreement, as amended (the "License Agreement"), with Toray, providing us with an exclusive global license with Toray, excluding Japan, to use their patents and know-how related to the Symphony detection cartridges for the manufacturing, marketing and sale of the products (as defined in the License Agreement).

On October 23, 2023, we entered into an Amended and Restated License Agreement (the "New Toray License Agreement") and a Master Supply Agreement (the "New Toray Supply Agreement") with Toray. Under the New Toray License Agreement, we continue to license from Toray intellectual property rights needed to manufacture single-use test cartridges, and we have received the right to sublicense certain Toray intellectual property to Sanyoseiko in connection with our ongoing agreement with Sanyoseiko to manufacture our Symphony analyzers and cartridges (including in connection with the Company's clinical trials). In addition, the New Toray License Agreement provided for the transfer of certain technology related to the cartridges to Sanyoseiko. The royalty payments we are required to pay Toray were reduced under the New Toray License Agreement from 15% to 7.5% (or less in certain circumstances) of net sales of certain cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. The New Toray License Agreement contemplates that applicable royalty payment obligations from us to Toray for other products will be determined separately in the future.

On July 23, 2025, we entered into an amendment (the "Amendment") to the New Toray License Agreement and the New Toray Supply Agreement with Toray. The Amendment provided that the deadline under the New Toray License Agreement for us to establish an alternative manufacturing site for our Symphony cartridges would be extended from October 23, 2025 to October 23, 2026, and we have agreed to use our best efforts to establish the site by such date. The Amendment confirms that Toray has provided to us all applicable know-how required under the New Toray License Agreement and is not under any further obligation to provide know-how or technical assistance to us. Pursuant to the Amendment, we paid $71,212 to Toray for a final supply of certain chip components prior to the expiration of the New Toray Supply Agreement, which occurred on October 23, 2025.

We have begun cartridge manufacturing process through Sanyoseiko, a third-party contractor who is managing such process modifications. Such modifications are intended to address several manufacturing challenges to bring Symphony to a level consistent with necessary performance and quality requirements for regulatory submission and commercialization. After the cartridge manufacturing process modification is completed, we plan to have the manufacturing process occur at Sanyoseiko, a FDA-registered CMO, including verification and validation testing and commercial manufacturing. The manufacturing site will be established by us without Toray's technical assistance. If Toray were to assert that we have not used our best efforts to establish the cartridge manufacturing site by October 2026, they could seek to terminate the license agreement as early as November 2026. If Toray were to be successful in terminating the license agreement, we would lose access to certain technology required to produce the cartridges that the Symphony system relies on to function, which would likely result in a material adverse effect on our commercialization efforts.

Intellectual Property, Proprietary Technology

In the fourth quarter of 2024, the Company filed a provisional patent application with the U.S. Patent and Trademark Office to establish a priority date related to certain utilizations of interleukin-6 (IL-6) in sepsis patients. After further evaluation of the scope, patentability, and potential commercial relevance of the subject matter, the Company determined that the provisional application was unlikely to result in patent protection that would be material to its business. As a result, the Company has elected not to pursue conversion of the provisional application or to file a corresponding Patent Cooperation Treaty (PCT) application. This decision reflects the Company's disciplined approach to capital allocation and its focus on deploying resources toward intellectual property and development activities that are expected to provide meaningful strategic and commercial value.

We do not currently directly hold any granted patents. We rely on a combination either directly or through the License Agreement with Toray of patent, copyright, trade secret, trademark, confidentiality agreements, and contractual protection to establish and protect our proprietary rights. Of these patents we rely on, the protections expire internationally in 2027 and 2028, while Toray patents in the U.S. expire on March 18, 2029 and February 22, 2030. As described above, we are currently working toward a goal of being in position to submit a 510(k) regulatory application to the FDA in 2027 with an objective of achieving FDA clearance sometime thereafter, which means that even if meet our timeline, the period of time we will have to commercialize our product under the protection of these patents is expected to be very narrow. See Part I, Item 1A. Risk Factors – "*We and Toray may be unable to protect or enforce the intellectual property rights licensed to us, which could impair our competitive position.*"

In connection with prior development work performed by Bluejay, we plan to apply for patent protections related to certain design improvements made to the Symphony technology platform.

Competition

There are currently no FDA cleared or approved IL-6 tests on the market. There are IL-6 tests granted under FDA Emergency Use Authorization (EUA) for use with only COVID-19 patients, including the Roche Cobas®, Siemens ADVIA Centaur® and Beckman Coulter Access 2®, which are central laboratory size equipment and require pre-processing of whole blood prior to performing their test. We believe that Symphony, which is designed for many liquid sample types including whole blood, provides us with a substantial competitive advantage over the existing competition that will sustain through commercialization, despite the major life science companies and consistent entry of innovative start-ups that define our competitive landscape.

Government Regulation

The design, development, manufacture, testing and sale of our products in the U.S. are subject to regulation by numerous governmental authorities, principally the FDA, and corresponding state and local regulatory agencies.

FDA Regulation

Medical Devices

Generally, the products we develop must be cleared by the FDA before they are marketed in the United States. Before and after approval, authorization, or clearance in the United States, our products are subject to extensive regulation by the FDA, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, recordkeeping, market clearance, authorization or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices, including IVDs. IVDs are a type of medical device and include reagents and instruments used in the diagnosis or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals or other biomarkers. Predictive, prognostic and screening tests can also be IVDs.

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and effectiveness:

- Class I: general controls, such as labeling and adherence to quality system regulations;
- Class II: special controls, premarket notification (often referred to as a 510(k)), specific controls such as performance standards, patient registries, post-market surveillance, additional controls such as labeling and adherence to quality system regulations; and
- Class III: special controls and requires a premarket approval ("PMA").

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a de novo application, or approval of a premarket approval (PMA).

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our initial product is a Class II device subject to 510(k) clearance.

510(k) Clearance Marketing Pathway

To obtain 510(k) clearance, a company must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

De Novo Classification

Devices of a new type that FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FDCA, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDCA. This provision allows FDA to classify a low- to moderate-risk device not previously classified into Class I or II. After de novo authorization, an authorized device may be used as a predicate for future devices going through the 510(k) process.

The FDA has classified Symphony as de novo, a device of a new type that the FDA has not previously classified. Once obtained, a de novo authorization may lead to Symphony's use as a predicate for future devices going through the 510(k) process.

Clinical Trials

Clinical trials are often required for a de novo authorization. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE study and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Sponsors of applicable clinical trials of devices also are required to register with www.clinicaltrials.gov, a public database of clinical trial information. Information related to the device, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration. Although the FDA's Quality System Regulation (QSR) does not fully apply to investigational devices, the requirement for controls on design and development does apply.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Once we have a commercialized product, our manufacturing processes will be required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;

- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;
- refusal to grant export approval for our products; or
- criminal prosecution.

Exploratory Artificial Intelligence Integration Initiative

The Company is pursuing an exploratory strategic initiative to evaluate the potential integration of artificial intelligence ("AI") capabilities into its Symphony™ platform. This initiative is intended to assess whether advanced analytics may enhance the clinical interpretation of biomarker data, including IL-6 measurements, and support the development of models related to sepsis risk stratification and patient outcomes. This initiative remains in the evaluation stage, and the Company has not entered into any definitive agreements related to AI integration. Any development activities are expected to be conducted in a phased and disciplined manner, with attention to data integrity, clinical validation, regulatory considerations, and capital allocation priorities. There can be no assurance that this exploratory initiative will result in a commercial product, regulatory authorization, revenue generation, or strategic collaboration.

Employees

As of March 2, 2026, we have 6 full-time employees, which includes one executive officer. We also contract with several consultants and contractors performing finance, accounting, regulatory advisory, investor relations and manufacturing scale-up support. To conserve costs, our President and Chief Executive Officer serves as our principal financial and accounting officer, in addition to being our principal executive officer. In addition, we do not employ any internal legal personnel. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Reverse Stock Splits and Increase to Authorized Capital

On July 24, 2023, we effected the first reverse stock split of our shares of common stock at a ratio of 1-for-20 (the "July 2023 Reverse Stock Split"). On June 20, 2024, we effected a second reverse stock split of our shares of common stock at a ratio of 1-for-8 (the "June 2024 Reverse Stock Split"). On November 18, 2024, we effected a third reverse stock split of our shares of common stock at a ratio of 1-for-50 (the "November 2024 Reverse Stock Split"). On January 29, 2026, we effected a fourth reverse stock split of our shares of common stock at a ratio of 1-for-4 (the "January 2026 Reverse Stock Split" and together with the July 2023 Reverse Stock Split, the June 2024 Reverse Stock Split and the November 2024 Reverse Stock Split, the "Reverse Stock Splits"). As such, collectively, the Company's common stock has undergone reverse stock splits that have combined the shares on a 1-for-32,000 aggregate basis since July 2023. Each of the Reverse Stock Splits were undertaken because the trading price of our common stock had fallen below the $1.00 per share minimum price that is required to maintain listing on Nasdaq, and the Company desired to maintain the common stock's Nasdaq listing. The Reverse Stock Splits became effective in the months noted above, when the Company's common stock opened for trading on Nasdaq on a post-split basis under the Company's existing trading symbol, "BJDX." All historical share and per share amounts reflected throughout this Form 10-K have been adjusted to reflect the Reverse Stock Splits. However, our periodic and current reports, and all other documents incorporated by reference into this Form 10-K that were filed prior to the dates noted above, do not give effect to the applicable Reverse Stock Splits.

On October 23, 2024, the stockholders of the Company approved and adopted an amendment to the Company's amended and restated certificate of incorporation, to increase the number of authorized shares of the Company's Common Stock to 250,000,000.

At the Company's annual meeting of stockholders on June 18, 2025, the Company's stockholders provided the Company's board of directors with authority to implement the January 2026 Reverse Stock Split, as well as an additional reverse stock split at a ratio of up to 1-for-20 (the "Additional Reverse Stock Split"). The Additional Reverse Stock Split may not be implemented if it would reduce the number of publicly held shares of the Company's common stock to less than 500,000. The Board's authority to implement the Additional Reverse Stock expires on June 18, 2026.

Available Information

Our principal executive offices are located at 360 Massachusetts Avenue, Suite 203, Acton, MA 01720 and our telephone number is (844) 327-7078. Our website address is www.bluejaydx.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, proxy statements and other information about us are made available, free of charge, through the Securities and Exchange Commission ("SEC") Filings section of our website at www.ir.bluejaydx.com/financial-information/sec-filings and at the SEC's website at www.sec.gov as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. We include our website address in this report only as an inactive textual reference and do not intend it to be an active link to our website. The contents of our website are not incorporated into this report.

In addition, our Board of Directors has adopted a written Code of Business Conduct and Ethics applicable to all officers, directors and employees, which is available through the "Governance Overview" section of our website at www.ir.bluejaydx.com/corporate-governance/governance-overview. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of the Code of Business Conduct and Ethics and by posting such information on the website address and location specified above.

ITEM 1A. RISK FACTORS

Investing in our securities carries a significant degree of risk. You should carefully consider the risks described below, together with all of the other information in this Form 10-K, including our consolidated financial statements and related notes included elsewhere in this Form 10-K, before deciding whether to invest in our securities. If any or a combination of the following risks were to materialize, our results of operations, financial condition and prospects could be materially adversely affected. If that were to be the case, the market price of our securities could decline, and investors could lose all or part of their investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception, do not currently generate any operating income, and expect to continue incurring losses as we work to obtain product approval, and thus we may never achieve or maintain profitability.

Since our inception, we have engaged primarily in development activities, including planning and implementing clinical trials to support commercialization and FDA clearance of our Symphony platform. We have funded our operations primarily through debt and equity financings, and have incurred losses since inception, including a net loss of approximately $6.8 million and approximately $7.7 million for the years ended December 31, 2025 and 2024, respectively, and from our inception through December 31, 2024, we had an accumulated deficit of approximately $41.5 million.

We currently have no product revenue and we may not be able to commercialize our Symphony technology platform or achieve significant revenues or profitability. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development process of our product candidates, including regulatory clearances, and thereafter achieve substantial acceptance in the marketplace for our products. We may be unable to achieve any or all of these goals.

We expect to need to raise at least $20 million between the date of this filing and the end of the 2027 fiscal year, and failure to do so could require us to undertake a process of liquidation under U.S. bankruptcy laws, which could cause holders of our common stock to recoup little, if any, value for their shares.

As of December 31, 2025, we possessed cash and cash equivalents of approximately $5.2 million, while having current liabilities of approximately $1.1 million. Consistent with prior years, we expect to incur a significant operating loss in 2026 and 2027 given that we do not currently generate any operating income. To achieve our current strategic plan, which strives to be in position to submit a 510(k) regulatory application to the FDA in 2027 and achieve FDA clearance thereafter, we expect to need to raise at least $20 million of further capital through the end of the 2027 fiscal year, which we hope to do in various tranches. If we do not raise additional capital, we expect to run out of available cash resources in the third quarter of 2026. There can be no assurance that such additional capital will be available on a timely basis or on terms that will be acceptable to us. We currently do not have any contracts or commitments for additional financing. In addition, any additional equity financing may involve substantial dilution to our existing stockholders, or provide that an equity or debt financing source obtains rights to control the membership of our board of directors.

Our financial results and financial position, and our expected forward-looking outlook of significant negative cash flow in the future, raise substantial doubt with respect to our ability to continue as a going concern. We expect that we will not be in position to submit a 510(k) regulatory application to the FDA for Symphony until 2027, at the earliest, if we are even able to generate sufficient clinical trial results to support such a submission.

If we fail to obtain additional financing, we likely will be forced to abandon operational activities entirely and file for bankruptcy protection, with the possible loss of properties or assets (including the license to our core technology). Based on our explorations to date, we do not expect that any other strategic alternatives, such as a potential sale of the Company or its assets or other restructuring efforts, will be available to us in the near-term. As a result, any inability to obtain additional financing in the near-term, including a material amount of financing over the next 2 years, would likely result in a material adverse effect on our business, results of operations, cash flow, financial condition and prospects and cause our stockholders to receive little or no return on their shares of common stock.

Since the initial public offering of our common stock in November 2021, the market price of our common stock has fallen by more than 99.9%, and we expect to need additional funding amounts substantially greater than the current market capitalization of our common stock, which may result in future dilution that coincides with further declines in the trading price of our common stock beyond the substantial declines that have occurred in recent years.

Since the initial public offering of our common stock in November 2021, the market price of our common stock has fallen by more than 99.9%, including declines of greater than 80% per year in each of 2025, 2024, 2023 and 2022. During such period of time, we have conducted several public offerings and private placements of securities to raise additional capital, and in each case, the market price of our common stock has declined after the consummation of such offerings. As described above, we expect to need to raise at least $20 million of funding over the next 2 years – an aggregate amount several times the current market capitalization of our outstanding common stock, and we do not expect to be able to complete necessary product re-development, troubleshooting and clinical trial work absent such material funding. This may cause new investors to demand terms in future offerings that substantially dilute existing shareholders, such as the inclusion of warrants with Black Scholes protections in the event of a sale transaction, which could cause our common stock to fall further from current levels on a per share basis.

The number of shares of common stock underlying our outstanding warrants is several times greater than our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive the Black Scholes value of such warrants, which may reduce the consideration otherwise available for payment to holders of our common stock.

As part of our public offerings and/or private placements of securities in October 2025, April 2025, June 2024, January 2024 and August 2023, we issued warrants to purchase shares of our common stock. As of the date of this filing, remaining warrants exercisable from these transactions included (i) Series F Warrants issued in October 2025 to purchase up to 1,125,000 shares of common stock at an exercise price of $7.00 per share, (ii) October 2025 Placement Agent Warrants to purchase up to 45,000 shares of common stock at an exercise price of $10.00 per share, (iii) Class E Warrants issued in April 2025 to purchase up to 271,277 shares of common stock at an exercise price of $13.68 per share, (iv) Class C Warrants issued in June 2024 to purchase 71,873 shares of common stock at an exercise price of $65.20 per share, (v) January 2024 Warrants to purchase up to 1,682 shares of common stock at an exercise price of $2,080.00 per share, (vi) January 2024 Placement Agent Warrants to purchase up to 117 shares of common stock at an exercise price of $2,600.00 per share, and (vii) warrants issued in August 2023 to purchase up to an aggregate of 142 shares of common stock at exercise prices ranging from $11,584.00 to $14,736.00 per share. All of such warrants expire either five or five and one-half years from the date of issuance (except for the October 2025 Prefunded Warrants, which do not expire).

The warrants generally are only exercisable by means of a cash exercise. In general, holders of these warrants may not exercise any portion of such warrants if such holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding common stock immediately after exercise. The warrants include certain rights upon a “fundamental transaction” (as defined in such warrants), including the right of the holders thereof to receive from us or a successor entity cash or the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction in the amount of the Black Scholes value (as defined in such warrants) of the unexercised portion of the applicable warrants on the date of the consummation of such fundamental transaction.

Although these warrants are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us and the holders of these warrants concerning the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline.

We have registered the issuance of shares upon exercise of these warrants under registration statements. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public market upon issuance. Sales of these shares into the public market in the future could cause the market price of our common stock to decline. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, particularly if the price of our common stock substantially exceeds the exercise price of such warrants. Such exercises, particularly if followed up with subsequent sales by the holders receiving shares of common stock, could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur.

Given the amount and terms of these warrants, we may find it more difficult to raise additional equity capital on favorable terms or at all while these warrants are outstanding.

Our common stock currently is listed for quotation on the Nasdaq Capital Market. We are required to meet specified financial requirements in order to maintain such listing, including a requirement that the bid price for our common stock remain above $1.00, and that the market value of our publicly held securities be at least $1 million. In addition, Nasdaq has recently proposed a new $5 million market value of listed securities requirement that we would not currently satisfy and therefore could cause our common stock be delisted by Nasdaq on an imminent basis, if approved by the SEC.

Nasdaq Listing Rule 5550(a)(2) requires listed companies to maintain a minimum bid price of $1.00 for continued inclusion on the Nasdaq Capital Market. As of the close of business on March 2, 2026, the most recent closing price of our common stock on the Nasdaq Capital Market. was $2.05 per share. If the trading price were to fall below $1.00 per share, we would not be compliant this requirement. In such event, we would be subject to delisting, and because we consummated a reverse stock split in January 2026, we would be ineligible for any compliance period under recently implemented Nasdaq listing rules if this event occurred prior to the one-year anniversary of such reverse stock split. As a result, such a decline in the price of our common stock, if it were to occur, would be expected to result in the prompt delisting of our common stock from the Nasdaq Capital Market.

