

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 13, 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 13, 2026, Bluejay Diagnostics, Inc. issued a press release regarding, among other things, the completion of certain manufacturing-related contractual obligations.

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 13, 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 13, 2026

Bluejay Achieves Toray Contractual Manufacturing Milestone, Advancing Supply-Chain Resilience and Commercialization Readiness***Company Achieves Toray Contractual Milestone with Establishment of Manufacturing Site***

ACTON, Mass. October 13, 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 that it has completed the establishment of a manufacturing site for Symphony™ cartridges, achieving a critical contractual milestone as the Company advances toward regulatory submission and potential commercialization.

The milestone was achieved ahead of the October 23, 2026 contractual deadline established under Bluejay’s amended license agreement with Toray Industries, Inc. (“Toray”). Bluejay has formally notified Toray that the Company has fulfilled its obligation to substantially complete establishment of a manufacturing site. Bluejay’s manufacturing strategy is being developed around complementary manufacturing capabilities at SanyoSeiko Co., Ltd. in Japan and ALURIS Sciences, (previously Argonaut Manufacturing Services) in the United States. SanyoSeiko serves as the manufacturing site established under Bluejay’s agreement with Toray and is an important component of the Company’s Symphony cartridge manufacturing infrastructure.

Together, these initiatives are intended to provide Bluejay with a more diversified and resilient manufacturing infrastructure, reducing reliance on a single manufacturing pathway while increasing operational flexibility as the Company prepares for potential commercialization. The Company believes that achieving this manufacturing milestone represents an important step in reducing business and commercial execution risk as Bluejay advances toward regulatory submission and potential commercialization.

“Achieving this manufacturing milestone is an important accomplishment for Bluejay and another tangible step in our progression toward regulatory and commercial readiness,” said Neil Dey, President and Chief Executive Officer of Bluejay Diagnostics. “Our manufacturing strategy is designed to extend beyond a single facility or geography. With the establishment of our manufacturing capability at SanyoSeiko and our strategic U.S. manufacturing relationship with ALURIS, we are working to build complementary manufacturing pathways that can provide greater flexibility, redundancy and supply-chain resilience.”

Bluejay continues to advance its manufacturing scale-up activities alongside its regulatory program for the Symphony™ IL-6 Test, the Company’s first product candidate.

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. The Symphony™ rapid diagnostic platform is an investigational device and is limited by United States law to investigational use.

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 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.

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