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 12, 2026

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. ☐

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

Item 2.02 Results of Operations and Financial Condition.

On November 12, 2026, Bluejay Diagnostics, Inc. issued a press release providing a corporate update, as well as certain financial results as of and for the fiscal quarter ended September 30, 2026. A copy of that press release is furnished with this report as Exhibit 99.1.

The information contained in Item 2.02 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 12, 2026
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 13, 2026

Bluejay Diagnostics Reports Third Quarter 2026 Financial Results and Provides Business Update

Completes SYMON-II clinical study enrollment and advances clinical validation activities

Achieves critical manufacturing milestone ahead of contractual deadline, strengthening supply chain and commercialization readiness

Targets FDA 510(k) submission in the first half of 2027

ACTON, Mass., November 12, 2026 — Bluejay Diagnostics, Inc. (NASDAQ: BJDX) ("Bluejay" or the "Company"), a medical diagnostics company developing rapid, near-patient testing solutions for critical care, today reported financial results for the quarter ended September 30, 2026, and provided an update on its clinical, regulatory and manufacturing progress for the Symphony™ platform.

During the quarter and subsequent weeks, Bluejay achieved several important milestones, including completion of enrollment in its SYMON-II clinical validation study, establishment of an alternative manufacturing facility ahead of a contractual deadline, and continued advancement of its U.S. manufacturing and commercialization infrastructure.

"The third quarter marked significant progress for Bluejay as we advanced several critical elements toward regulatory submission and commercialization," said Neil Dey, President and Chief Executive Officer. "With SYMON-II enrollment completed, important manufacturing milestones achieved, and U.S. supply chain infrastructure enhanced, I believe that we have meaningfully reduced several key development and operational risks. Going forward, our focus remains on completing clinical and analytical validation and preparing for company's planned FDA submission in the first half of 2027."

Third Quarter and Recent Business Highlights

Clinical Development and Regulatory Progress

- Successfully completed SYMON-II clinical study enrollment, exceeding the original target of 750 patients.
- Preliminary baseline analysis of 777 evaluable patients identified 140 deaths within 28 days, representing approximately 18% mortality, providing a substantial clinical dataset for evaluating IL-6 prognostic performance.
- Initiated preliminary sample testing and patient data analysis, with final analytical testing to follow cartridge verification and validation.
- Continued advancing toward a planned FDA 510(k) submission for Symphony IL-6 during the first half of 2027, subject to successful validation.

Manufacturing and Commercial Readiness

- Established an alternative Symphony cartridge manufacturing site through Sanyoseiko ahead of the October 23, 2026 contractual deadline under the Company's agreement with Toray Industries.
- Advanced U.S. manufacturing capabilities through ALURIS Sciences (previously Argonaut Manufacturing), supporting cartridge production, quality activities, packaging and distribution.
- Continued developing commercial infrastructure, including a entering into a distribution agreement with Lovell Government Services to support potential access to U.S. government healthcare markets.
- Progressed an exploratory artificial intelligence initiative evaluating the potential integration of IL-6 measurements and clinical data for future sepsis risk stratification applications.

These initiatives are intended to strengthen manufacturing reliability, reduce supply chain concentration risk and support potential commercialization following regulatory authorization.

As of September 30, 2026, Bluejay had $7.38 million in cash and cash equivalents, compared with $5.16 million at December 31, 2025.

Net cash used in operating activities for the nine months ended September 30, 2026 was approximately $5.09 million. Based on current operating plans, the Company estimates that existing cash resources will support operations through the second quarter of 2027. Additional financing will be required to support its longer-term development and commercialization plans.

Outlook

Bluejay remains focused on completing SYMON-II clinical analysis, advancing analytical validation and manufacturing qualification, and preparing its planned FDA 510(k) submission during the first half of 2027.

“Our achievements in clinical development and manufacturing have positioned us to focus on the next critical phase of execution towards commercial readiness,” continued Mr. Dey. “We remain committed to disciplined capital allocation, regulatory progress and building a scalable diagnostic platform with the potential to address important unmet needs in critical care.”

Potential Importance of Rapid IL-6 Information

Sepsis is a highly heterogeneous and rapidly evolving condition. Patients presenting with severe infection may follow substantially different clinical trajectories, creating a need for timely information that can help clinicians assess patient risk.

Bluejay is developing the Symphony™ Suite as a rapid quantitative biomarker assay platform. The Company’s development strategy is intended to bring quantitative biomarker information closer to the patient and make results available rapidly enough to potentially complement clinical assessment and established measures of disease severity.

The Company is continuing its analysis of clinical samples and data as part of its SYMON-II pivotal study, including evaluation of IL-6 measurements and their relationship to 28-day mortality and other relevant clinical parameters. The baseline characteristics announced to date do not themselves establish the prognostic performance, clinical utility, sensitivity, specificity or regulatory acceptability of the Symphony™ IL-6 Test. Those conclusions will depend upon completion of the planned analyses.

The Symphony™ IL-6 Test has not been cleared or approved by the U.S. Food and Drug Administration (“FDA”) and is not currently available for commercial clinical use in the United States.

About the SYMON Clinical Study Program:

The SYMON Clinical Study Program includes SYMON-I (clinicaltrials.gov ID NCT06181604), SYMON-II (NCT06654895), and SYMON-III (NCT07425587). SYMON-I is a pilot study to determine IL-6 levels associated with various endpoints, including, but not limited to 28-day all-cause mortality and in-hospital mortality. The SYMON-II study is the pivotal study to validate the outcomes of the SYMON-I study, which the Company plans to use to support a 510(k) application to FDA. The SYMON-III study is a pilot study to determine IL-6 levels associated with patients presenting with increasing severity of infection in the emergency department and risk of developing sepsis.

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 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 the Company's Annual Report on Form 10-K for the fiscal year ended December 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, 2026, June 30, 2026 and September 30, 2026. 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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