In addition, Nasdaq Listing Rules 5550(a)(5) and 5550(b)(1) require that the market value of our publicly held common stock (which is our only outstanding class of capital stock) to be at least $1 million and that our stockholders' equity as reported in our most recent quarterly balance sheet to be at least $2.5 million. As of the close of business on March 2, 2026, the market value of our publicly held common stock was approximately $2.0 million, and as of December 31, 2025, our stockholders' equity was approximately $6.0 million. If the market value of our publicly held common stock declines below $1 million or our stockholders' equity falls below $2.5 million, we would also be subject to Nasdaq delisting proceedings on that basis.

Nasdaq's staff also maintains discretionary authority under its listing rules to delist companies whose capital structure or public offerings raise public interest and investor protection concerns, including as a result of highly dilutive issuances, and it is possible that Nasdaq could assert that past offerings that we have consummated, or future offerings we may consummate, raise such concerns. In addition, to raise the significant amount of capital that we expect to need to fund our strategic plan, potential investors may require us to accept terms (such as board representation rights in excess of an investor's beneficial ownership of our common stock) that could conflict with Nasdaq listing standards and result in us being delisted.

In addition to the foregoing requirements, Nasdaq has recently proposed a new listing requirement that would require each Nasdaq listed issuer to maintain a minimum market value of listed securities of at least $5 million. Under this proposal, if the value of an issuer's listed securities, as measured by each applicable trading day's closing price, continues to be less than $5 million for a period of 30 consecutive trading days, the issuer's securities would immediately be delisted, with no compliance or cure period. The proposed rule would also preclude an issuer's ability to seek stay of delisting during any appeals process, and would preclude Nasdaq hearings panels from reversing the delisting determination to situations where there was an error and the company never actually failed to satisfy the requirement. The panel would also not be able to consider any facts indicating that issuer subsequently regained compliance with the requirement or grant an issuer any additional time to regain compliance. The proposed rule is subject to review and approval by the SEC, and it is unknown whether the SEC will approve the proposal. If approved by the SEC, the rule could become effective on an imminent basis. Our common stock currently trades at levels that are below the $5 million aggregate market value threshold proposed by Nasdaq. As such, if this proposal is approved by the SEC, our common stock could be imminently delisted by Nasdaq on this basis.

If our common stock is delisted, we may seek to have our common stock quoted on an over-the-counter marketplace, such as on the OTCQX. The OTCQX is not a stock exchange, and if our common stock trades on the OTCQX rather than a securities exchange, there may be significantly less trading volume and analyst coverage of, and significantly less investor interest in, our common stock, which may lead to lower trading prices for our common stock.

Any potential delisting of our common stock from the Nasdaq Capital Market may have materially adverse consequences to our stockholders, including:

- A reduced market price and liquidity with respect to our shares of common stock;
- limited dissemination of the market price of our common stock;
- limited news coverage;
- limited interest by investors in our common stock;
- volatility of the prices of our common stock, due to low trading volume;
- our common stock being considered a "penny stock," which would result in broker-dealers participating in sales of our common stock being subject to the regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act;
- increased difficulty in selling our common stock in certain states due to "blue sky" restrictions; and
- limited ability to issue additional securities or to secure additional financing.

Our ability to raise additional capital via a registered public offering on Form S-3 will be limited in the near-term as a result of the SEC's "baby shelf" rules.

In June 2023 we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on June 20, 2023 (the "Shelf Registration Statement"). The Shelf Registration Statement allows us to sell from time to time up to $25 million of common stock, preferred stock, debt securities, debentures, warrants, rights or units comprised of any combination of these securities, for our own account in one or more offerings. In August 2023, we completed a public offering under the Shelf Registration Statement pursuant to which we raised gross proceeds of approximately $1.6 million. Under applicable SEC rules, smaller companies like us are only permitted to raise up to 1/3rd of their public float under Form S-3 over a 12-month period. As a result, based on our current public float, we are only able to sell up to approximately $700,000 as of the date of this filing pursuant to our Form S-3, assuming we continue the applicable eligibility requirements thereof. This limit on our use of Form S-3 in the near-term may make it more difficult for us to raise equity capital in the public markets, as we expect to be required to conduct any such fundraising via private placements, or sales on Form S-1, which sales of Form S-1 may be more difficult for us to execute in a timely manner.

We may be obligated to current and/or prior financial advisors under engagement letters that we enter into from time to time, and we are currently subject to such an obligation.

As part of our capital raising and financial planning measures, we have entered into, and may in the future enter into, various engagement letters with financial advisors. Such engagement letters have included, and may in the future include, rights of first offer or refusal and similar provisions that require us to offer such financial advisors the right to serve as underwriter, placement agent or in similar roles in connection with certain future public or private financing transactions, or that require us to pay prior financial advisors fees in connection with certain transactions consummated using other financial advisors.

Risks Related to Our Business

To preserve cash resources, we downsized our organization in 2025, which may reduce business continuity, affect our ability to apply for certain patents, and affect our product development and timelines.

To preserve cash resources, we implemented a series of cost savings measures in 2025 related to our product development operations. As of the date of this filing, we have reduced our overall Company-wide full-time employee headcount to 6 persons. To the extent we obtain sufficient funding, we may hire appropriate personnel in the future to expedite our commercialization efforts, but there is no assurance that we will be able to do so.

We are subject to the risks associated with new businesses.

We are effectively a new business with a plan to commercialize our licensed technology. Our limited operating history may not be adequate to enable you to fully assess our ability to develop and market our Symphony platform and test cartridges, assuming we receive regulatory clearances, for which there is no assurance, and respond to competition. Our efforts to date have related to the organization and formation of our Company, research and development and performing clinical trials. We have no approved products, have not yet generated sustainable revenue, and we cannot guarantee we will ever be able to generate future revenues. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties, inherent in a new business focused on the development and sale of new medical devices. As a result, we may be unable to further develop, obtain regulatory clearance for, manufacture, market, sell and derive revenues from our Symphony platform and test cartridges and the other product candidates in our pipeline, and our inability to do so would materially and adversely impact our viability. In addition, we still must optimize many functions necessary to operate a business, including expanding our managerial, personnel and administrative structure, continuing product research and development, and assessing and commencing our marketing activities.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies that have not yet commercialized their products, particularly those in the medical device field. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, or that our business plan is sound;
- maintain our management team and Board of Directors;
- determine that the technologies that have been developed are commercially viable;
- attract, enter into or maintain contracts with, and retain customers; and
- raise any necessary additional funds in the capital markets or otherwise to effectuate our business plan.

In the event that we do not successfully address these risks, our business, prospects, financial condition, and results of operations could be materially and adversely affected.

Our agreements with Toray, which relate to the license of the core technology used in our Symphony cartridges and for Sanyoseiko to manufacture cartridges for Bluejay, are subject to significant risks that may threaten our viability or otherwise have a material adverse effect on us and our business, assets and its prospects.

We have an exclusive license with Toray for the entire world, excluding Japan, to use their patents and know-how related to our Symphony test cartridges for the manufacturing, marketing and sale of such products. We also have a nonexclusive license for manufacturing purposes in Japan. We have a right to sublicense these Toray patents and know-how (upon either (a) obtaining consent from Toray prior to obtaining FDA clearance or (b) giving notice to Toray after obtaining FDA clearance), and for the purpose of obtaining FDA clearance, we will need to exercise this sublicence to have the cartridges manufactured for Bluejay by a Japanese manufacturer, Sanyoseiko, Inc. ("Sanyoseiko"). We have no contractual rights to the intellectual property covered in the license agreement other than as expressly set forth therein. Our plans, business, prospects and viability are substantially dependent on that intellectual property and subject to the limitations relating thereto as set forth in the license agreement. Some of the risks this may give rise to are described below.

- We are required to use our best efforts to establish a cartridge manufacturing site by October 2026. We have begun cartridge manufacturing process modifications through Sanyoseiko, a third-party contractor who is managing such modification. Such modification is intended to address several technical challenges to bring Symphony to a level consistent with necessary performance and quality requirements. After the cartridge manufacturing process modification is completed, we plan to have the manufacturing process occur at Sanyoseiko, a FDA-registered CMO, including for verification and validation testing and commercial manufacturing. The manufacturing site is being established by us without Toray's technical assistance. If Toray were to assert that we have not used our best efforts to establish the cartridge manufacturing site by October 2026, they could seek to terminate the license agreement as early as November 2026. If Toray were to be successful in terminating the license agreement, we would lose access to certain technology required to produce the cartridges that the Symphony system relies on to function, which would likely result in a material adverse effect on our commercialization efforts.

- After the receipt of regulatory clearance in a country, we are required to pay Toray a minimum royalty of $60,000 for the initial year that royalties are payable increasing to a minimum of $100,000 thereafter, regardless of the actual amount of sales by us of licensed products. Accordingly, we could be obligated to pay royalties even though we have generated no or limited revenue. Such payments could materially and adversely affect our profitability and could limit our investment in our business.

- The license and regulatory clearances (once obtained) are non-assignable. These restrictions may limit our flexibility to structure our operations in the most advantageous manner.

- At our sole expense, we must file for, prosecute the application for, and obtain all regulatory clearances for the licensed products and obtain all legal permits necessary for promoting, marketing, offering or selling each licensed product. The regulatory clearance process can be expensive and time consuming, and there can be no assurances that we will be able to obtain or maintain any or all required permits.

- We are required to use reasonable efforts to obtain market approval for the products in the United States or the European Union by October 2026 or we may lose exclusivity in territory of the license agreement with Toray. We will not obtain market approval by this date, though we believe we have used and are continuing to use reasonable efforts to do so.

- We are required to use reasonable efforts to start commercial sales by October 2028, though this period may be extended in 6-month increments for up to 2 years in total if such inability to start commercial sales is due to reasons not attributable to us. If we are unable to start commercial sales by such later date, Toray would have the right to terminate the license agreement or make it non-exclusive.

- Except with respect to (a) Toray's ownership of, or rights to license, all intellectual property rights in respect of the licensed property and (b) Toray's applicable patents being duly maintained and in effect, Toray provides no, and disclaims all, representations, warranties or covenants relating to the licensed intellectual property or any other matters under the license agreement and in particular disclaims any fitness of the intellectual property for any purpose or any warranty against infringement of any third-party patent. These provisions limit our recourse in the event that the licensed intellectual property is flawed, defective, inadequate, incomplete, uncommercial, wrongly described or otherwise not useful for our purposes. We have not independently verified all of the technical, scientific, commercial, legal, medical or other circumstances or nature of the licensed intellectual property and therefore there can be no assurances that any of the foregoing risks have been reduced or eliminated. We have performed numerous evaluations of the Symphony product and have identified numerous risks. These risks are described below. These provisions represent a significant risk of a material adverse impact on us, our business and our prospects.

- While we are in principle permitted, even after the license agreement expires or is terminated, to continue manufacturing and selling products that incorporate Toray intellectual property and the royalties for which are fully paid up, if we commit certain material breaches of the agreement, Bluejay may be obligated to use reasonable efforts to arrange for the transfer to Toray of FDA or any other regulatory clearances for any products the royalties for which are not fully paid up. Where any such transfer is possible and approved by the regulator (if necessary), then depending on the nature of the material breach, we may be required to undertake the transfer at no cost to Toray or on reasonable terms and conditions. The loss of any such market approvals, especially if we are unable to receive any consideration for them, could have a material adverse impact on us, our business and our prospects, and depending on the timing and extent of the loss, it could even threaten our viability.

In addition, see the risks in "*Risks Related to Our Intellectual Property*" below. These risks are not the only risks inherent in the license agreement with Toray.

As an intermediate step to regulatory submission, we need to demonstrate that our collected clinical samples do not degrade over time.

We are currently conducting testing to demonstrate specimen stability of the samples collected from the SYMON-II clinical study, which is one of the integral aspects that we will have to establish before we can proceed to FDA clearance. We plan to establish sample stability using standard plate ELISA technology that is accepted by the FDA. If we fail to prove that IL-6 is stable over time, we might have to redesign our business plan.

There is a risk that validation of the primary outcome measure of our SYMON-I study will not achieve statistical significance.

Although our SYMON-I study found promising results, there is a risk that subsequent validation will not achieve statistical significance, which would render those results subject to scrutiny and subject us to setbacks, including having to redesign our preliminary study at considerable expense and time delay.

There is a risk of our cartridges not passing analytical validation, one of the key requirements of FDA clearance.

There is a risk that our cartridges, a core component of our Symphony system, will not pass analytical validation due to failures in performance. We are working on plans in order to reduce this risk, but we cannot be sure that our attempts will be successful until they have been tested and have successfully passed analytical validation themselves.

FDA requirements could change prior to submission and lead to delays and additional costs.

The Symphony analyzer has previously passed all safety validations required by the FDA. However, due to recent FDA requirement changes should other FDA standards change, we could need to perform those tests as well, incurring additional expenses and delays that are impossible to predict due to the uncertain nature of what standards the FDA might change in the future.

The FDA could request additional data or testing after our application submission, requiring additional costs and delaying approval.

Although we have had a pre-submission meeting with FDA and included FDA feedback into our plan, the FDA could decide to request additional data or testing after we have submitted our FDA application. This could result in significant additional costs generated in the process of gathering whatever additional data or developing and running the additional testing requested by the FDA. Furthermore, it can take several months to years to conduct testing and collect data, and depending on the extent of the FDA's additional request, the delay caused could be significant. During any such period of delay, not only would we be incurring the additional expenses of the testing, but we would also continue to not generate any revenue.

We depend on, and are liable for, Sanyoseiko as our Symphony analyzer and cartridge contract manufacturing organization (CMO), so its inability or failure to perform appropriately in that capacity may threaten our viability or have a material adverse effect on us and our business, assets and its prospects.

We are dependent on Sanyoseiko to maintain compliance with the FDA requirements, and continuously manufacture and supply us with our Symphony analyzers and cartridges. If Sanyoseiko is unable to do so for any reason and we are unable to activate a new CMO to produce analyzers, we may be unable to obtain FDA clearance and commence any commercial sales or unable to supply products to our customers in a timely manner or at all, either of which could threaten our viability.

We are also liable for Sanyoseiko's performance and actions as our CMO, and any breach by Sanyoseiko of our license and/or supply agreements with Toray may have a material adverse effect on us and our business.

We have not yet launched any products and the ability to do so will depend on the acceptance of our Symphony platform in the healthcare market.

We have not yet launched or received regulatory clearances in any country or territory for our Symphony platform or test cartridges. Even if we receive regulatory clearances, we are faced with the risk that our Symphony platform will not be accepted over competing products and that we will be unable to enter the marketplace or compete effectively. We cannot assure you that our Symphony platform or test cartridges will gain market acceptance. If the market for our future products fails to develop or develops more slowly than expected, or if any of the technology and standards supported by us do not achieve or sustain market acceptance, our business and operating results would be materially and adversely affected.

We cannot accurately predict the volume or timing of any sales, making the timing of any revenues difficult to predict.

We may be faced with lengthy and unpredictable customer evaluation and approval processes associated with our Symphony platform. Consequently, we may incur substantial expenses and devote significant management effort and expense in developing customer adoption of our Symphony platform, which may not result in revenue generation. We must also obtain regulatory clearances or approvals of our Symphony platform and test cartridges in jurisdictions in which we pursue approvals, which is subject to risk and potential delays. The same risks apply to other tests we may develop based on our Symphony platform. As such, we cannot accurately predict the volume, if any, or timing of any future sales.

If third-party payors do not provide coverage and reimbursement for the use of our platform, our business and prospects may be negatively impacted.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in certain countries, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Our Symphony platform, including its software and systems, may contain undetected errors, which could limit our ability to provide our products and diminish the attractiveness of our offerings.

Our Symphony platform may contain undetected errors, defects, or bugs. As a result, our customers or end users may discover errors or defects in our products, software or systems, or our products, software or systems may not operate as expected. We may discover significant errors or defects in the future that we may not be able to fix. Our inability to fix any of those errors could limit our ability to provide our products and services, impair the reputation of our brand and diminish the attractiveness of our product and service offerings to our customers.

In addition, we may utilize third party technology or components in our products, and we rely on those third parties to provide support services to us. The existence of errors, defects, or bugs in third party technology or components, or the failure of those third parties to provide necessary support services to us, could materially adversely impact on our business.

We will rely on the proper function, security and availability of our information technology systems and data to operate our business, and a breach, cyber-attack or other disruption to these systems or data could materially and adversely affect our business, results of operations, financial condition, cash flows, reputation, or competitive position.

We will depend on sophisticated software and other information technology systems to operate our business, including to process, transmit and store sensitive data, and our future products and services may include information technology systems that collect data regarding patients. We could experience attempted or actual interference with the integrity of, and interruptions in, our technology systems, as well as data breaches, such as cyber-attacks, malicious intrusions, breakdowns, interference with the integrity of our products and data or other significant disruptions. Furthermore, we may rely on third-party vendors to supply and/or support certain aspects of our information technology systems. These third-party systems could also become vulnerable to cyber-attack, malicious intrusions, breakdowns, interference, or other significant disruptions, and may contain defects in design or manufacture or other problems that could result in system disruption or compromise the information security of our own systems.

If in the future we pursue foreign jurisdictions, such international operations will mean that we are subject to laws and regulations, including data protection and cybersecurity laws and regulations, in many jurisdictions. Furthermore, there has been a developing trend of civil lawsuits and class actions relating to breaches of consumer data held by large companies or incidents arising from other cyber-attacks. Any data security breaches, cyber-attacks, malicious intrusions or significant disruptions could result in actions by regulatory bodies and/or civil litigation, any of which could materially and adversely affect our business, results of operations, financial condition, cash flows, reputation, or competitive position.

In addition, our information technology systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving legal and regulatory standards, the increasing need to protect patient and customer information, changes in the techniques used to obtain unauthorized access to data and information systems, and the information technology needs associated any new products and services. There can be no assurance that our process of consolidating, protecting, upgrading and expanding our systems and capabilities, continuing to build security into the design of our products, and developing new systems to keep pace with continuing changes in information processing technology will be successful or that additional systems issues will not arise in the future.

If our information technology systems, products or services or sensitive data are compromised, patients or employees could be exposed to financial or medical identity theft or suffer a loss of product functionality, and we could lose existing customers, have difficulty attracting new customers, have difficulty preventing, detecting, and controlling fraud, be exposed to the loss or misuse of confidential information, have disputes with customers, physicians, and other health care professionals, suffer regulatory sanctions or penalties, experience increases in operating expenses or an impairment in our ability to conduct our operations, incur expenses or lose revenues as a result of a data privacy breach, product failure, information technology outages or disruptions, or suffer other adverse consequences including lawsuits or other legal action and damage to our reputation.

If we are not able to attract and retain highly skilled managerial, scientific and technical personnel, we may not be able to implement our business model successfully, and our limited cash resources could require us to make further cost reductions.

We believe that our management team must be able to act decisively to apply and adapt our business model in the markets in which we will compete. Our future performance depends to a large extent on the continued service of our President and Chief Executive Officer, Neil Dey, who is our sole executive officer. In addition, we rely upon technical and scientific employees or third-party contractors to effectively establish, manage and grow our business. Consequently, we believe that our future viability will depend largely on our ability to attract and retain highly skilled managerial, sales, scientific and technical personnel.

