

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): December 29, 2025



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.

Item 7.01 Regulation FD Disclosure.

On December 29, 2025, Bluejay Diagnostics, Inc. issued a press release providing an update regarding the status of its commercial-scale IL-6 antibody production. 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, unless specifically identified therein as being incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release, dated December 29, 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: December 30, 2025



Bluejay Diagnostics Announces Completion of Commercial-Scale IL-6 Antibody Production

Acton, Massachusetts — December 29, 2025 — Bluejay Diagnostics, Inc. (NASDAQ: BJDY) (“Bluejay” or the “Company”) announced that it has completed commercial-scale production of both polyclonal and monoclonal antibodies targeting interleukin-6 (IL-6), a biomarker relevant to inflammatory and critical-care applications.

The Company stated that both polyclonal and monoclonal antibodies met internal performance criteria, including reactivity, for use in Symphony™ cartridge manufacturing intended for clinical and potential future commercial applications.

Bluejay has generated polyclonal antibodies using both third-party and internally developed immunogens. The Company intends to utilize antibodies produced from its proprietary immunogen for ongoing development activities in support of its intellectual-property strategy. The monoclonal antibodies produced by the Company, designated for use as detection antibodies in the IL-6 assay, have demonstrated acceptable binding, specificity, and signal performance characteristics for their intended diagnostic use, based on internal testing conducted to date.

Based on current antibody inventory, Bluejay estimates that it has sufficient material to support production of more than nine million Symphony cartridges for clinical and commercial manufacturing purposes. The Company has also established the capability to produce additional antibodies as needed.

The Company noted that Symphony™ remains under development and subject to further validation, regulatory review, and clearance, and that there can be no assurance regarding the timing or success of these activities.

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 the status of Bluejay’s commercialization of its 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.

Investor Contact:

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