

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): October 6, 2026



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

DELAWARE

(State or Other Jurisdiction of
Incorporation or Organization)

001-41031

(Commission File No.)

47-3552922

(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-4(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 7.01 Regulation FD Disclosure.

On October 6, 2026, Bluejay Diagnostics, Inc. issued a press release regarding baseline clinical characteristics from its SYMON-II clinical validation study.

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, nor shall it be incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, dated October 6, 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: October 6, 2026

For Immediate Release

Bluejay Diagnostics Announces SYMON-II Clinical Dataset Details Supporting Evaluation of Mortality Risk in Sepsis and Septic Shock.

SYMON-II Clinical Validation Dataset Represents a Key Milestone as Bluejay Advances the Symphony™ IL-6 Test Toward Regulatory Submission

ACTON, Mass. October 6, 2026 - Bluejay Diagnostics, Inc. (NASDAQ: BJDY) (“Bluejay” or the “Company”), a medical diagnostics company focused on improving patient outcomes through its Symphony™ near-patient diagnostic platform, today announced baseline clinical characteristics from the SYMON-II clinical validation study, highlighting a substantial and diverse population of critically ill patients and clinically meaningful mortality events for evaluating interleukin-6 (“IL-6”) as a biomarker associated with 28-day mortality risk in patients with sepsis and septic shock.

The current preliminary SYMON-II analysis includes 777 evaluable patients, consisting of 637 28-day survivors and 140 28-day non-survivors, representing an overall 28-day mortality rate of approximately 18%. The study population included patients across a broad spectrum of illness severity, ethnicity and geographical distribution with 39.5% meeting Sepsis-3 criteria for septic shock.

The clinical characteristics demonstrate substantial disease burden and severity. 84.0% of patients had bacterial infection reported, 32.4% had a positive blood culture, and infection was considered highly likely or likely in 86.5% of the study population.

Patients who did not survive through 28 days demonstrated greater baseline illness severity. Septic shock was present in 56.4% of non-survivors compared with 35.8% of survivors.

“These clinical data are important because the value of a prognostic biomarker depends upon its evaluation in a sufficiently large and clinically relevant patient population with meaningful outcomes,” said Dr. Mark Feinberg, Chief Medical Advisor of Bluejay Diagnostics. “The SYMON-II clinical validation study provides a substantial number of 28-day mortality events across patients with differing levels of sepsis severity, creating an important clinical foundation for evaluating the prognostic performance of IL-6.”

“The company’s earlier SYMON-I pilot study provided an encouraging clinical signal supporting the potential role of IL-6 in mortality risk assessment,” said Dr. Feinberg. “The SYMON-II clinical validation study gives us the opportunity to evaluate that signal in a substantially larger and clinically diverse population.”

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, including evaluation of IL-6 measurements and their relationship to 28-day mortality and other relevant clinical parameters. The baseline characteristics announced today 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™ Suite, 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™ Suite, 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 and June 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.

Investor Contact:

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