In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we currently expect, and such higher compensation payments would have a negative effect on our operating results. Competition for experienced, high-quality personnel is intense and we cannot assure that we will be able to recruit and retain such personnel, or that we will possess the cash resources to do so. For example, our limited cash resources have caused us to reduce our overall full-time employment headcount to 6 persons, and we could need to implement further personnel-related cost reductions in the future. As such, we may not be able to hire or retain the necessary personnel to implement our business strategy. For example, Mr. Dey is currently serving as our principal financial and accounting officer, in addition to serving as our principal executive officer. Our failure to hire and retain such personnel could impair our ability to develop new products and manage our business effectively. In the event that we lose the continued services of such key personnel for any reason, this could have a material adverse effect on our business, operations and prospects.

We do not have a meaningful amount of authorized shares remaining under our equity compensation plans and therefore cannot incentivize our directors and employees with non-cash compensation, and our cash compensation obligations for directors and officers are substantial relative to our market capitalization.

We have undergone a series of reverse stock splits at a cumulative ratio of 1-for-32,000 since our equity incentive plans were adopted. As a result, the authorized shares in such plans have been correspondingly reduced, and we only possess a de minimus amount of equity under these plans. As a result, we currently cannot incentivize our directors and employees with non-cash compensation, and even if we possessed such available shares, the substantial declines in the value of our common stock in each of the prior three years may substantially depress the desired incentive effects of using such shares for compensatory purposes. We believe that stock incentive plans serve to closely align the interests of directors and officers with the interests of the Company's shareholders, and without this tool we are left paying all compensation in cash. Giving effect to compensation increases approved by our board of directors (and its compensation committee) in the fourth quarter of 2025, our anticipated cash compensation fees owed to non-employee directors in 2026 is expected to be $540,000 in the aggregate, and Mr. Dey receives annual base cash compensation of $400,000. Given our lack of available equity incentives as a compensatory tool, we expect to continue incurring significant cash compensation expense relative to our overall market capitalization. We currently expect to seek stockholder approval at our 2026 annual meeting of stockholders to reload the shares available under our equity incentive plans, but there is no assurance that such proposal will be approved by stockholders.

If we or our manufacturers fail to comply with the regulatory quality system regulations or any applicable equivalent regulations, our proposed operations could be interrupted, and our operating results would suffer.

We and any third-party manufacturers and suppliers of ours will be required, to the extent of applicable regulation, to follow the quality system regulations of each jurisdiction we will seek to penetrate and also will be subject to the regulations of these jurisdictions regarding the manufacturing processes. If we or any third-party manufacturers or suppliers of ours are found to be in significant non-compliance or fail to take satisfactory corrective action in response to adverse regulatory findings in this regard, regulatory agencies could take enforcement actions against us and such manufacturers or suppliers, which could impair or prevent our ability to produce our products in a cost-effective and timely manner in order to meet customers' demands. Accordingly, our operating results would suffer.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of our Symphony platform or test cartridges. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If our Symphony platform or test cartridges, or any future tests based on our Symphony platform, are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our devices or failing to adhere to the operating guidelines or our devices producing inaccurate readings could cause significant harm to patients. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we expect to maintain product liability insurance, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenue. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of laws around the world protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. Privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. We may face difficulties in holding such information in compliance with applicable law. If we are found to be in violation of the privacy rules, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Significant raw material shortages, supplier capacity constraints, supplier disruptions, and sourcing issues may adversely impact or limit our products sales and or impact our product margins.

Our key suppliers are limited- or sole-source suppliers. Disruptions in deliveries, capacity constraints, production disruptions up- or down-stream, price increases, or decreased availability of raw materials or commodities, including as a result of war, natural disasters (including the effects of climate change such as sea level rise, drought, flooding, wildfires and more intense weather events), actual or threatened public health emergencies or other business continuity events, adversely affect our operations and, depending on the length and severity of the disruption, can limit our ability to meet our commitments to customers or significantly impact our operating profit or cash flows.

Specific raw materials used in the production of Symphony IL-6 cartridges are being limited in supply and the process of finding a suitable substitute could be expensive, use important resources, reduce the efficacy of the platform, or lead to other delays and setbacks.

Certain raw materials used in production of Symphony IL-6 cartridges are being discontinued and we might need to be validate new materials to use as substitutes. These materials include hydrophobic coating solution, side film plastic laminate, and antibody. Testing new raw materials might add extra expense and delay. We cannot currently predict what substitute materials will be found to work for the discontinued ones, whether they will perform as well, their availability, or their precise cost.

We might not be able to resolve certain causes of a Symphony performance reproducibility issue, and if the issues persist we might have to take a different approach.

We continue to face a performance reproducibility issue with the Symphony cartridges, and might not be able to resolve the issues in a timely manner, and might significantly delay the FDA clearance process.

If there is a shift in customer demand for the type of near-patient diagnostic test that we are working to develop, we would be left without a commercially marketable product in the pipeline.

Our only viable product in development at this time is a near-patient diagnostic test. If there is a shift in consumer demand away from such tests, for any reason, by or before the time we are ready to reach the market, we might find ourselves without a viable product sales market. We cannot be certain that there will be demand for our product by the time it is ready for commercial use or sale, and if there is not, we could be left without a revenue-generating product, as we do not currently have any other products under development.

Our relationships with customers, health care professionals, and patients may be subject to applicable healthcare laws, which could expose us to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm, the curtailment or restructuring of our operations and diminished future profits and earnings.

Healthcare professionals will play a primary role in the recommendation and use of any product candidates for which we obtain marketing approval and commercialize. Our current and future arrangements with customers, healthcare professionals, and patients may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute any products for which we obtain marketing approval. Federal and state healthcare laws and regulations that may affect our operations, directly or indirectly, include the following, among others:

- the federal Anti-Kickback Statute, which prohibits persons and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- federal false claims laws, including civil whistleblower or qui tam actions under the federal False Claims Act, which impose criminal and civil penalties 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 or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of the covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the federal Physician Payments Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report information related to certain payments or other transfers of value provided to physicians and any ownership and investment interests held by physicians or their immediate family members. Beginning in 2022, applicable manufacturers were also required to report such information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and

- analogous state laws and regulations, including (among others) state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require medical device companies to comply with the voluntary compliance guidelines and the relevant compliance guidance promulgated by the United States federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require medical device companies to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Efforts to comply with applicable healthcare laws and regulations will involve substantial costs. Interpretations of standards of compliance under these laws and regulations are rapidly changing and subject to varying interpretations and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, imprisonment, additional reporting obligations and oversight (if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws), and the curtailment or restructuring of our operations, any of which could diminish our future profits or earnings. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Healthcare legislative reform measures could have a material adverse effect on our business, future revenue, if any, and results of operations.

Our ability to commercialize any product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidates. In the United States, there have been a number of legislative and regulatory initiatives and changes affecting the healthcare system, including focused efforts on containing the cost of healthcare. Private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for certain products and services. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our future revenues from the sale of our product candidates once they are approved and commercialized.

For example, the Patient Protection and Affordable Care Act (the "ACA") substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the healthcare industry. The ACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, and impose additional health policy reforms. Changes in healthcare policy, including changes in the implementation or the repeal of the ACA, could increase our costs, decrease our future revenue, and impact future sales of and reimbursement and coverage for our product candidates. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges or any healthcare measures promulgated will impact the ACA or our business.

Additionally, the increased emphasis on managed healthcare in the United States may put additional pressure on product pricing, reimbursement, and utilization, which may adversely affect our future product sales, if any, and results of operations. These pressures can arise from rules and practices of managed care groups, competition from other products, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, and healthcare reform, and pricing in general. Future sales of our product candidates will depend substantially on the extent to which the costs of our products will be paid by health maintenance, managed care, and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers, and other third-party payors. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products or exclusion of our products from coverage.

Further legislative and regulatory changes remain possible. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. At the state level, legislatures have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. We expect that additional federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement, additional pricing pressures, and reduced demand for our products once they are approved and commercialized.

Risks Related to Product Development and Regulatory Clearance

We adapted our clinical trial design in 2023 to obtain more patient data to reflect recent FDA feedback, and our regulatory pathway remains subject to further FDA review and feedback and the results of ongoing and future clinical studies.

In the second quarter of 2024, we completed a multicenter SYmphony IL-6 MONitoring Sepsis ("SYMON") clinical study investigating the role of interleukin-6 (IL-6) in patients diagnosed with sepsis and septic shock. This prospective study assessed the performance of IL-6 upon initial presentation to the intensive care unit (ICU). A primary endpoint of the SYMON-I pilot clinical study (registered clinical trial number NCT06181604) suggested that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU may predict patient mortality out to 28 days. Furthermore, a secondary endpoint of the SYMON-I study suggested that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU is a predictor of patient mortality during their hospitalization. Other secondary endpoints suggested that lactate and Sequential Organ Failure Assessment (SOFA), standard clinical tests used for sepsis and septic shock patients, were not predictors of patient mortality out to 28 days. We believe that the findings underscore the potential importance of IL-6 as a predictor and provide new insights into the potential pathways for improving sepsis outcomes.

Using the data analysis from the SYMON-I pilot clinical study, we initiated the SYMON-II pivotal clinical study in the third quarter of 2024. The SYMON II clinical study has three components: (1) collection, freezing, and biobanking of patient samples, (2) measuring IL-6 concentrations in the biobanked samples near the end of patient enrollment or after the patient enrollment has completed, and (3) analysis of the IL-6 data with the patient outcomes to see if the established IL-6 cutoff value has been validated for 28-day all-cause mortality. Patient enrollment started during the fourth quarter of 2024. As of the date of this filing, we have enrolled approximately 583 hospital patients among a target of 750 patients, and we have collected, frozen and biobanked blood samples from the enrolled patients, while also obtaining all patient related data regarding their disease progression and outcomes. We expect to complete patient enrollment in the study in the summer of 2026. Our goal is to use the Symphony IL-6 test to complete the testing in the SYMON-II clinical trial. We are not yet testing the samples because we are simultaneously working with Sanyoseiko to manufacture the cartridges that will be used in the test, and these cartridges are still being manufactured and verified to ensure that they meet FDA requirements for submission and commercial production. Our goal is to produce and verify these cartridges during 2026.

Although we believe that we have a sound strategy for obtaining FDA regulatory clearance, there can be no assurance that it will ultimately be obtained. Reasons that approval and clearance might not be obtained, on our expected timeline or at all, include that we are unable to complete our planned studies (due to lack of funding, delays or interruptions in the manufacturing of quality-sufficient cartridges needed to be used in the study, or otherwise), that clinical results are not sufficient to demonstrate required efficacy, or that the FDA does not agree with our study design or aspects of our submission. In addition, the FDA could also change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which could prevent or delay approval or clearance. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

The regulatory clearance process which we may be required to navigate may be expensive, time-consuming, and uncertain and may prevent us from obtaining clearance for our planned products.

We intend to market our Symphony platform and test cartridges following regulatory clearance. To date, we have not received regulatory clearance in any jurisdiction. The research, design, testing, manufacturing, labeling, selling, marketing, and distribution of medical devices are subject to extensive regulation by country-specific regulatory authorities, which regulations differ from country to country. There can be no assurance that, even after such time and expenditures, we will be able to obtain necessary regulatory clearances for clinical testing or for the manufacturing or marketing of any products. In addition, during the regulatory process, other companies may develop other technologies with the same intended use as our products.

We also will be subject to numerous post-marketing regulatory requirements, which may include labeling regulations and medical device reporting regulations, which may require us to report to different regulatory agencies if our device causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by regulatory agencies, which may include, among others, any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notification, or orders for repair, replacement, or refunds;
- voluntary or mandatory recall or seizure of our products;
- imposing operating restrictions, suspension, or shutdown of production;
- refusing our requests for clearance or pre-market approval of new products, new intended uses or modifications to any products;
- rescinding clearance or suspending or withdrawing pre-market approvals that have already been granted; and
- criminal prosecution.

The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Product clearances and approvals can often be denied or significantly delayed.

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the de novo classification process, or is the subject of a PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data.

The PMA process typically is more costly, lengthy, and stringent than either the 510(k) process or the de novo classification process. Unlike a 510(k) review, which determines “substantial equivalence,” a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the United States and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements, de novo classification, or additional 510(k) pre-market clearances to market modifications to our products once they are approved and commercialized. The FDA requires device manufacturers to make and document a determination of whether a device modification requires approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing of the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not clear or approve our product submissions or applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

The FDA may also change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

International regulatory clearance processes may take more or less time than the FDA's clearance process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA's clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. Any failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations.

Clinical data obtained in the future may not meet the required objectives, which could delay, limit or prevent any regulatory clearance.

There can be no assurance that we will successfully complete any clinical evaluations necessary to receive regulatory clearances. While preliminary results have been encouraging and indicative of the potential performance of our Symphony platform and test cartridges, data already obtained, or in the future obtained, from clinical studies do not necessarily predict the results that will be obtained from later clinical evaluations. The failure to adequately demonstrate the performance characteristics of the device under development could delay or prevent regulatory clearance of the device, which could prevent or result in delays to market launch and could materially harm our business. There can be no assurance that we will be able to receive approval for any potential applications of our principal technology, or that we will receive regulatory clearances from targeted regions or countries.

We may be unable to complete required clinical evaluations, or we may experience significant delays in completing such clinical evaluations, which could prevent or significantly delay our targeted product launch timeframe and impair our viability and business plan.

The completion of any future clinical evaluations of our Symphony platform or test cartridges, or other studies that we may be required to undertake in the future, could be delayed, suspended, or terminated for several reasons, including:

- we may fail to or be unable to conduct the clinical evaluation in accordance with regulatory requirements;
- sites participating in the trial may drop out of the trial, which may require us to engage new sites for an expansion of the number of sites that are permitted to be involved in the trial;
- patients may not enroll in, remain in or complete, the clinical evaluation at the rates we expect; and
- clinical investigators may not perform our clinical evaluation on our anticipated schedule or consistent with the clinical evaluation protocol and good clinical practices.

If our clinical evaluations are delayed it will take us longer to ultimately launch our Symphony platform and test cartridges in the market and generate revenues. Moreover, our development costs will increase if we have material delays in our clinical evaluation or if we need to perform more or larger clinical evaluations than planned.

We and our suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.

As a medical device manufacturer, we will need to register with the FDA and various non-U.S. regulatory agencies and will be subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain Good Manufacturing Practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our product and component suppliers may also be required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our products or component suppliers will comply with all regulatory requirements. The failure by us or one of our suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, until a new supplier has been identified and evaluated. Our or any product or component supplier's failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we can locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition and results of operations.

We may be liable if the FDA or another regulatory agency concludes that we have engaged in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of our products. Once our products are cleared or approved for clinical use, healthcare providers may use our products for off-label uses, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional, or training materials for sales representatives or physicians constitute promotion of an off-label use, the FDA could request that we modify our training, promotional materials and/or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, significant penalties, including civil fines and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion, reimbursement or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In those possible events, our reputation could be damaged, and adoption of the products would be impaired.

Our products may be subject to recalls after receiving FDA or foreign approval or clearance or cause or contribute to a death or a serious injury or malfunction in certain ways prompting voluntary corrective actions or agency enforcement actions, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.

The FDA and similar foreign governmental authorities have the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture, or if there is a reasonable likelihood our products might cause or contribute to a death or a serious injury or malfunction. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality-related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation, and adversely affect our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

In addition, we will be subject to medical device reporting regulations that will require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals, and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation, and have a material adverse effect on our business, financial condition and results of operations. Any adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of any future products and to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval process, manufacture and marketing of regulated products, or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new products would have an adverse effect on our ability to expand our business. 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 clearance that we may have obtained and we may not achieve or sustain profitability.

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from Toray, and any dispute over the license would significantly harm our business.

We are dependent on the intellectual property licensed from Toray. Disputes may arise between us and Toray regarding intellectual property subject to our license agreement with Toray. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and launch our Symphony platform and our other product candidates. If we or Toray fail to adequately protect this intellectual property, our ability to launch our products in the market could be limited. For so long as we are dependent on the intellectual property covered by the license agreement for the pursuit of our business, any such disputes relating to the license agreement or failure to protect the intellectual property could threaten our viability.

We will depend primarily on Toray to file, prosecute, maintain, defend and enforce intellectual property that we license from it and that is material to our business.

The key underlying intellectual property relating to our Symphony platform is owned by Toray. Under our license agreement with Toray, Toray generally has the right to file, prosecute, maintain and defend the intellectual property we have licensed from Toray. If Toray fails to conduct these activities for intellectual property protection covering any of our product candidates, our ability to develop and launch those product candidates may be adversely affected and we may not be able to prevent competitors from making, using or selling competing products. In addition, pursuant to the terms of the license agreement, Toray generally has the right to control the enforcement of our licensed intellectual property and the defense of any claims asserting the invalidity of that intellectual property. We cannot be certain that Toray will allocate sufficient resources to and otherwise prioritize the enforcement of such intellectual property or the defense of such claims to protect our interests in the licensed intellectual property. In the absence of action by Toray, we may be unable to protect and enforce the proprietary rights on which our business relies. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent or impede us from continuing to use the licensed intellectual property that we need to operate our business or from realizing the full commercial benefit contemplated by the agreement. In addition, even if we take control of the prosecution of licensed intellectual property and related applications, enforcement of licensed intellectual property, or defense of claims asserting the invalidity of that intellectual property, we may still be adversely affected or prejudiced by actions or inactions of Toray and its counsel that took place prior to or after our assuming control, and we cannot ensure the cooperation of Toray in any such action. Furthermore, if we take action to protect, enforce or defend the licensed intellectual property, we may incur significant costs and the attention of our management may be diverted from our normal business operations. As a result, our business, results of operations and financial condition could be materially and adversely affected.

We and Toray may be unable to protect or enforce the intellectual property rights licensed to us, which could impair our competitive position.

In order for our business to be viable and to compete effectively, the proprietary rights with respect to the technologies and intellectual property used in our products must be developed and maintained. Toray relies primarily on patent protection and trade secrets to protect its technology and intellectual property rights. There are significant risks associated with Toray's ability (or our ability, in the absence of action by Toray) to protect the intellectual property licensed to us, including:

- pending intellectual property applications may not be approved or may take longer than expected to result in approval in one or more of the countries in which we operate;
- Toray's intellectual property rights may not provide meaningful protection;
- other companies may challenge the validity or extent of Toray's patents and other proprietary intellectual property rights through litigation, oppositions and other proceedings. These proceedings can be protracted as well as unpredictable;
- other companies may have independently developed (or may in the future independently develop) similar or alternative technologies, may duplicate Toray's technologies or may design their technologies around Toray's technologies;
- enforcement of intellectual property rights is complex, uncertain and expensive, and may be subject to lengthy delays. In the event we take control of any such action under the our license agreement with Toray, our ability to enforce our intellectual property protection could be limited by our financial resources; and
- the other risks described in "— Risks Related to Our Intellectual Property."

