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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 10, 2025

BLUEJAY DIAGNOSTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

DELAWARE	**001-41031**	**47-3552922**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File No.)	(I.R.S. Employer Identification No.)

360 Massachusetts Avenue, Suite 203
Acton, MA 01720
(Address of principal executive offices and zip code)

(844) 327-7078
(Registrant's telephone number, including area code)

(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-14(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 7.01 Regulation FD Disclosure.

On November 10, 2025, following the prior filing on November 7, 2025 of its Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2025, Bluejay Diagnostics, Inc. issued a press release providing a 2025 third quarter financial and corporate update. A copy of that press release is furnished with this report as Exhibit 99.1.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended ("Securities Act"), unless specifically identified therein as being incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release, dated November 10, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

Bluejay Diagnostics, Inc.

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

Date: November 10, 2025

Bluejay Diagnostics Corporate Update: Advancing Clinical Milestones and Strategic Partnerships

- *Company focused on advancing clinical milestones and strategic partnerships, with goal of positioning itself for future FDA clearance and product commercialization.*
- *Patient enrollment in SYMON-II clinical trial now approximately 50% completed.*
- *Recent private placement transaction completed in October 2025; Company continues to explore further financing opportunities.*

ACTON, MA – November 10, 2025 – Bluejay Diagnostics, Inc. (NASDAQ: BJDX) ("Bluejay" or the "Company"), a medical diagnostics company developing near-patient testing solutions for critical care, announced financial results for the quarter ended September 30, 2025, and highlighted continued progress across its clinical, operational, and financial initiatives.

Third Quarter 2025 and Recent Corporate Highlights

- **SYMON-II Pivotal Clinical Study Continues:** Bluejay continues patient enrollment in the SYMON-II pivotal clinical trial, designed to validate findings from its 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. The Company's goal is to use the Symphony IL-6 test to complete the testing in the SYMON-II clinical trial. Subject to receipt of further financing, the Company expects to complete sample testing by late 2026, positioning Symphony for a potential submission to the U.S. Food and Drug Administration in 2027.
- **Strategic Partnerships and Supply-Chain Independence:** Through an amended Master Service Agreement and the Master Supply Agreement with SanyoSeiko Co., Ltd. ("SanyoSeiko"), a Japan-based contract manufacturer specializing in medical devices and precision engineering, Bluejay aims to strengthen its manufacturing process. The amended agreement was entered into in connection with Bluejay expanding SanyoSeiko's role in helping to commercialize Bluejay's Symphony platform.
- **Cash Position and Recent Financings:**
  As of September 30, 2025, the Company reported $3.08 million in cash and cash equivalents and $3.69 million in stockholders' equity, following successful completion of a $3.85 million warrant-inducement financing in April and an additional $4.5 million PIPE financing in October. (For further details on financing please refer to our SEC filings)

- **Future Outlook:** Sepsis remains one of the leading causes of mortality worldwide, with over 1.7 million cases annually in the United States alone. The Symphony IL-6 test is designed to deliver actionable results in approximately 20 minutes, enabling faster triage in ICU and emergency settings. The global sepsis diagnostic market is projected to reach $1.8 billion by 2030, which the Company believes creates a compelling potential market opportunity for near-patient testing of sepsis biomarkers. 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 current plan, subject to achieving necessary financing, is to begin testing of samples it is collecting as part of its ongoing 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, with an objective of achieving FDA clearance thereafter.

"Bluejay is executing against a clear vision—to redefine sepsis management through fast, data-driven, near patient diagnostics," said Neil Dey, President and Chief Executive Officer. "The Symphony platform combines clinical precision with operational efficiency, addressing one of the largest unmet needs in hospital medicine today. Our team remains steadfast in driving operational excellence and scientific innovation. Each milestone brings us closer to transforming critical-care diagnostics and realizing meaningful returns for our investors. Bluejay's trajectory is one of progress, purpose, and potential—and we are committed to unlocking its full value."

About Bluejay Diagnostics:

Bluejay Diagnostics, Inc. is a medical diagnostics company focused on improving patient outcomes using its Symphony System, a cost-effective, rapid, near-patient testing system for sepsis triage and monitoring of disease progression. Bluejay does not yet have regulatory clearance for the Symphony System, and we will need to receive regulatory authorization from the U.S. Food and Drug Administration before Symphony can be marketed as a diagnostic product in the United States. Bluejay's first product candidate, an IL-6 Test for sepsis, is designed to provide accurate, reliable results in approximately 20 minutes from' sample-to-result' to help medical professionals make earlier and better triage/treatment decisions. More information is available at www.bluejaydx.com.

Forward-Looking Statements:

This press release contains statements that the Company believes are "forward-looking statements" within the meaning of the Private Litigation Reform Act. Forward-looking statements in this press release include, without limitation, statements pertaining to Bluejay's relationship with SanyoSeiko and the work SanyoSeiko has been requested to undertake for Bluejay supporting the manufacturing process redevelopment, supply chain management, and manufacturing of Bluejay's Symphony platform. Forward-looking statements may be identified by words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "suggest," "will," and similar expressions. The Company has based these forward-looking statements on its current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements the Company makes. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including market and other conditions and those discussed under item 1A. "Risk Factors" in our Form 10-K for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission (the "SEC") on March 31, 2025, and in Part II, Item 1A, "Risk Factors" in its Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2025, June 30, 2025 and September 30, 2025, filed with the SEC on May 13, 2025, August 7, 2025 and November 7, 2025, respectively. You should not place undue reliance on these forward-looking statements, as they are subject to risks and uncertainties, and actual results and performance in future periods may not occur or may be materially different from any future results or performance suggested by the forward-looking statements in this release. This press release speaks as of the date indicated above. The Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law. The Company expressly disclaims any obligation to update or revise any forward-looking statements found herein to reflect any future changes in the Company's expectations of results or any future change in events, except as required by law.

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