If any of Toray's patents or other intellectual property rights fail to protect the technology licensed by us, it would make it easier for our competitors to offer similar products. Any inability on Toray's part (or on our part, in the absence of action by Toray) to adequately protect its intellectual property may have a material adverse effect on our business, financial condition and results of operations. In addition, the patents we rely on are generally set to expire within the next five years, which could have a material impact on the future of our products.

We and/or Toray may be subject to claims alleging the violation of the intellectual property rights of others.

We may face significant expense and liability as a result of litigation or other proceedings relating to intellectual property rights of others. In the event that another party has intellectual property protection relating to an invention or technology licensed by us from Toray, we and/or Toray may be required to participate in an interference proceeding declared by the regulatory authorities to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome was favorable to us. We and/or Toray also could be required to participate in interference proceedings involving intellectual property of another entity. An adverse outcome in an interference proceeding could require us and/or Toray to cease using the technology, to substantially modify it or to license rights from prevailing third parties, which could delay or prevent the launch of our products in the market or adversely affect our profitability.

The cost to us of any intellectual property litigation or other proceeding relating the intellectual property licensed by us from Toray, even if resolved in our favor, could be substantial, especially given our early stage of development. A third party may claim that we and/or Toray are using inventions claimed by their intellectual property and may go to court to stop us and/or Toray from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume significant time and other resources. There is a risk that a court will decide that we and/or Toray are infringing the third party's intellectual property and will order us to stop the activities claimed by the intellectual property. In addition, there is a risk that a court will order us and/or Toray to pay the other party damages for having infringed their intellectual property. Moreover, there is no guarantee that any prevailing intellectual property owner would offer us a license so that we could continue to engage in activities claimed by the intellectual property, or that such a license, if made available to us, could be acquired on commercially acceptable terms.

We and Toray may be subject to claims challenging the invention of the intellectual property that we license from Toray.

We and Toray may be subject to claims that former employees, collaborators or other third parties have an interest in intellectual property as an inventor or co-inventor. For example, we and Toray may have inventorship disputes arising 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 claims challenging inventorship. If we and Toray fail in defending any such claims, in addition to paying monetary damages, we and Toray 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 effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. As a result, it is unclear whether and, if so, to what extent employees of ours and Toray may be able to claim compensation with respect to our future revenue. We may receive less revenue from future products if any of our or Toray's employees successfully claim compensation for their work in developing our intellectual property, which in turn could impact our future profitability.

Risks Related to Our Industry

We face intense competition in the diagnostic testing market, particularly in the IL-6 space, and as a result we may be unable to effectively compete in our industry.

We expect to compete directly and primarily with large medical device companies. These large companies have most of the diagnostic testing business and strong research and development capacity. Their dominant market position and significant control over markets could significantly limit our ability to introduce our Symphony platform or effectively market and generate sales of our products.

We have not yet entered the revenue stage and most of our competitors have long histories and strong reputations within the industry. They have significantly greater brand recognition, financial and human resources than we do. They also have more experience and capabilities in researching and developing testing devices, obtaining and maintaining regulatory clearances and other requirements, manufacturing and marketing those products than we do. There is a significant risk that we may be unable to overcome the advantages held by our competition, and our inability to do so could lead to the failure of our business.

Competition in the diagnostic testing markets is intense, which can lead to, among other things, price reductions, longer selling cycles, lower product margins, loss of market share and additional working capital requirements. To succeed, we must, among other critical matters, gain consumer acceptance for our products, technical solutions, prices and response time, or a combination of these factors. If our competitors offer significant discounts on certain products, we may need to lower our prices or offer other favorable terms in order to compete successfully. Moreover, any broad-based changes to our prices and pricing policies could make it difficult to generate revenues or cause our revenues, if established, to decline. Moreover, if our competitors develop and commercialize products that are more desirable than the products that we may develop, we may not convince customers to use our products. Any such changes would likely reduce our commercial opportunity and revenue potential and could materially adversely impact our operating results.

If we or Toray fail to respond quickly to technological developments, our products may become uncompetitive and obsolete.

The diagnostic testing market may experience rapid technology developments, changes in industry standards, changes in customer requirements and frequent new product introductions and improvements. If we or Toray are unable to respond to these developments, we may lose competitive position, and our products or technology may become uncompetitive or obsolete, causing our business and prospects to suffer. In order to compete, we and Toray may have to develop, license or acquire new technology on a schedule that keeps pace with technological developments and the requirements for products addressing a broad spectrum and designers and designer expertise in our industries.

Risks Related to Ownership of Our Common Stock

Sales of substantial amounts of our securities in the public market could depress the market price of our common stock.

Our common stock is listed for trading on the Nasdaq Capital Market. If our stockholders sell substantial amounts of our common stock in the public market, including the shares of common stock issuable upon the exercise of our outstanding warrants, or the market perceives that such sales may occur, the market price of our securities could fall and we may be unable to sell our securities in the future.

We could issue "blank check" preferred stock without stockholder approval with the effect of diluting interests of then-current stockholders and impairing their voting rights, and provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable.

Our Certificate of Incorporation provides for the authorization to issue up to 5,000,000 shares of "blank check" preferred stock with designations, rights and preferences as may be determined from time to time by our Board of Directors. Our Board of Directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying or preventing a change in control. For example, it would be possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our Company. In addition, advanced notice is required prior to stockholder proposals, which might further delay a change of control.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our common stock could be negatively affected.

Any trading market for our common stock will be influenced in part by any research reports that securities industry analysts publish about us. We do not currently have and may never obtain research coverage by securities industry analysts. If no securities industry analysts commence coverage of us, the market price and market trading volume of our common stock could be negatively affected. In the event we are covered by analysts, and one or more of such analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage or us, the market price and market trading volume of our common stock could be negatively affected.

As an "emerging growth company" under applicable law, we are subject to lessened disclosure requirements, which could leave our stockholders without information or rights available to stockholders of other public companies that are not "emerging growth companies."

For as long as we remain an "emerging growth company" as defined in the JOBS Act, we have elected to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We expect to take advantage of these reporting exemptions until we are no longer an "emerging growth company." We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of: (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the date on which we are deemed to be a large accelerated filer, which is the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the end of our most recent second fiscal quarter, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Because of these lessened regulatory requirements, our stockholders would be left without information or rights available to stockholders of other public companies that are not "emerging growth companies." In addition, we cannot predict if investors will find our common stock less attractive because we rely on 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 suffer or be more volatile.

Because we have elected to use the extended transition period for complying with new or revised accounting standards for an "emerging growth company" our financial statements may not be comparable to companies that comply with public company effective dates.

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. While we are not currently delaying the implementation of any relevant accounting standards, in the future we may avail ourselves of these rights, and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. Because our financial statements may not be comparable to companies that comply with public company effective dates, investors may have difficulty evaluating or comparing our business, performance or prospects in comparison to other public companies, which may have a negative impact on the value and liquidity of our common stock.

Anti-takeover provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our Company and may affect the trading price of our common stock.

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and by-laws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and bylaws will:

- provide for the issuance of "blank check" preferred stock that could be issued by our Board of Directors to thwart a takeover attempt;
- provide that stockholders will not be able to take action by written consent, and special meetings of stockholders may only be called by our Chief Executive Officer, our President, our Board of Directors or a majority of our stockholders;
- provide that our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our Board of Directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our Company; and
- do not provide stockholders with the ability to cumulate their votes, which limits the ability of minority stockholders to elect director candidates.

These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

We will continue incurring increased costs as a result of operating as a public company, and our management is now required to devote substantial time to new compliance initiatives and corporate governance practices.

Our common stock began trading on the NASDAQ Global Select Market in November 2021. As a public company, and particularly after we are no longer an EGC, we are incurring and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. These requirements result in significant legal and financial compliance costs and make some activities more time-consuming and costly. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This results in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have material adverse effect on our business and stock price, and our limited internal staffing may enhance the likelihood of such a controls failure. To reduce expenses, our President and Chief Executive Officer, in addition to serving as principal executive officer, currently serves as our principal financial and accounting officer, and we have no employees devoted on a full-time basis to our finance, accounting, legal or compliance functions, which may substantially increase the likelihood that we will fail to successfully maintain effective internal controls over financial reporting, or effective disclosure controls and procedures.

Pursuant to SOX Section 404 we are required to furnish a report by our management on our internal control over financial reporting in our Annual Reports on Form 10-K with the SEC since becoming a public company, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To comply with SOX Section 404, we document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have and will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, we may identify one or more material weaknesses (as we did in connection with the preparation of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024), which could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Neil Dey, our President and Chief Executive Officer, serves as our principal financial and accounting officer, in addition to serving as our principal executive officer, and Mr. Dey is not a certified public accountant. We also do not presently employ an internal legal officer. Our lack of a directly employed principal financial and accounting officer or principal legal officer may increase the likelihood that we will fail to successfully maintain effective internal controls over financial reporting, or effective disclosure controls and procedures.

Our amended and restated certificate of incorporation will provide, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our amended and restated certificate of incorporation will require, to the fullest extent permitted by law, subject to limited exceptions, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel in any action brought to enforce the exclusive forum provision. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our amended and restated certificate of incorporation.

Notwithstanding the foregoing, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will provide that the Court of Chancery and the federal district court for the District of Delaware will have concurrent jurisdiction over any action arising under the Securities Act or the rules and regulations thereunder, and the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction. To the extent the exclusive forum provision restricts the courts in which our stockholders may bring claims arising under the Securities Act and the rules and regulations thereunder, there is uncertainty as to whether a court would enforce such provision. Investors cannot waive compliance with the federal securities laws and the rules and regulations promulgated thereunder.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. By requiring a stockholder to bring such a claim in the Court of Chancery (or the federal district court for the District of Delaware, in the case of an action under the Securities Act or the rules and regulations thereunder), the exclusive forum provision also may increase the costs to a stockholder of bringing such a claim. Alternatively, if a court were to find the exclusive forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats.

Our President and Chief Executive Officer is responsible for overseeing our cybersecurity processes and works directly with third party service providers, as applicable, to identify, assess and manage the Company's cybersecurity threats and risks. In doing so, he seeks to identify and assess risks from cybersecurity threats in a manner appropriate for a company of comparable size and resources.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our IT Consulting Firm works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

Governance

Our Board of Directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Board is responsible for overseeing Company's cybersecurity risk management processes. Our cybersecurity risk assessment and management processes are implemented and maintained by our President and Chief Executive Officer.

Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents to members of management and/or the Board of Directors depending on the circumstances. The Board receives periodic reports and updates from our senior management concerning cybersecurity threats and risks, and the processes that the Company has implemented to address them.

We are not aware of any instances of material cybersecurity incidents that have impacted the Company.

ITEM 2. PROPERTIES

We have leased two facilities in Acton, Massachusetts, one which is month-to-month beginning March 2025 and the other will expire in March 2027.

Our President and Chief Executive Officer and his spouse, who is also a director of our Company, serve as officers and/or directors of Laminar Pharma, Inc., a business that is unaffiliated with us, and we permit this entity to use our main facility as its registered business address.

ITEM 3. LEGAL PROCEEDINGS

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. We have insurance policies covering any potential losses where such coverage is cost effective.

The Company records accruals for outstanding legal proceedings, investigations, or claims when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company evaluates developments in legal proceedings, investigations, and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable on a quarterly basis. When a loss contingency is not both probable and reasonably estimable, the Company does not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then the Company discloses a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If the Company cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed. In addition, legal fees and other directly related costs are expensed as incurred.

Shareholder Complaint Filed in New Jersey Civil Court

On December 8, 2025, the Company received by certified mail copy of a complaint filed in the New Jersey Special Civil Division (Sussex County) by a New Jersey resident. In the complaint, the plaintiff asserted claims for negligent misrepresentation, misrepresentation, and consumer deception against the Company and its former Chief Financial Officer, Kenneth Fisher, and sought total damages of $20,000.

The plaintiff's complaint stated that the plaintiff had traded in the Company's common stock between 2022 and 2023 and relied on e-mail communications between the plaintiff and Mr. Fisher when deciding whether to continue holding and purchasing shares. The plaintiff asserted that such communications misrepresented matters related to regulatory progress, financial condition and capital actions. The complaint also attached a copy of a report that the plaintiff stated they had submitted to the Securities and Exchange Commission detailing what the plaintiff described as a multi-year pattern of material misstatements and omissions, market manipulation and governance failures by the Company.

The Company believes that the complaint was without merit and included several allegations that were directly contradicted by the Company's public filings and were not based in fact. The Company believes that the complaint took good faith e-mail communications between the plaintiff and Mr. Fisher and portrayed them in a manner that was highly misleading and out of context. On January 20, 2026, the Company filed an answer and counterclaim with the court in which the Company denied the allegations and asserted counterclaims against the plaintiff for defamation based on a series of message board posts that the plaintiff admitted making about the Company that the Company believes were verifiably untrue. On January 21, 2026, the court scheduled a trial for the matter on March 24, 2026.

Though the Company was willing to contest these matters in a trial, to avoid further legal expenses, the Company accepted on February 17, 2026 an offer from the plaintiff to enter into a mutual release of claims pursuant to which the plaintiff withdrew the New Jersey civil court complaint and the matter was dismissed. Pursuant to the agreement between the parties, the Company agreed to reimburse the plaintiff for $1,050 in out-of-pocket expenses related to the matter. No other payments were made between the parties.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "BJDX".

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in any financing instruments, provisions of applicable law and other factors our Board of Directors deems relevant.

Holders of Common Stock

As of March 2, 2026, we had 972,215 shares of common stock outstanding held by thirteen stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Equity Compensation Plan Information

See Part III, Item 12 to this Form 10-K for information relating to securities authorized for issuance under our equity compensation plans.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with our Consolidated Financial Statements and the notes thereto included elsewhere in this Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. For additional discussion, see "CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS" above.

Overview

We are a clinical-stage medical diagnostics company developing rapid tests using whole blood on our Symphony platform ("Symphony") to improve patient outcomes in critical care settings, with a focus on sepsis. Our Symphony technology platform is an exclusively licensed, patented system that consists of an analyzer and single-use protein detection cartridges that we believe, if cleared, authorized, or approved by the U.S. Food and Drug Administration ("FDA"), could provide a solution to a significant market need in the United States. The Symphony device candidate is designed to produce laboratory-quality results in approximately 20 minutes in critical care settings, including Intensive Care Units ("ICUs") and Emergency Rooms ("ERs"), where rapid and reliable results are required.

Since inception, we have incurred net losses from operations each year and we expect to continue to incur losses for the foreseeable future. We incurred net losses of approximately $6.8 million and $7.7 million for the years ended December 31, 2025 and 2024, respectively. We had negative cash flow from operating activities of approximately $6.1 million and $7.8 million for the years ended December 31, 2025 and 2024, respectively, and had an accumulated deficit of approximately $41.5 million and $34.7 million as of December 31, 2025 and 2024, respectively.

Results of Operations

Comparison of Years Ended December 31, 2025 and 2024

The following table sets forth our results of operations for the years ended December 31, 2025 and 2024:

	For Years Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 3,046,448	$ 3,471,671
General and administrative	3,906,524	3,689,648
Sales and marketing	-	8,297
Total operating expenses	6,952,972	7,169,616
Operating loss	(6,952,972)	(7,169,616)
Other income (expense):		
Interest expense	(839)	(823,028)
Interest income	97,559	145,823
Other income, net	7,769	129,027
Total other income (expense)	104,489	(548,178)
Net loss	(6,848,483)	(7,717,794)
Deemed dividend on warrant modification	-	13,223,053
Net loss applicable to common shareholders	$ (6,848,483)	$ (20,940,847)

Research and development

Research and development expenses decreased approximately $0.4 million, or 12%, for the year ended December 31, 2025, as compared to 2024. The decrease in research and development expenses was primarily due to a $0.2 million decrease in personnel related costs, a $0.1 million decrease in other costs, and a $0.2 million decrease in product development costs, which was partially offset by a $0.1 million increase in clinical development costs.

The decrease in research and development expenses was primarily due to a reduction in technology transfer efforts which offset increased clinical trial expenses. We expect future research and development expenses to be focused on costs specifically associated with our clinical trial program supporting our regulatory strategy, technology transfer efforts and any necessary manufacturing improvements.

General and administrative

General and administrative expenses increased approximately $0.2 million, or 6%, for the year ended December 31, 2025, as compared to 2024. The increase in general and administrative expenses is primarily due to a $0.3 million increase in Delaware franchise tax cost and a $0.1 million increase in personnel related costs, with was partially offset by a $0.2 million decrease in consulting expenses.

We expect to monitor and continue to reduce our general and administrative spend, as necessary, to optimize operational alignment.

Sales and marketing

Sales and marketing expenses decreased 100%, for year ended December 31, 2025, as compared to 2024. The low sales and marketing expenses in 2025 are due to a reduction in spending in all sales and marketing efforts.

Other income (expense)

Total other income (expense) decreased approximately $0.7 million for the year ended December 31, 2025 as compared to 2024. The decreases primarily related to the $0.8 million in interest expense associated with the 2024 Bridge Note Financing.

Deemed dividend on warrant modification

Upon stockholder approval of the issuance of Class C Warrants and Class D Warrants on August 21, 2024, the Class C Warrants, which had an initial exercise price of $392.00 per share of common stock, were adjusted to be exercisable at an exercise price of $65.20 per share and the number of shares of common stock issuable upon exercise was proportionately increased to 343,146 shares. Concurrently, the number of shares of common stock issuable upon exercise of the Class D Warrants increased to four shares per warrant for the remaining unexercised warrants. In connection with the reset in the exercise price and number of shares issuable pursuant to exercise of the Class C Warrants and Class D Warrants, we recorded a deemed dividend of $13,223,053 based on the excess of the fair value of the modified Class C Warrants and Class D Warrants over the fair value of the Class C Warrants and Class D Warrants before the modification, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the year ended December 31, 2024.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented.

	Years Ended December 31,	
	2025	**2024**
Cash proceeds provided by (used in):		
Operating activities	$ (6,053,575)	$ (7,820,822)
Investing activities	(173,735)	(306,783)
Financing activities	7,090,240	10,221,034
Net increase in cash and cash equivalents	$ 862,930	$ 2,093,429

Net cash used in operating activities

During 2025, we used approximately $6.1 million in cash for operating activities, a decrease of approximately $1.8 million from 2024. The decrease in net cash used in operating activities was primarily due to a decrease in the net loss and partially offset by the timing of payments to vendors and other decreases in working capital during 2025.

Net cash used in investing activities

During 2025, we used approximately $0.2 million in cash from investing activities, an approximately $0.1 million decrease from 2024. The Company acquired less manufacturing equipment for the development of the Symphony devices in 2025 and 2024.

Net cash provided by financing activities

During 2025, we generated approximately $7.1 million in cash from financing activities, as compared to $10.2 million in 2024. The decrease in net cash provided by financing activities was primarily due to the proceeds from our private placements in April 2025 and October 2025 compared to our public offerings in January 2024 and June 2024.

Contractual Obligations

See Note 9 to consolidated financial statements for our lease obligations and Note 10 to the consolidated financial statements for our other non-cancellable contractual obligations.

Liquidity and Going Concern

The Company had cash and cash equivalents of $5,164,875 and current liabilities of $1,119,197 on its balance sheet as of December 31, 2025. The Company has incurred net losses since its inception, and has negative cash flows from operations and had an accumulated deficit of $41,517,267 as of December 31, 2025. The Company continues to develop its Symphony device and its first test for the measurement of IL-6. The Company remains committed to obtaining FDA clearance and hopes to conduct clinical trials to obtain sufficient data to support its FDA submission, while also continuing to build its manufacturing operations with its contract manufacturing organizations. Current cash resources and expected operating expenses are considered in determining its liquidity requirements. The Company estimates cash resources will be sufficient to fund its operations up to the third quarter of 2026. The Company will need additional capital to fund its planned operations for the next 12 months. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these financial statements are issued.

The consolidated financial statements for the years ended December 31, 2025 and 2024 were prepared under the assumption that the Company will continue as a going concern, and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company expects that it will seek to raise such additional capital through public or private equity offerings. Additional funds may not be available when it needs them on terms that are acceptable to them, or at all. If adequate funds are not available, it may be required to delay its FDA regulatory strategy, and to delay or reduce the scope of its research or development programs, its commercialization efforts or its manufacturing commitments and capacity. In addition, if it raises additional funds through collaborations, strategic alliances or distribution arrangements with third parties, it may have to relinquish valuable rights to its technologies or future revenue streams.

Recent Offerings

January 2024 Public Offering

On January 2, 2024, the Company sold in a public offering (such transaction, the "January 2024 Offering") (i) 336 shares of the Company's common stock and (ii) prefunded warrants to purchase up to an aggregate 1,346 shares of common stock (the "January Prefunded Warrants"). The Shares and January Prefunded Warrants were sold together with warrants to purchase up to an aggregate of 1,682 shares of common stock at an exercise price of $2,080.00 per share (the "January 2024 Warrants"). The combined public offering price was $2,080.00 per share of common stock and related January 2024 Warrant and $2,079.84 per January Prefunded Warrant and related January 2024 Warrant.

As of December 31, 2024, all January Prefunded Warrants have been exercised in full. The January 2024 Warrants are exercisable for a period of five years following the date of issuance.

Pursuant to an engagement letter, dated as of August 7, 2023, as amended October 11, 2023, by and between the Company and the Placement Agent, the Company paid the Placement Agent a total cash fee of $245,000 equal to 7.0% of the gross proceeds received in the January 2024 Offering. The Company also paid the Placement Agent in connection with the January Offering a management fee of $35,000 equal to 1.0% of the gross proceeds raised in the January 2024 Offering and certain expenses incurred in connection with the January Offering. In addition, the Company issued to the Placement Agent, warrants to purchase up to an aggregate 117 shares of common stock (the "January 2024 Placement Agent Warrants"), which represents 7.0% of the aggregate number of shares of common stock and Prefunded Warrants sold in the January 2024 Offering. The January 2024 Placement Agent Warrants have substantially the same terms as the January 2024 Warrants, except that the January 2024 Placement Agent Warrants have an exercise price equal to $2,600.00, or 125% of the offering price per share of common stock and related January 2024 Warrant sold in the January Offering and expire on the fifth anniversary from the date of the commencement of sales in the January 2024 Offering.

The gross proceeds to the Company from the January 2024 Offering were $3,500,000. The Company incurred offering costs of $711,031.

May 2024 Bridge Note Financing

On May 31, 2024, the Company entered into a Note Purchase Agreement with an accredited investor (the "NPA"), and a Securities Purchase Agreement with three accredited investors (the "SPA"). Under the terms of the NPA, the investor provided the Company with a $1,000,000 cash subscription in exchange for the issuance of a senior secured note. As of December 31, 2024, a total of $1,176,470 was repaid to the NPA investors. The difference between such note and the subscription amount, initially recorded as a discount on the notes, was the result of the discount factor included in the NPA of approximately 17.6%.

Under the terms of the SPA, the three investors agreed to collectively provide the Company with a separate $1,000,000 cash subscription in exchange for the issuance of senior secured notes ($333,333 each), and the collective issuance of 362 shares of the Company's common stock. The fair value of the common stock issued in connection with the SPA was $307,563. As of December 31, 2024, a total of $1,111,110 was repaid to the SPA investors. The difference between such notes and the subscription amounts, initially recorded as a discount on the notes, was the result of the discount factor included in the SPA of 11.11%.

Interest expense recorded on the NPA and SPAs was $807,797 for the year ended December 31, 2024, including debt issuance costs related to the NPA and SPA totaling $212,654.

June 2024 Offering

On June 28, 2024, the Company sold in a public offering (the "June 2024 Offering"), (i) 2,888 common units (the "Common Units"), each consisting of one share of common stock, two Class C Warrants and one Class D Warrant and (ii) 23,953 prefunded warrants (the "Prefunded Units"), each consisting of one prefunded warrant to purchase one share of common stock (each, a "Prefunded Warrant"), two Class C Warrants and one Class D Warrant to purchase Common Shares. Aegis Capital Corp. ("Aegis" or, the "Underwriter") partially exercised its over-allotment option in respect to 3,393 Class C Warrants and 1,696 Class D Warrants (the "Over-Allotment Warrants"). The Common Units were sold at a price of $326.00 per unit and the Prefunded Warrants were sold at a price of $325.98 per unit. As of December 31, 2024, all Prefunded Warrants have been exercised in full.

Pursuant to an engagement letter dated June 6, 2024, by and between the Company and Aegis, the Company paid Aegis a total cash fee of $743,750 equal to 8.5% of the gross proceeds received in the June 2024 Offering.

The gross proceeds to the Company from the June 2024 Offering were $8,569,075. The Company incurred offering costs of $1,133,419.

April 2025 Private Placement

On April 7, 2025, the Company entered into inducement letter agreements with certain existing holders of the Company's Class C Warrants, pursuant to which such holders agreed to purchase an aggregate of 271,277 shares of the Company's common stock (or, to the extent the applicable holder would have exceeded a specified beneficial ownership limitation, prefunding the future exercise of such warrants, other than a remaining $0.0004 per share exercise price). The Class C Warrants were originally issued on June 28, 2024 for an exercise price of $392.00 per share and were subsequently reduced to $65.20 per share pursuant to stockholder approval on August 21, 2024. Pursuant to the inducement letter agreements, the applicable holders agreed to exercise their Series C Warrants at a reduced exercise price of $13.68 per share, and to purchase an equivalent number of new Class E Warrants for an additional $0.50 per share. The Class E Warrants have an exercise price of $13.68 per share and expire on April 8, 2030.

The transaction closed on April 8, 2025. The exercise of the Class C Warrants resulted in the Company issuing 170,551 shares of common stock at closing pursuant to the inducement letters, and the exercise price of 100,726 of the Class C Warrants being amended to 0.0004 per share. As of December 31, all such reduced exercise price Class C Warrants had been exercised.

The gross proceeds to the Company from the exercise of the Class C Warrants and the sale of the new Class E Warrants were $3,846,692 million. The Company incurred total offering costs of $464,670, including a 10% financial advisory fee to Aegis Capital Corp. of $384,670.

The modification of the terms or conditions of the Class C Warrants in this transaction is treated as an exchange of the original instrument for a new instrument. Using the Black Scholes option pricing model, the fair value of the Series C Warrants immediately prior to the inducement transaction was $479,299 and immediately after the inducement transaction was $1,590,930. In addition, Series E Warrants with a fair value of $1,730,652 were provided as part of the inducement transaction for a purchase price of $135,638. The Company recorded additional equity issuance costs of $2,706,645 related to the modification of the Series C Warrants and issuance of Series E Warrants related to the inducement transaction. As this equity issuance cost was a non-cash transaction, the Company recorded an increase to additional paid-in capital to offset the expense.

October 2025 Private Placement

On October 9, 2025, the Company entered into a securities purchase agreement with two institutional investors pursuant to which the Company sold in a private placement (i) an aggregate of 43,750 shares of common stock and prefunded warrants to purchase up to 518,750 shares of common stock (the "October 2025 Prefunded Warrants"), and (ii) Series F warrants (the "Series F Warrants") to purchase up to 1,125,000 shares of common stock. The combined price of the securities sold in the private placement was $8.00 per share of common stock (or prefunded warrant in lieu thereof, in which case such price was reduced by $0.0004) and accompanying Series F Warrants to acquire two shares of common stock. The October 2025 Prefunded Warrants, were exercisable for shares of common stock at an exercise price of $0.0004 per share and were immediately exercisable, have all been fully exercised as of the date hereof. The Series F Warrants are exercisable for shares of common stock at an exercise price of $7.00 per share, are immediately exercisable and expire five and one-half years from the date of issuance.

The transaction closed on October 10, 2025. The gross proceeds to the Company from the sale of the securities sold in the private placement were approximately $4.5 million. The Company incurred total offering costs of $787,755, including a 8% financial advisory fee to Rodman and Renshaw LLC ("Rodman"), the placement agent, of approximately $360,000. Under the terms of the Company's engagement letter with Rodman, the Company issue Rodman's designees warrants to purchase up to 45,000 of common stock at an exercise price of $10.00 per share, which expire 5.5 years from the date of issuance (the "October 2025 Placement Agent Warrants").

In connection with this private placement, the Company filed a registration statement on Form S-3, which became effective on November 26, 2025, to register 1,732,500 shares of common stock (including any shares of common stock issued in the future pursuant to the Series F Warrants or October 2025 Placement Agent Warrants) for resale in public markets.

Critical Accounting Policies and Estimates

Some of our critical accounting policies require us to make difficult, subjective or complex judgments or estimates. An accounting estimate is considered to be critical if it meets both of the following criteria: (i) the estimate requires assumptions about matters that are highly uncertain at the time the accounting estimate is made, and (ii) different estimates reasonably could have been used, or changes in the estimate that are reasonably likely to occur from period to period may have a material impact on the presentation of our financial condition, changes in financial condition or results of operations.

As an emerging growth company, we have elected to opt-in to the extended transition period for new or revised accounting standards. As a result, our consolidated financial statements may not be comparable to those of companies that comply with public company effective dates.

See Note 2 to consolidated financial statements for a summary of significant accounting policies.

Recently Adopted Accounting Standards

See Note 2 to consolidated financial statements (under the caption "Recently Adopted Accounting Standards").

Recently Issued Accounting Standards

See Note 2 to consolidated financial statements (under the caption "Recently Issued Accounting Standards").

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information requested by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements and The Report of Independent Registered Public Accounting Firm are included in this Form 10-K on pages F-1 through F-22.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our President and Chief Executive Officer, who serves as our principal executive officer and our principal financial and accounting officer, has conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer, to allow timely decisions regarding required disclosure. Based on this evaluation, our President and Chief Executive Officer concluded that our disclosure controls and procedures were effective as of December 31, 2025.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Our President and Chief Executive Officer, who serves as our principal executive officer and our principal financial and accounting officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, our President and Chief Executive Officer used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework. Based on that assessment and using the COSO criteria, our President and Chief Executive Officer have concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financial reporting for as long as we are an "emerging growth company" pursuant to the provisions of the Jumpstart Our Business Startups Act.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the most recent fiscal quarter, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. Controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a 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 management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2025.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans at December 31, 2025:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities (by class) remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	10	$ 46,400.00	34
Equity compensation plans not approved by security holders (2)	27	$ 28,720.00	-

(1) Represents shares of common stock issuable upon exercise of outstanding stock options and rights under our 2018 Stock Incentive Plan (the "2018 Plan") and 2021 Stock Plan (the "2021 Plan"). Both plans permit the Company to grant incentive and nonqualified stock options for the purchase of common stock, and restricted stock awards. The maximum number of shares of common stock reserved for issuance under the 2018 Plan and 2021 Plan are 20 and 61, respectively. At December 31, 2025 there were 9 and 25 shares of common stock available for grant under the 2018 Plan and 2021 Plan, respectively.

(2) Consists of warrants issued to placement agents, underwriters and consultants.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2026 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2025.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements—See Index to Consolidated Financial Statements at Part II, Item 8 on page F-1 of this Form 10-K.

(2) All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the financial statements or the Notes thereto.

(3) See the accompanying Index to Exhibits filed as a part of this Form 10-K, which list is incorporated by reference in this Item.

(b) See the accompanying Index to Exhibits filed as a part of this Form 10-K.

(c) Other schedules are not applicable.

INDEX TO EXHIBITS

Exhibit No.	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on July 21, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 21, 2023).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on May 14, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 16, 2024).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on June 17, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 20, 2024).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on August 28, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on August 23, 2024).
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on November 15, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 18, 2024).
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on January 27, 2026 and effective as of January 29, 2026 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 30, 2026).
3.8	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
3.9	Amendment No. 1 to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 16, 2024).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.2	Form of Pre-Funded Common Stock Purchase Warrant for October 2025 Private Placement (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on October 14, 2025).

4.3	Form of Series F Warrant for October 2025 Private Placement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on October 14, 2025).
4.4	Form of Placement Agent Warrant for October 2025 Private Placement (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on October 14, 2025).
4.5	Form of Class E Common Stock Purchase Warrant for April 2025 Private Placement (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on April 9, 2025).
4.6	Form of Class C Warrant for June 2024 Public Offering (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on June 28, 2024).
4.7	Form of Prefunded Common Stock Warrant (January 2024 Public Offering) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 2, 2024).
4.8	Form of Common Stock Warrant for January 2024 Public Offering (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on January 2, 2024).
4.9	Form of Placement Agent Common Stock Warrant for January 2024 Public Offering (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on January 2, 2024).
4.10	Form of Common Stock Warrant for August 2023 Offering (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed on August 28, 2023).
4.11	Form of Class A Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 16, 2021).
4.12	Form of Class B Warrant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.13	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.14	Form of IPO Underwriters' Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.15	Description of Securities of Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 4.10 to the Company's Annual Report on Form 10-K filed on March 31, 2025).
10.1**	2021 Stock Plan (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.2**	Employment Agreement, dated July 1, 2021, between Neil Dey and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.3**	First Amendment to Employment Agreement, dated January 27, 2023, between Neil Dey and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 27, 2023).
10.4**	Employment Agreement, dated July 1, 2021, between Jason Cook and Bluejay Diagnostics, Inc. * (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.5**	Separation and Release Agreement, entered into on May 28, 2025, by and between Bluejay Diagnostics, Inc. and Jason Cook (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 28, 2025).
10.6	Settlement Agreement and Release, dated as of May 8, 2025, by and among Bluejay Diagnostics, Inc. and Nanohybrids, Inc (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2025, filed on May 13, 2025).

10.7	Securities Purchase Agreement, dated October 9, 2025, between Bluejay Diagnostics, Inc. and the purchaser parties thereto (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025, filed on November 7, 2025).
10.8	Registration Rights Agreement, dated October 9, 2025, between Bluejay Diagnostics, Inc. and the purchaser parties thereto (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025, filed on November 7, 2025).
10.9	Engagement Letter, entered into on August 29, 2025, between Bluejay Diagnostics, Inc. and Rodman & Renshaw LLC (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-3 (File No. 291402) filed on October 23, 2025).
10.10	Form of Inducement Letter Agreement, by and between the Company and each purchaser identified on the signature pages thereto, dated as of April 7, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 9, 2025).
10.11	Master Supply Agreement dated July 30, 2021, between Bluejay Diagnostics, Inc. and Sanyoseiko Co., Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025, filed on November 7, 2025).
10.12	Master Service Agreement dated July 30, 2021, between Bluejay Diagnostics, Inc. and Sanyoseiko Co., Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 9, 2025).
10.13	Agreement to Amend Master Supply Agreement and Master Service Agreement, dated October 3, 2025, between Bluejay Diagnostics, Inc. and Sanyoseiko Co., Ltd. (Master Supply Agreement dated July 30, 2021, between Bluejay Diagnostics, Inc. and Sanyoseiko Co., Ltd. (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025, filed on November 7, 2025).
10.14	Amended and Restated License Agreement, entered into on October 23, 2023, by and between Bluejay Diagnostics, Inc. and Toray Industries, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 26, 2023).
10.15	Amendment to License Agreement and Master Supply Agreement, entered into on July 23, 2025, by and between Bluejay Diagnostics, Inc. and Toray Industries, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 28, 2025).
14.1	Code of Ethics (incorporated by reference to Exhibit 14.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed on March 31, 2025.
21.1	List of Subsidiaries. (incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
32.1*	Certification of Principal Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Incentive Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed on March 28, 2024)
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and included in Exhibit 101)

* Filed herewith.

** Management contract or compensatory plan, contract or arrangement.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 6, 2026.

Bluejay Diagnostics, Inc.

By: /s/ Neil Dey
Neil Dey
President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Neil Dey Neil Dey	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)	March 6, 2026
/s/ Donald R. Chase Donald R. Chase	Chairman of the Board of Directors	March 6, 2026
/s/ Douglas C. Wurth Douglas C. Wurth	Director	March 6, 2026
/s/ Svetlana Dey Svetlana Dey	Director	March 6, 2026
/s/ Fred S. Zeidman Fred S. Zeidman	Director	March 6, 2026

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Bluejay Diagnostics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Bluejay Diagnostics, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of Matter Regarding Going Concern

The accompanying 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 incurred net losses since its inception, and has negative cash flows from operations and will need additional funding to complete planned development efforts. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The 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 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/ Wolf & Company, P.C.

We have served as the Company's auditor since 2017.

Boston, Massachusetts
March 6, 2026

Bluejay Diagnostics, Inc.
Consolidated Balance Sheets

	December 31,	
	2025	**2024**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,164,875	$ 4,301,945
Prepaid expenses and other current assets	275,957	596,938
Assets held for sale	22,770	-
Total current assets	5,463,602	4,898,883
Property and equipment, net	1,534,441	1,513,495
Operating lease right-of-use assets	113,289	209,788
Other non-current assets	7,905	35,257
Total assets	$ 7,119,237	$ 6,657,423
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 214,255	$ 145,122
Operating lease liability, current	100,000	113,260
Accrued expenses	804,942	551,986
Total current liabilities	1,119,197	810,368
Operating lease liability, non-current	20,211	108,989
Other non-current liabilities	4,540	8,567
Total liabilities	1,143,948	927,924
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 604,534 and 138,503 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	60	14
Additional paid-in capital	47,492,496	40,398,269
Accumulated deficit	(41,517,267)	(34,668,784)
Total stockholders' equity	5,975,289	5,729,499
Total liabilities and stockholders' equity	$ 7,119,237	$ 6,657,423

See report of independent registered public accounting firm and notes to consolidated financial statements.
Reflects a 1-for 4 reverse stock split effective January 29, 2026, a 1-for-50 reverse stock split effective November 18, 2024 and a 1-for-8 reverse stock split effective June 20, 2024.

Bluejay Diagnostics, Inc.
Consolidated Statements of Operations

	For Years Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 3,046,448	$ 3,471,671
General and administrative	3,906,524	3,689,648
Sales and marketing	-	8,297
Total operating expenses	6,952,972	7,169,616
Operating loss	(6,952,972)	(7,169,616)
Other income (expense):		
Interest expense	(839)	(823,028)
Interest income	97,559	145,823
Other income, net	7,769	129,027
Total other income (expense), net	104,489	(548,178)
Net loss	(6,848,483)	(7,717,794)
Deemed dividend on warrant modification	-	13,223,053
Net loss applicable to common stockholders	$ (6,848,483)	$ (20,940,847)
Net loss per share to common stockholders - Basic and diluted	$ (15.25)	$ (456.75)
Weighted average common shares outstanding:		
Basic and diluted	449,043	45,848

See report of independent registered public accounting firm and notes to consolidated financial statements.
Reflects a 1-for-4 reverse stock split effective January 29, 2026, a 1-for-50 reverse stock split effective November 18, 2024 and a 1-for-8 reverse stock split effective June 20, 2024.

Bluejay Diagnostics, Inc.
Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2023	774	$ -	$ 29,845,838	$ (26,950,990)	$ 2,894,848
Stock-based compensation expense	-	-	20,094	-	20,094
Issuance of common stock in connection with January 2024 Offering, net of issuance costs of $711,031	1,683	-	2,788,969	-	2,788,969
Issuance of common stock in connection with Bridge Note Financing	363	-	307,563	-	307,563
Issuance of common stock in connection with June 2024 Offering, net of issuance costs of $1,133,419	26,839	3	7,435,653	-	7,435,656
Exercise of Series D Warrants	108,844	11	547	-	558
Cash for fractional shares from reverse stock split	-	-	(395)	-	(395)
Net loss	-	-	-	(7,717,794)	(7,717,794)
Balance as of December 31, 2024	138,503	14	40,398,269	(34,668,784)	5,729,499
Stock-based compensation expense	-	-	6	-	6
Issuance of common stock for vested restricted stock units	4	-	-	-	-
Issuance of common stock in connection April 2025 Warrant Inducement, net of issuance costs of $464,670 and warrant inducement cost of $2,706,645	271,277	27	675,350	-	675,377
Warrant inducement cost	-	-	2,706,645	-	2,706,645
Issuance of common stock in connection with October 2025 Private Placement, net of issuance costs of $787,755	43,750	4	3,712,241	-	3,712,245
Exercise of October 2025 Prefunded Warrants	151,000	15	(15)	-	-
Net loss	-	-	-	(6,848,483)	(6,848,483)
Balance as of December 31, 2025	604,534	$ 60	$ 47,492,496	$ (41,517,267)	$ 5,975,289

See report of independent registered public accounting firm and notes to consolidated financial statements.
Reflects a 1-for-4 reverse stock split effective January 29, 2026, a 1-for-50 reverse stock split effective November 18, 2024 and a 1-for-8 reverse stock split effective June 20, 2024.

Bluejay Diagnostics, Inc.
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,848,483)	$ (7,717,794)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	74,182	75,618
Stock-based compensation expense	6	20,094
Amortization of right-of-use asset	96,499	123,479
Non-cash interest expense for note payable	-	307,563
Write-off and impairment of property and equipment	42,937	3,411
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	333,881	150,325
Deferred offering costs	-	265,081
Other non-current assets	27,352	(6,594)
Accounts payable	69,133	(346,352)
Accrued expenses and other current and non-current liabilities	150,918	(695,653)
Net cash used in operating activities	(6,053,575)	(7,820,822)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(173,735)	(306,783)
Net cash used in investing activities	(173,735)	(306,783)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, gross	8,346,692	12,069,075
Payment for issuance costs of common stock	(1,252,425)	(1,844,450)
Proceeds from issuance of notes payable	-	2,000,000
Repayment of notes payable	-	(2,000,000)
Proceeds from exercise of Class D warrants	-	558
Fractional shares adjustment for reverse stock split	-	(395)
Payment of finance lease	(4,027)	(3,754)
Net cash provided by financing activities	7,090,240	10,221,034
Net increase in cash and cash equivalents	862,930	2,093,429
Cash and cash equivalents, beginning of period	4,301,945	2,208,516
Cash and cash equivalents, end of period	$ 5,164,875	$ 4,301,945
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH INVESTING ACTIVITIES		
Fair value of common stock issued in connection with notes payable	$ -	$ 307,563

See report of independent registered public accounting firm and notes to consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Bluejay Diagnostics, Inc. ("Bluejay" and/or the "Company") is a medical diagnostics company focused on improving patient outcomes in critical care settings, with a focus on sepsis. The Company is working on developing rapid, near-patient tests using whole blood on its Symphony technology platform ("Symphony"), which consists of an analyzer and single-use protein detection cartridges. The Company does not yet have regulatory clearance for Symphony, and it will need to receive regulatory authorization from the U.S. Food and Drug Administration (the "FDA") before Symphony can be marketed as a diagnostic product in the United States. The Company has completed the pre-clinical development of the Symphony analyzer. During 2025, the Company transferred the intellectual property underlying the production of the Symphony cartridges from the original developer and outside supplier, Toray Industries, to a contract manufacturing facility with FDA certification run by Sanyoseiko. The Company is also working with Sanyoseiko to modify the manufacturing process of the Symphony cartridges to address certain technical issues to bring Symphony to a level consistent with necessary performance and quality requirements for regulatory submission. To achieve its plan, the Company expects to need to raise at least $20 million of further capital by the end of the 2027 fiscal year, which the Company hopes to do in various tranches.

The Company's Symphony platform is a combination of Bluejay's intellectual property ("IP") and exclusively licensed and patented IP on the Symphony technology that the Company believes if cleared, authorized, or approved by the FDA, could provide a solution to a significant market need in the United States. The Symphony device candidate is designed to produce laboratory-quality results in approximately 20 minutes in critical care settings, including Intensive Care Units ("ICUs") and Emergency Rooms ("ERs"), where rapid and reliable results are required.

The Company's first product candidate, the Symphony IL-6 test, is an immunoassay for the measurement of interleukin-6 (IL-6) to be used for the monitoring of disease progression in critical care settings. The Company is currently focused on pursuing the Symphony IL-6 test in the context of sepsis. IL-6 is a clinically established inflammatory biomarker, and is considered a 'first-responder,' for assessment of severity of infection and inflammation across many disease indications, including sepsis. A current challenge of healthcare professionals is the excessive time and cost associated with determining a patient's level of severity at triage and the Company believes that its Symphony IL-6 test, if ultimately successful and approved, could have the ability to consistently monitor this critical care biomarker with rapid results.

If the Company succeeds with the foregoing plan, in the future it hopes to develop additional tests for Symphony, including tests for myocardial infarction and congestive heart failure (cardiac biomarkers hsTNT and NT pro-BNP) as well as other tests using the Symphony platform.

The Company was incorporated under the laws of Delaware on March 20, 2015. Its headquarters are located in Acton, Massachusetts.

On June 4, 2021, the Company formed Bluejay Spinco, LLC, a wholly-owned subsidiary of the Company, for purposes of further development of the Company's ALLEREYE diagnostic test. ALLEREYE is a point-of-care device offering healthcare providers a solution for diagnosing Allergic Conjunctivitis. The Company currently is not actively pursuing development of the ALLEREYE diagnostic test.

FDA Regulatory Strategy

The design, development, manufacture, testing and sale of the Company's products in the U.S. are subject to regulation by numerous governmental authorities, principally the FDA, and corresponding state and local regulatory agencies. Generally, the products we develop must be cleared by the FDA before they are marketed in the United States. Before and after approval, authorization, or clearance in the United States, our products are subject to extensive regulation by the FDA, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, recordkeeping, market clearance, authorization or approval, labeling and promotion, import and export, marketing and sales, and distribution of medical devices.

The Company's current regulatory strategy is designed to support commercialization of Symphony in the United States if and when the Company receives marketing authorization from the FDA. In May 2023, the Company submitted a pre-submission application to the FDA presenting study designs to validate Symphony IL-6 for use with hospitalized sepsis patients. The Company participated in a pre-submission meeting with the FDA in August 2023, and at the meeting the FDA provided feedback on the study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Based on this feedback, the Company determined to proceed on this basis, which considers the FDA's feedback.

In the second quarter of 2024, the Company completed a multicenter SYmphony IL-6 MONitoring Sepsis ("SYMON") clinical study investigating the role of interleukin-6 (IL-6) in patients diagnosed with sepsis and septic shock. This prospective study assessed the performance of IL-6 upon initial presentation to the intensive care unit (ICU). A primary endpoint of the SYMON-I pilot clinical study (registered clinical trial number NCT06181604) suggested that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU may predict patient mortality out to 28 days. Furthermore, a secondary endpoint of the SYMON-I study suggested that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU is a predictor of patient mortality during their hospitalization. Other secondary endpoints suggested that lactate and Sequential Organ Failure Assessment (SOFA), standard clinical tests used for sepsis and septic shock patients, were not predictors of patient mortality out to 28 days. We believe that the findings underscore the potential importance of IL-6 as a predictor and provide new insights into the potential pathways for improving sepsis outcomes.

Using the data analysis from the SYMON-I pilot clinical study, the Company initiated the SYMON-II pivotal clinical study in the third quarter of 2024. The SYMON II clinical study has three components: (1) collection, freezing, and biobanking of patient samples, (2) measuring IL-6 concentrations in the biobanked samples near the end of patient enrollment or after the patient enrollment has completed, and (3) analysis of the IL-6 data with the patient outcomes to see if the established IL-6 cutoff value has been validated for 28-day all-cause mortality. Patient enrollment started during the fourth quarter of 2024. As of March 2, 2026, the Company has enrolled approximately 583 hospital patients among a target of 750 patients, and it has collected, frozen and biobanked blood samples from the enrolled patients, while also obtaining all related patient data regarding their disease progression and outcomes. The Company expects to complete patient enrollment in the study in the summer of 2026. The Company's goal is to use the Symphony IL-6 test to complete the testing in the SYMON-II clinical trial. The Company is not yet testing the samples because it is simultaneously working with Sanyoseiko to manufacture the cartridges that will be used in the test, and these cartridges are still being manufactured and verified to ensure that they meet FDA requirements for submission and commercial production. The Company's goal is to produce and verify these cartridges during 2026.

If the Company is able to complete the SYMON-II clinical study and the results are positive, the Company intends to use the data generated from SYMON-II to support a 510(k) application to the FDA. This application is currently expected to be based on the following intended use: "Symphony IL-6 is intended for use to determine the IL-6 concentration as an aid in assessing the cumulative 28-day risk of all-cause mortality in conjunction with other laboratory findings and clinical assessments for patients diagnosed with sepsis or septic shock in the ICU." The Company also plans to present the SYMON-I and SYMON-II results at future national scientific meetings and publish them in peer-reviewed journals, subject to future completion of the SYMON-II study and the results being positive. Subject to achieving needed funding and successfully addressing the manufacturing process challenges with its cartridges, the Company's plan is to begin testing of samples it is collecting as part of the SYMON-II clinical trial by the end of 2026, with a goal of being in position to submit a 510(k) regulatory application to the FDA in 2027, and an objective of achieving FDA clearance thereafter.

The Company's ability to engage in and complete the activities needed for an FDA submission will be contingent upon it addressing these and other challenges, including possessing and/or raising sufficient capital, remaining a going concern, and producing product capable of supporting our product requirements and meeting analytical validation and clinical validation.

Product Manufacturing

The Company plans to manufacture its analyzers and cartridges through Sanyoseiko Co. Ltd. ("Sanyoseiko"), as a contract manufacturing organization ("CMO"), and the Company has entered into master supply and master service agreements with Sanyoseiko governing these matters. Pursuant to statements of work that the Company will provide to Sanyoseiko under these agreements, Sanyoseiko will provide end-to-end support for the Symphony platform, including supporting the manufacturing redevelopment process for analyzers and cartridges (with hardware, software, and design updates), managing raw material sourcing and vendor compliance, and serving as the Company's contract manufacturing organization for analyzers, cartridges, and related components. In this capacity, Sanyoseiko will oversee fulfillment, kit assembly, labeling, packaging, shipping, and quality control of manufactured products, while also providing regulatory and quality management support, and equipment storage and maintenance.

Sanyoseiko had been selected as the Company's CMO due to their core competencies in manufacturing and quality systems recognized by the FDA. Sanyoseiko's facilities are located in Japan. The Company currently licenses the technology for the Symphony cartridges from Toray Industries, Inc. ("Toray"). The Company's license grants it exclusive global marketing rights, with the exception of Japan. The Company holds the rights to manufacture the analyzers and the cartridges.

Risks and Uncertainties

As noted above, the Company will be reliant upon its CMO, Sanyoseiko to provide analyzers and, once manufacturing processes have been redeveloped, cartridges, in sufficient quantity and quality to complete the validations for its FDA application. The Company's FDA application submission could be delayed if the Company encounters any material supply interruptions. In addition, there can be no assurance that the Company will be able to obtain necessary regulatory authorization for the manufacturing or marketing of the Symphony in the United States or elsewhere. There also can be no assurance that the Company will successfully complete any clinical evaluations necessary to receive regulatory clearances, or that the clinical study will demonstrate sufficient safety and effectiveness of the Symphony IL-6 test. The failure to adequately demonstrate the clinical performance of the Symphony IL-6 test could delay or prevent regulatory clearance, which could prevent or result in delays to market launch and could materially harm the Company's business.

In addition to the FDA regulatory strategy risks and uncertainties, the Company is subject to a number of risks similar to other companies in its industry, including rapid technological change, competition from larger biotechnology companies and dependence on key personnel. Additional risk and uncertainties regarding the Company are described in "Part I – Item 1A. Risk Factors" of this Annual Report on Form 10-K.

Reverse Stock Splits and Increase to Authorized Capital

On July 24, 2023, the Company effected the first reverse stock split of its shares of common stock at a ratio of 1-for-20 (the "July 2023 Reverse Stock Split"). On June 20, 2024, the Company effected a second reverse stock split of its shares of common stock at a ratio of 1-for-8 (the "June 2024 Reverse Stock Split"). On November 18, 2024, the Company effected a third reverse stock split of its shares of common stock at a ratio of 1-for-50 (the "November 2024 Reverse Stock Split"). On January 29, 2026, the Company effected a fourth reverse stock split of its shares of common stock at a ratio of 1-for-4 (the "January 2026 Reverse Stock Split" and, together with the July 2023 Reverse Stock Split, June 2024 Reverse Stock Split, and the November 2024 Reverse Stock Split, the "Reverse Stock Splits"). As such, collectively, the Company's common stock has undergone reverse stock splits that have combined the shares on a 1-for-32,000 aggregate basis since July 2023. All of the Company's historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect these reverse stock splits.

At the Company's annual meeting of stockholders on June 18, 2025, the Company's stockholders provided the Company's board of directors with authority to implement the January 2026 Reverse Stock Split, as well as an additional reverse stock split at a ratio of up to 1-for-20 (the "Additional Reverse Stock Split"). The Additional Reverse Stock Split may not be implemented if it would reduce the number of publicly held shares of the Company's common stock to less than 500,000. The Board's authority to implement the Additional Reverse Stock expires on June 18, 2026.

On October 23, 2024, the stockholders of the Company approved and adopted an amendment to the Company's amended and restated certificate of incorporation, to increase the number of authorized shares of the Company's common stock to 250,000,000.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("US GAAP") and include all adjustments necessary for the presentation of the Company's consolidated financial position, results of operations and cash flows for the periods presented. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Going Concern

The consolidated financial statements for the years ended December 31, 2025 and 2024 were prepared under the assumption that the Company will continue as a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business.

The Company had cash and cash equivalents of $5,164,875 and current liabilities of $1,119,197 as of December 31, 2025. The Company has incurred net losses since its inception, has incurred negative cash flows from operations and has an accumulated deficit of $41,517,267 as of December 31, 2025. The Company expects that its net cash used in operating activities will continue to be negative over at least the next several years as it attempts to redevelop aspects of the manufacturing process for Symphony cartridges and conducts clinical trial work and, if such redevelopment and trials are successful, begins preparation of an FDA submission. These financial results and financial position, and the Company's expected forward-looking outlook of significant negative cash flow in the future, raise substantial doubt with respect to its ability to continue as a going concern. The Company expects that it will not be in position to submit a 510(k) regulatory application to the FDA for Symphony until 2027, at the earliest, if it is even able to generate sufficient clinical trial results to support such a submission. If the Company fails to obtain sufficient future financing, its clinical trials and targeted FDA submission timeline could be delayed, and it could be forced to abandon such activities entirely and cease operations, with the possible loss of such properties or assets. If the Company is unable to obtain additional financing as it continues to generate negative cash flow, its board of directors could determine to cause the Company to undertake a process of liquidation under Chapter 7 of applicable U.S. bankruptcy laws, or otherwise seek other protection under such laws. In such event, holders of shares of the Company's common stock could recoup little, if any, value in such process. The Company currently estimates cash resources will be sufficient to fund its operations up to the third quarter of 2026.

These accompanying financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in these consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. The Company evaluates its estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the consolidated financial statements.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents, consisting of highly liquid money market funds are carried at fair market value which approximates cost. The Company recognized interest income associated with cash equivalents of $97,559 and $145,823 for the years ended December 31, 2025 and 2024, respectively.

Leases

The Company accounts for its leases under the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") ASC 842, *Leases* ("ASC 842").

The Company has arrangements involving the lease of facilities and the lease of copiers. Under ASC 842, at inception of the arrangement, the Company determines whether the contract is or contains a lease and whether the lease should be classified as an operating or a financing lease. This determination, among other considerations, involves an assessment of whether the Company can control the underlying asset and have the right to obtain substantially all of the economic benefits or outputs from the asset. The Company accounts for the leases of less than 12 months as short-term leases.

The Company recognizes right-of-use ("ROU") assets and lease liabilities as of the lease commencement date based on the net present value of the future minimum lease payments over the lease term. The Company amortizes the right-of-use assets over the remaining terms of the lease. ASC 842 requires the leases to use the rate implicit in the lease unless it is not readily determinable and then it may use its incremental borrowing rate ("IBR") to discount the future minimum lease payments. Most of the Company's leases do not provide an implicit rate; therefore, the Company uses its IBR to discount the future minimum lease payments. The Company determines its IBR with its credit rating and other economic information available as of the commencement date, as well as the identified lease term. During the assessment of the lease term, the Company considers its renewal options and extensions within the arrangements and the Company includes these options when it's reasonably certain to extend the term of the lease.

The Company has lease arrangements that contain incentives for tenant improvements as well as fixed rent escalation clauses. For contracts with tenant improvement incentives that are determined to be leasehold improvements and the Company is reasonably certain to exercise, it records a reduction to the lease liability and amortizes the incentive over the identified term of the lease as a reduction to rent expense. The Company records rental expense on a straight-line basis over the identified lease term on contracts with rent escalation clauses.

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and requires disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company determines fair value for cash equivalents with Level 1 inputs through the reference to the quoted market prices.

There were no liabilities measured at fair value on a recurring basis, and no assets or liabilities measured at fair value on a non-recurring basis as of December 31, 2025 and 2024.

The carrying values of financial instruments such as prepaid expenses, accounts payable, and accrued expenses approximated fair value as of December 31, 2025 and 2024 due to their short-term maturities.

Impairment of Property and Equipment

The Company evaluates its long-lived assets with definite lives, such as fixed assets and right-of-use assets for impairment. The carrying value of fixed assets and right-of use assets is reviewed on a regular basis for the existence of facts or circumstances, both internally and externally, that may suggest impairment. Some factors which the Company considers to be triggering events for impairment review include classification of an asset as held for sale, a significant decrease in the market value of an asset, a significant change in the extent or manner in which an asset is used, a significant adverse change in the business climate that could affect the value of an asset, an accumulation of costs for an asset in excess of the amount originally expected, a current period operating loss or cash flow decline combined with a history of operating loss or cash flow uses or a projection that demonstrates continuing losses and a current expectation that, it is more likely than not, a long-lived asset will be disposed of at a loss before the end of its estimated useful life. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If the assets are not recoverable, the impairment charge is measured as the amount by which the carrying value of the asset group exceeds the fair value.

During the year ended December 31, 2025, the Company made the decision to close its internal lab and transferred the related fixed assets with a net book value of $62,376 to a third party to be marketed and sold. The Company recognized an impairment charge of $26,706 which is included in research and development expenses. There was no impairment charge in 2024.

Concentration of Credit Risk

Cash, and cash equivalents consist of financial instruments that potentially subject the Company to a concentration of credit risk in the event of a default by the related financial institution holding the securities, to the extent of the value recorded in the balance sheet. The Company invests cash that is not required for immediate operating needs primarily in highly liquid instruments with lower credit risk.

Research and Development Expenses

Costs incurred in the research and development of new products are expensed as incurred. Research and development costs include, but are not limited to, salaries, benefits, stock-based compensation, laboratory supplies, fees for professional service providers and costs associated with product development efforts, including preclinical studies and clinical trials.

The Company estimates preclinical study and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Stock-Based Compensation

Share-based compensation expense for all share-based payment awards made to employees, directors and non-employees is measured based on the grant-date fair value of the award. Share-based compensation expense for awards granted to non-employees is determined using the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured.

The Company uses the Black-Scholes option pricing model to determine the fair value of options granted. The Company recognizes the compensation cost of share-based awards on a straight-line basis over the requisite service period. For stock awards for which vesting is subject to performance-based milestones, the expense is recorded over the implied service period after the point when the achievement of the milestone is probable, or the performance condition has been achieved.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The Company does not have a history of market prices of its common stock, and as such, volatility is estimated using historical volatilities of similar public entities. The expected life of the awards is estimated based on the simplified method for grants to employees and is based on the contractual term for non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the awards. The dividend yield assumption is based on history and expectation of paying no dividends.

The Company recognizes forfeitures related to employee share-based payments when they occur.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in the Financial Accounting Standards Board, or the FASB, ASC, 480, Distinguishing Liabilities from Equity, or ASC 480, and ASC 815, Derivatives and Hedging, or ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. Finally, the Company determines if the warrants meet the definition of a derivative based on their contractual terms. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and at each balance sheet date thereafter. Changes in the estimated fair value of liability-classified warrants are recognized as a non-cash gain or loss on the consolidated statements of operations. The Company also evaluates if changes in contractual terms or other considerations would result in the reclassification of outstanding warrants from liabilities to stockholders' equity (or vice versa).

Segment Reporting

The Company follows the guidance in ASC 280, Segment Reporting. Management has determined that the Company operates as one operating and reportable segment, as the Chief Executive Officer, who serves as the Chief Operating Decision Maker, evaluates performance of the operating segment and allocates resources based on amounts as reported on the consolidated statements of operations and cash flows. Segment expenses are presented on the Company's consolidated statements of operations. The operating segment assets are reported on the consolidated balance sheets as total assets. The Company's operations consist solely of the development of its Symphony diagnostic platform, a near-patient diagnostic platform designed to provide rapid results for critical care settings, and no discrete financial information is produced for separate business components. Accordingly, the consolidated financial statements represent the Company's single reportable segment.

Income Taxes

The Company follows accounting guidance regarding the recognition, measurement, presentation and disclosure of uncertain tax positions in the consolidated financial statements. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the consolidated financial statements. There are no uncertain tax positions that require accrual or disclosure as of December 31, 2025. Any interest or penalties are charged to expense. During the years ended December 31, 2025 and 2024, the Company had no significant interest and penalties. Tax years subsequent to December 31, 2022 are subject to examination by federal and state authorities.

The Company recognizes deferred tax assets and liabilities based on the impact of temporary differences between assets and liabilities recognized for tax and financial reporting purposes measured by applying enacted tax rates and laws that will be in effect when the differences are expected to reverse, net operating loss carryforwards and tax credits. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized. The deferred tax benefit or expense for the period represents the change in the deferred tax asset or liability from the beginning to the end of the period.

Deferred Offering Costs

Deferred offering costs consist of underwriting, legal, accounting and other expenses incurred through December 31, 2023 that are directly related to the January 2024 Offering and that were charged to stockholders' equity upon the completion of the January 2024 Offering.

Net Loss per Share

Basic net loss per share to common stockholders is computed by dividing the net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury stock and if-converted methods. Dilutive common stock equivalents are comprised of options outstanding under the Company's stock option plan, restricted stock units, and warrants. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, are as follows (in common stock equivalent shares):

	December 31,	
	2025	**2024**
Options to purchase common stock	5	18
Restricted stock units (RSUs)	-	-
Pre-2024 warrants for common stock	159	165
Class A warrants for common stock	77	77
Class B warrants for common stock	2	2
January 2024 warrants for common stock	1,682	1,682
January 2024 placement agent warrants for common stock	117	117
Class C warrants for common stock	71,873	343,147
Class E warrants for common stock	271,277	-
Class F warrants for common stock	1,125,000	-
Class F placement agent warrants for common stock	45,000	-

Recently Adopted Accounting Standards

Reportable Segment Disclosures

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures. The change in the standard improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The changes improve financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. The guidance will be effective for annual reporting periods beginning after December 15, 2023, and for interim periods beginning after December 15, 2024. Early adoption is permitted. The standard will be applied retrospectively. Since the Company has one reportable segment, adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

Income Taxes Disclosures

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740), Improvements to Income Tax Disclosures. This change requires enhanced income tax disclosures, primarily related to existing rate reconciliation and income taxes paid information. The guidance will be effective for annual reporting periods beginning after December 15, 2024. Adoption of this new standard increased disclosure in the notes to the Company's consolidated financial statements.

Recently Issued Accounting Standards

Expense Disaggregation Disclosures

In November 2024, the FASB issued ASU 2024-03, Reporting Comprehensive Income-Expense Disaggregation Disclosures. This change requires disaggregated disclosures of certain categories of expenses that are included in expense line items on the face of the income statement. The disclosures are required on an annual and interim basis. The guidance also requires the total amount of selling expenses to be disclosed and, on an annual basis, the definition of selling expenses. The guidance will be effective for annual reporting periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027. Early adoption is permitted. This new guidance will result in increased disclosures in the notes to the financial statements.

3. LICENSE AND SUPPLY AGREEMENT WITH TORAY INDUSTRIES

The Company depends on Toray's intellectual property for the Symphony cartridges upon which the Symphony platform relies. On October 6, 2020, the Company entered into a License and Supply Agreement (the "License Agreement") with Toray, providing the Company with an exclusive global license (excluding Japan) to use Toray's patents and know-how related to the Symphony detection cartridges for manufacturing, marketing and sale of the products (as defined in the License Agreement). In exchange for the license, the Company committed to make two payments of $120,000 each to Toray, both of which were made in 2021. In addition, following the first sale of the cartridges after regulatory clearance, the Company is obligated to make royalty payments to Toray based on the net sales of the cartridges for the period that any underlying patents exist or ten years after the first sale. Following the first sale after obtaining regulatory clearance, the Company will make minimum annual royalty payments of $60,000 for the first year and $100,000 for each year thereafter, which shall be creditable against any royalties owed to Toray in such calendar year.

On October 23, 2023, the Company and Toray entered into an Amended and Restated License Agreement (the "New Toray License Agreement") and a Master Supply Agreement (the "New Toray Supply Agreement"). Under the New Toray License Agreement, the Company continues to license from Toray intellectual property rights needed to manufacture single-use test cartridges, and the Company has received the right to sublicense certain Toray intellectual property to Sanyoseiko in connection with Sanyoseiko's ongoing agreement with the Company to manufacture the Company's Symphony analyzers and cartridges (including in connection with the Company's clinical trials). In addition, the New Toray License Agreement provided for the transfer of certain technology related to the cartridges to Sanyoseiko. The royalty payment percentage payable by the Company to Toray was reduced under the New Toray License Agreement from 15% to 7.5% (or less in certain circumstances) of net sales of certain cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. The New Toray License Agreement contemplates that applicable royalty payment obligations from the Company to Toray for other products will be determined separately by the parties in the future.

On July 23, 2025, the Company entered into an amendment (the "Amendment") to the New Toray License Agreement and the New Toray Supply Agreement with Toray. The Amendment provided that the deadline under the New Toray License Agreement for the Company to establish an alternative manufacturing site for the Company's Symphony cartridges would be extended from October 23, 2025 to October 23, 2026, and the Company has agreed to use its best efforts to establish the site by such date. The Amendment confirms that Toray has provided to the Company all applicable know-how required under the New Toray License Agreement and is not under any further obligation to provide know-how or technical assistance to the Company. Pursuant to the Amendment, the Company paid $71,212 to Toray for a final supply of certain chip components prior to the expiration of the New Toray Supply Agreement, which occurred on October 23, 2025. There were no sales of or revenues from the cartridges during the years ended December 31, 2025 and 2024.

The Company has begun cartridge manufacturing process redevelopment through Sanyoseiko, a third-party contractor who is managing such redevelopment. Such redevelopment is intended to address several technical challenges to bring Symphony to a level consistent with necessary performance and quality requirements. After the cartridge manufacturing process redevelopment is completed, the Company plans to have the manufacturing process occur at Sanyoseiko, a FDA-registered CMO, including for verification and validation testing and commercial manufacturing. The manufacturing site will be established by the Company without Toray's technical assistance. If Toray were to assert that the Company has not used its best efforts to establish the cartridge manufacturing site by October 2026, they could seek to terminate the license agreement as early as November 2026. If Toray were to be successful in terminating the license agreement, the Company would lose access to certain technology required to produce the cartridges that the Symphony system relies on to function, which would likely result in a material adverse effect on the Company's commercialization efforts. At December 31, 2025 and 2024, there were no amounts accrued related to the New Toray License Agreement or the License Agreement.

4. FINANCINGS

October 2025 Private Placement

On October 9, 2025, the Company entered into a securities purchase agreement with two institutional investors pursuant to which the Company sold in a private placement (i) an aggregate of 43,750 shares of common stock and prefunded warrants to purchase up to 518,750 shares of common stock (the "October 2025 Prefunded Warrants"), and (ii) Series F warrants (the "Series F Warrants") to purchase up to 1,125,000 shares of common stock. The combined price of the securities sold in the private placement was $8.00 per share of common stock (or prefunded warrant in lieu thereof, in which case such price was reduced by $0.0004) and accompanying Series F Warrants to acquire two shares of common stock. The October 2025 Prefunded Warrants are exercisable for shares of common stock at an exercise price of $0.0004 per share, are immediately exercisable and expire once exercised in full. The Series F Warrants are exercisable for shares of common stock at an exercise price of $7.00 per share, are immediately exercisable and expire five and one-half years from the date of issuance.

The transaction closed on October 10, 2025. The gross proceeds to the Company from the sale of the securities sold in the private placement were approximately $4.5 million. The Company incurred total offering costs of $787,755, including a 8% financial advisory fee to Rodman and Renshaw LLC ("Rodman"), the placement agent, of approximately $360,000. Under the terms of the Company's engagement letter with Rodman, the Company issue Rodman's designees warrants to purchase up to 45,000 of common stock at an exercise price of $10.00 per share, which expire 5.5 years from the date of issuance (the "October 2025 Placement Agent Warrants").

In connection with this private placement, on November 26, 2025, the Company filed a prospectus under rule 424(b)(3) to register 1,732,500 shares of common stock for resale in public markets.

Holders of the warrants will not have the right to exercise any portion of such warrants if such holder, together with its affiliates, would beneficially own in excess of 4.99% or 9.99% (at the initial election of the holder) of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise, provided that a holder may increase or decrease such beneficial ownership limitation up to, and no higher than, 9.99%, by giving 61 calendar days' notice to the Company.

April 2025 Private Placement

On April 7, 2025, the Company entered into inducement letter agreements with certain existing holders of the Company's Class C warrants (the "Class C Warrants"), pursuant to which such holders agreed to purchase an aggregate of 271,277 shares of the Company's common stock (or, to the extent the applicable holder would have exceeded a specified beneficial ownership limitation, prefunding the future exercise of such warrants, other than a remaining $0.0004 per share exercise price). The Class C Warrants were originally issued on June 28, 2024 for an exercise price of $392.00 per share and were subsequently reduced to $65.20 per share pursuant to stockholder approval on August 21, 2024. Pursuant to the inducement letter agreements, the applicable holders agreed to exercise their Series C Warrants at a reduced exercise price of $13.68 per share, and to purchase an equivalent number of new Class E warrants (the "Class E Warrants") for an additional $0.50 per share. The Class E Warrants have an exercise price of $13.68 per share and expire on April 8, 2030.

The transaction closed on April 8, 2025. The exercise of the Class C Warrants resulted in the Company issuing 170,551 shares of common stock at closing pursuant to the inducement letters, and the exercise price of 100,726 of the Class C Warrants being amended to 0.0004 per share. As of December 31, 2025, all such reduced exercise price Class C Warrants had been exercised.

The gross proceeds to the Company from the exercise of the Class C Warrants and the sale of the new Class E Warrants were $3,846,707. The Company incurred total cash offering costs of $464,670, including a 10% financial advisory fee to Aegis Capital Corp. of $384,670.

The modification of the terms or conditions of the Class C Warrants in this transaction is treated as an exchange of the original instrument for a new instrument. Using the Black Scholes option pricing model, the fair value of the Series C Warrants immediately prior to the inducement transaction was $479,299 and immediately after the inducement transaction was $1,590,930. In addition, Series E Warrants with a fair value of $1,730,652 were provided as part of the inducement transaction for a purchase price of $135,638. The Company recorded additional equity issuance costs of $2,706,645 related to the modification of the Series C Warrants and issuance of Series E Warrants related to the inducement transaction. As this equity issuance cost was a non-cash transaction, the Company recorded an increase to additional paid-in capital to offset the expense.

June 2024 Public Offering

On June 28, 2024, the Company sold in a public offering (the "June 2024 Offering"), (i) 2,885 common units (the "Common Units"), each consisting of one share of common stock, two Class C Warrants and one Class D Warrant and (ii) 23,953 prefunded units (the "Prefunded Units"), each consisting of one prefunded warrant to purchase one share of common stock (each, a "June 2024 Prefunded Warrant"), two Class C Warrants and one Class D Warrant. The Common Units were sold at a price of $326.00 per unit and the Prefunded Warrants were sold at a price of $325.98 per unit. Aegis Capital Corp. ("Aegis") partially exercised its over-allotment option in respect to 3,393 Class C Warrants and 1,696 Class D Warrants (the "Over-Allotment Warrants). As of December 31, 2024, all Prefunded Warrants had been exercised in full.

Pursuant to an engagement letter dated June 6, 2024, by and between the Company and Aegis, the Company paid Aegis a total cash fee of $743,750 equal to 8.5% of the gross proceeds received in the June 2024 Offering.

The gross proceeds to the Company from the June 2024 Offering were $8,569,075. The Company incurred offering costs of $1,133,419.

May 2024 Bridge Note Financing

On May 31, 2024, the Company entered into a Note Purchase Agreement with an accredited investor (the "NPA"), and a Securities Purchase Agreement with three accredited investors (the "SPA"). This transaction closed on June 3, 2024. Debt issuance costs related to the NPA and SPA totaled $212,654. Under the terms of the NPA, the first investor provided the Company with a $1,000,000 cash subscription in exchange for the issuance of a senior secured note (the "Bridge Note"). As of December 31, 2024, a total of $1,176,470 was repaid to the NPA investor in full satisfaction of the Bridge Note. The difference between the Bridge Note and the subscription amount, initially recorded as a discount on the notes, was the result of the discount factor included in the NPA of approximately 17.6%.

Under the terms of the SPA, the three additional investors agreed to collectively provide the Company with a separate $1,000,000 cash subscription in exchange for the issuance of senior secured notes (the "SPA Notes"), and the collective issuance of 362 shares of the Company's common stock. The fair value of the common stock issued in connection with the SPA was $307,563. As of December 31, 2024, a total of $1,111,110 has been repaid to the SPA investors, in full satisfaction of the SPA Notes. The difference between the SPA Notes and the subscription amounts, initially recorded as a discount on the SPA Notes, was the result of the discount factor included in the SPA of 11.11%.

The interest expense recorded on the NPA and SPAs was $807,797 for the year ended December 31, 2024, including debt issuance costs related to the NPA and SPA totaling $212,654.

January 2024 Public Offering

On January 2, 2024, the Company sold in a public offering (such transaction, the "January 2024 Offering") (i) 336 shares of common stock and (ii) prefunded warrants to purchase up to an aggregate 1,346 shares of common stock (the "January 2024 Prefunded Warrants"). The Shares and January 2024 Prefunded Warrants were sold together with warrants to purchase up to an aggregate of 1,682 shares of common stock at an exercise price of $2,080.00 per share (the "January 2024 Warrants"). The combined public offering price was $2,080.00 per share of common stock and related January 2024 Warrant and $2,079.84 per January 2024 Prefunded Warrant and related January 2024 Warrant.

As of December 31, 2024, all January 2024 Prefunded Warrants had been exercised in full. The January 2024 Warrants were exercisable immediately and remain exercisable for a period of five years following the date of issuance.

Pursuant to an engagement letter, dated as of August 7, 2023, as amended October 11, 2023, by and between the Company and the H.C. Wainwright & Co., LLC ("H.C. Wainwright"), the Company paid H.C. Wainwright a total cash fee of $245,000 equal to 7.0% of the gross proceeds received in the January 2024 Offering. The Company also paid H.C. Wainwright a management fee of $35,000 equal to 1.0% of the gross proceeds raised in the January 2024 Offering and certain expenses incurred in connection with the January Offering. In addition, the Company issued to H.C. Wainwright's designees, warrants to purchase up to an aggregate 117 shares of common stock (the "January 2024 Placement Agent Warrants"), which represents 7.0% of the aggregate number of shares of Common Stock and January 2024 Prefunded Warrants sold in the January 2024 Offering. The January 2024 Placement Agent Warrants have substantially the same terms as the January 2024 Warrants, except that the January 2024 Placement Agent Warrants have an exercise price equal to $2,600.00, or 125% of the offering price per share of common stock and related January 2024 Warrant sold in the January 2024 Public Offering and expire on the fifth anniversary from the date of the commencement of sales in the January 2024 Offering.

The gross proceeds to the Company from the January 2024 Offering were $3,500,000. The Company incurred offering costs of $711,031.

5. WARRANTS

The following table summarizes information with regard to warrants outstanding at December 31, 2025:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
October 2025 Prefunded warrants	367,750	Common Stock	$ 0.0004	N/A
Class F warrants for common stock	1,125,000	Common Stock	$ 7.00	5.3
Class F Placement Agent warrants for common stock	45,000	Common Stock	$ 10.00	5.3
Class E warrants for common stock	271,277	Common Stock	$ 13.68	4.3
June 2024 Class C warrants for common stock	71,873	Common Stock	$ 65.20	3.5
January 2024 warrants for common stock	1,682	Common Stock	$ 2,080.00	3.0
January 2024 Placement Agent warrants for common stock	117	Common Stock	$ 2,600.00	3.0
August 2023 warrants for common stock	134	Common Stock	$ 11,584.00	2.6
August 2023 Placement Agent warrants for common stock	8	Common Stock	$ 14,736.00	2.6
Class A warrants for common stock	77	Common Stock	$ 224,000.00	0.9
Class B warrants for common stock	2	Common Stock	$ 320,000.00	0.9
Other Pre-2024 warrants for common stock	17	Common Stock	$ 132,849.00	0.5

October 2025 Private Placement

On October 9, 2025, the Company entered into a securities purchase agreement with two institutional investors pursuant to which the Company sold in a private placement (i) an aggregate of 43,750 shares of common stock and prefunded warrants to purchase up to 518,750 shares of common stock (the "October 2025 Prefunded Warrants"). The October 2025 Prefunded Warrants were exercisable for shares of common stock at an exercise price of $0.0004 per share, were immediately exercisable and expired once exercised in full. As of December 31, 2025, 367,750 of the October 2025 Prefunded Warrants remained unexercised. Between January 1, 2026 and February 19, 2026, all of the remaining October 2025 Prefunded Warrants were exercised in full.

October 2025 Class F Warrants

Pursuant to the October 2025 private placement, the Company issued 1,125,000 Class F warrants for common stock with an exercise price of $7.00 per share and 45,000 Placement Agent Class F warrants for common stock with an exercise price of $10.00 per share. The Class F warrants and Placement Agent Class F warrants became exercisable immediately upon issuance and for a period of five and one half years following the date of issuance.

April 2025 Class E Warrants

Pursuant to the April 2025 private placement, certain existing holders of the Company's Class C Warrants agreed to purchase an aggregate of 271,277 shares of the Company's common stock. As a part of the April 2025 private placement, the Company sold 271,277 Series E Warrants to the Class C Warrant exercising holders for $0.50 per warrant. The Class E warrants have an exercise price of $13.68 per share, became exercisable immediately upon issuance and for a period of five years following the date of issuance.

June 2024 Class C and Class D Warrants and June 2024 Underwriter Over-Allotment Warrants

As a part of the June 2024 Offering, the Company issued 53,680 Class C Warrants and 26,840 Class D Warrants. Aegis (the "Underwriter") partially exercised its over-allotment option with respect to 3,393 Class C Warrants and 1,696 Class D Warrants (the "Over-Allotment Warrants").

Upon stockholder approval of the issuance of Class C Warrants on August 21, 2024, the Class C Warrants, which had an initial exercise price of $392.00 per share of common stock, were adjusted to be exercisable at an exercise price of $65.20 per share (the "floor price, which represented 20% of the minimum price under Nasdaq's listing rules on the date of pricing of the June 2024 Offering), and the number of shares of common stock issuable upon exercise were proportionately increased to 343,146 shares. In connection with the reset in the exercise price and number of shares issuable pursuant to the Class C Warrants, the Company recorded a deemed dividend of $9,282,075 based on the excess of the fair value of the modified Class C Warrants over the fair value of the Class C Warrants before the modification, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the year ended December 31, 2024. The Class C Warrants may be exercised at any time for a period of five (5) years following the date of stockholder approval in August 2024.

The Class D Warrants were immediately exercisable at an exercise price of $0.02 per share of common stock for a period of five (5) years following the date of issuance. Upon stockholder approval of the issuance of the Class D Warrants on August 21, 2024, the number of shares of common stock issuable upon exercise increased to four shares per warrant for the remaining unexercised Class D Warrants as the weighted average price of our common stock over a rolling five (5)-trading day period fell below $65.20 per share (the "floor" price, which represented 20% of the "minimum price" under Nasdaq's listing rules on the date of pricing of the June 2024 Public Offering) following the issuance date. In connection with the reset of the number of shares issuable pursuant to the Class D Warrants, the Company recorded a deemed dividend of $3,940,978 based on the excess of the fair value of the modified Class D Warrants over the fair value of the Class D Warrants before the modification, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the year ended December 31, 2024. As of December 31, 2024, all Class D Warrants have been exercised and none remain outstanding.

During 2024, the Company issued 108,844 shares of common stock upon exercise of the June 2024 Class D Warrants. The Class D Warrants were exercised on either a cash basis at $0.02 per share exercise price or on a proportional cashless basis.

January 2024 Common Stock Warrants and January 2024 Placement Agent Warrants

As part of the January 2024 Offering, the Company issued January 2024 warrants to acquire 1,682 shares of common stock at an exercise price of $2,080.00 per share and January 2024 Placement Agent Warrants to acquire 117 shares of common stock with an exercise price of $2,600.00 per share. The January 2024 warrants and January 2024 Placement Agent Warrants became exercisable immediately upon issuance for a period of five years following the date of issuance.

Fundamental Transaction

The warrants described above include certain rights upon a "fundamental transaction" (as defined in such warrants), including the right of the holders thereof to receive from the Company or a successor entity cash or the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction in the amount of the Black Scholes value (as defined in such warrants) of the unexercised portion of the applicable warrants on the date of the consummation of such fundamental transaction.

Warrant Accounting

Each of the Company's warrants to acquire shares of common stock were accounted for as equity classified financial instruments as they meet the requirements for equity classification under ASC 815, *Derivatives and Hedging*.

6. STOCK COMPENSATION

Stock Incentive Plans

In 2018, the Company adopted the 2018 Stock Incentive Plan (the "2018 Plan") for employees, consultants, and directors. The 2018 Plan, which is administered by the Company's Board of Directors, permits the Company to grant incentive and nonqualified stock options for the purchase of common stock, and restricted stock awards. The maximum number of shares of common stock reserved for issuance under the 2018 Plan is 20. At December 31, 2025 there were 9 shares of common stock available for grant under the 2018 Plan.

On July 6, 2021, the Company's Board of Directors and stockholders approved and adopted the Bluejay Diagnostics, Inc. 2021 Stock Plan (the "2021 Plan"). A total of 61 shares of common stock were approved to be initially reserved for issuance under the 2021 Stock Plan. At December 31, 2025 there were 25 shares of common stock available for grant under the 2021 Plan.

Stock Award Activity

The following table summarizes the status of the Company's non-vested restricted stock awards for years ended December 31, 2025:

	Non-vested Restricted Stock Awards	
	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2024	-	$ 41,280
Granted	-	-
Vested	(-)	41,280
Cancelled / forfeited	-	-
Outstanding at December 31, 2025	-	$ -

Stock Option Plan Summary

The following is a summary of stock option activity for the year ended December 31, 2025:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2024	18	$ 59,864	5.8	$ -
Granted	-	-		-
Exercised	-	-		-
Cancelled / forfeited	(13)	75,052		-
Outstanding at December 31, 2025	5	$ 20,376	3.0	$ -
Exercisable at December 31, 2025	5	$ 20,376	3.0	$ -

Stock-Based Compensation Expense

For the years ended December 31, 2025 and 2024, the Company recorded stock-based compensation expense as follows:

	Year ended December 31,	
	2025	2024
Research and development	$ (193)	$ 16,648
General and administrative	199	3,446
Marketing and business development	-	-
Total stock-based compensation	$ 6	$ 20,094

At December 31, 2025, there was no unrecognized compensation expense related to non-vested stock option awards and non-vested restricted stock awards.

7. RELATED PARTY TRANSACTIONS

NanoHybrids, Inc.

In December 2021, the Company entered into an agreement with NanoHybrids, Inc. ("NanoHybrids"), an entity in which the Company's former Chief Technology Officer, Jason Cook, served as Chief Executive Officer of prior to becoming employed by the Company, to enable NonoHybrids to utilize the Company's research and development staff and laboratory facility (the "Sharing and Services Agreement"). Any hours worked by Company employees for NanoHybrids were billed to NanoHybrids at a bill rate of the respective employee's fully burdened personnel cost plus 10%. Additionally, the Company purchased certain lab supplies for NanoHybrids and rebilled those costs to NanoHybrids. Dr. Cook was the majority shareholder of NanoHybrids during the time of this arrangement. The table below summarizes the amounts earned for the years ended December 31, 2025 and 2024 and balances due from NanoHybrids as of December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	**2024**
Income from NanoHybrids included in Other Income	$ 6,873	$ 127,079
Cash receipts from NanoHybrids	$ 21,437	$ 153,783

	As of December 31,	
	2025	**2024**
Amounts receivable from NanoHybrids included in Prepaids and Other Current Assets	$ -	$ 14,564

8. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2025 and 2024:

		December 31,	
	Depreciable lives	**2025**	**2024**
Construction in process		$ 1,279,173	$ 1,351,179
Manufacturing equipment	3-5 years	239,872	-
Furniture, fixtures, and equipment	3-5 years	116,782	136,312
Software	3 years	-	4,457
Lab equipment	3-5 years	-	173,268
Leasehold improvements	Life of lease	43,231	43,231
		1,679,058	1,708,447
Less: accumulated depreciation		(144,617)	(194,952)
Property and equipment, net		$ 1,534,441	$ 1,513,495

The Company reviews long-lived assets for impairment when events, expectations, or changes in circumstances indicate that the asset's carrying value may not be recoverable. During the year ended December 31, 2025, the Company made the decision to close its internal lab and transferred the related fixed assets with a net book value of $62,376 to a third party to be marketed and sold. The Company wrote-off $9,549 of lab equipment and recognized an impairment charge of $26,706, both of which are included in research and development expenses. As of December 31, 2025, the expected realizable value of the remaining assets held for sale of $22,770 is recorded as assets held for sale in the Company's balance sheets.

Construction in process consists of symphony cartridge manufacturing equipment. The Company placed $239,872 of manufacturing equipment into service in 2025 and expects to place the remaining construction in process into service in 2026 to support its SYMON II clinical study. All of the Company's construction in process and manufacturing equipment is held and operated by Sanyoseiko Co. LTD, its contract manufacturing organization in Japan.

9. LEASES

The Company primarily enters into lease arrangements for office, laboratory space, and copiers. A summary of supplemental lease information is as follows:

	December 31,	
	2025	2024
Weighted average remaining lease term - operating leases (in years)	1.2	2.1
Weighted average remaining lease term - finance leases (in years)	2.1	3.1
Weighted average discount rate – operating leases	7.0%	7.0%
Weighted average discount rate – finance leases	7.0%	7.0%
Operating cash flows from operating leases	$ 113,259	$ 177,081
Operating cash flows from finance leases	$ 780	$ 1,053

A summary of the Company's lease assets and liabilities are as follows:

	December 31,	
	2025	2024
Operating lease right-of-use asset	$ 113,289	$ 209,788
Finance leases in Property and Equipment	5,689	10,421
Total lease assets	$ 118,978	$ 220,209
Current portion of operating lease liability	$ 100,000	$ 113,260
Current portion of finance lease liability included in accrued expenses	4,807	4,807
Noncurrent operating lease liabilities	20,211	108,989
Noncurrent finance lease liabilities	4,540	8,567
Total lease liabilities	$ 129,558	$ 235,623

The following table reconciles the undiscounted lease liabilities to the total lease liabilities recognized on the consolidated balance sheet as of December 31, 2025:

Year	Operating Lease	Finance Lease
2026	$ 100,000	$ 4,807
2027	25,000	4,807
2027	-	400
Total future lease payments	125,000	10,014
Less: Imputed interest	4,789	667
Present value of lease liability	$ 120,211	$ 9,347

10. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

Information pertaining to legal proceedings and related contingencies can be found in "Item 3. Legal Proceedings" of this Annual Report on Form 10-K.

Minimum Royalties

As required under the License Agreement (see Note 3), following the first sale of cartridges, the Company will also make royalty payments to Toray equal to 7.5% of the net sales of the cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. There were no sales of or revenues from the cartridges through December 31, 2025.

Indemnification

The Company has certain agreements with service providers with which it does business that contain indemnification provisions pursuant to which the Company typically agrees to indemnify the party against certain types of third-party claims. The Company accrues for known indemnification issues when a loss is probable and can be reasonably estimated. The Company would also accrue for estimated incurred but unidentified indemnification issues based on historical activity. As the Company has not incurred any indemnification losses to date, there were no accruals for or expenses related to indemnification issues for any period presented.

11. SUPPLEMENTAL BALANCE SHEET INFORMATION

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2025	2024
Prepaid insurance	$ 183,211	$ 489,174
Vendor prepayments	-	21,946
Prepaid other	92,746	85,818
Total prepaid expenses and other current assets	$ 275,957	$ 596,938

Accrued expenses and other current liabilities consist of the following:

	December 31,	
	2025	2024
Accrued personnel costs	$ 47,117	$ 100,974
Accrued legal fees	43,077	48,860
Accrued clinical trial expenses	274,532	191,673
Accrued board of director fees	147,500	95,000
Accrued Delaware franchise tax	136,149	-
Accrued other	156,567	115,479
Total accrued expenses and other current liabilities	$ 804,942	$ 551,986

12. INCOME TAX

No provision for federal income taxes has been recorded for the years ended December 31, 2025 and 2024 due to net losses and the valuation allowance established.

Significant components of the Company's deferred tax assets are as follows:

	As of December 31,	
	2025	2024
Deferred tax assets:		
Net operating losses	$ 8,696,586	$ 6,356,812
Tax credits	1,005,896	812,541
Intangible assets	47,562	52,813
Capitalized R&D expenses	2,140,990	2,619,730
Fixed assets	9,246	-
Other	189,326	193,197
Total deferred tax assets	12,089,606	10,035,093
Valuation allowance	(12,089,606)	(10,035,093)
Deferred tax asset, net of allowance	$ -	$ -

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 2025 and 2024 is as follows:

	Year Ended December 31,	
	2025	2024
Federal statutory rate	21.00%	21.00%
Research tax credits	2.22%	2.43%
Nontaxable and nondeductible items	(0.05)%	(0.08)%
Other	(0.02)%	(0.20)%
Change in valuation allowance	(23.15)%	(23.16)%
Effective tax rate	0.00%	0.00%

The Company regularly assesses the need for a valuation allowance against its deferred tax assets. In making that assessment, the Company considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets to determine, based on the weight of available evidence, whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. In assessing the realizability of deferred tax assets, the Company considers taxable income in prior carryback years, as permitted under the tax law, forecasted taxable earnings, tax planning strategies, and the expected timing of the reversal of temporary differences. This determination requires significant judgment, including assumptions about future taxable income that are based on historical and projected information and is performed on a jurisdiction-by-jurisdiction basis.

The Company continues to maintain a full valuation allowance against its deferred tax assets. During the years ended December 31, 2025 and 2024, management assessed the positive and negative evidence in its operations, and concluded that it is more likely than not that its deferred tax assets as of December 31, 2025 and 2024 will not be realized given the Company's history of operating losses. The valuation allowance against deferred tax assets increased by approximately $2.1 million and $2.3 million during 2025 and 2024, respectively, related to a full valuation allowance recorded against capitalized research expenditures, additional net operating losses and tax credits generated in the year.

As of December 31, 2025, the Company had federal net operating losses of approximately $32.0 million. The Company's federal net operating losses incurred prior to 2018 totaling $713,000 expire through 2037, while its federal net operating losses incurred in 2018 to 2025 totaling approximately $31.3 million can be carried forward indefinitely but are limited to 80% utilization against future taxable income each year. As of December 31, 2024, the Company had federal net operating losses of $23.4 million, which may be available to offset future federal income tax liabilities.

As of December 31, 2025, the Company had post-apportioned state net operating losses of approximately $31.3 million that can generally be carried forward 20 years and will expire at various dates through 2045. As of December 31, 2024, the Company had post-apportioned Massachusetts net operating losses of approximately $22.8 million that can generally be carried forward 20 years and will expire at various dates through 2044.

As of December 31, 2025, the Company had $721,000 and $359,000 of federal and state research and development credits, respectively, which will expire at various dates through 2045. As of December 31, 2024, the Company had $569,000 and $307,000 of federal and state research and development credits, respectively, which will expire at various dates through 2044.

13. SUBSEQUENT EVENTS

January 2026 Reverse Stock Split

On January 12, 2026, the Board of Directors approved a 1-for-4 reverse stock split of the Company's shares of common stock. This 1-for-4 reverse stock split became effective on January 29, 2026.

Additional Exercises of Prefunded Warrants

367,750 shares of common stock were issued for October 2025 prefunded warrant exercises in January and February 2026.

Exhibit 31.1

CERTIFICATION
PURSUANT TO RULE 13a-14 AND 15d-14
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Neil Dey, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bluejay Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 6, 2026

By: /s/ Neil Dey
Neil Dey
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION
PURSUANT TO RULE 13a-14 AND 15d-14
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Neil Dey, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bluejay Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 6, 2026

By: /s/ Neil Dey
Neil Dey
President and Chief Executive Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. 1350
(SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)

In connection with the Annual Report of Bluejay Diagnostics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neil Dey, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2026

By: /s/ Neil Dey
Neil Dey
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. 1350
(SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)

In connection with the Annual Report of Bluejay Diagnostics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neil Dey, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2026

By: /s/ Neil Dey
Neil Dey
President and Chief Executive Officer
(principal financial and accounting officer)