

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): May 19, 2023

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 8.01 Other Events.

On May 19, 2023, Bluejay Diagnostics, Inc. (the “Company”), issued a press release to announce updates on its Symphony IL-6 Regulatory Strategy. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits**(d) Exhibits****Exhibit No. Exhibit Description**

99.1	Press release dated May 19, 2023
------	--

104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
-----	---

SIGNATURE

Pursuant to the requirements of the Securities and 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/ Kenneth Fisher
Kenneth Fisher
Chief Financial Officer

Dated: May 19, 2023



Bluejay Diagnostics Updates Symphony IL-6 Regulatory Strategy

ACTON, Mass., May 19, 2023 – Bluejay Diagnostics, Inc. (NASDAQ: BJDY) (“Bluejay” or the “Company”), a medical technology company developing rapid diagnostics on its Symphony platform to improve patient outcomes in critical care settings, today announced an updated clinical and regulatory strategy for the Symphony IL-6 biomarker test to measure acuity in sepsis patients. The Company plans to modify the clinical trials design to evaluate Symphony IL-6 as a tool to risk stratify hospitalized sepsis patients.

Bluejay is adapting its clinical trial design to obtain more patient data, which aligns the regulatory strategy with recent FDA feedback. The trial previously included only severe COVID-19 patients, which have substantively declined since the trial initiated. The Company plans to amend the study to include hospitalized sepsis patients, expanding the inclusion to facilitate a rate of enrollment necessary to maintain the previously disclosed Symphony IL-6 regulatory submission timeline of the first half of 2024. The trial modification may also support an FDA regulatory submission with an initial indication for risk stratification of hospitalized sepsis patients. Bluejay plans to submit a pre-submission application to the FDA presenting the new study design during the second quarter of 2023.

“We believe that our updated clinical strategy puts us on the most efficient pathway to obtain regulatory clearance for Symphony IL-6,” said Neil Dey, CEO of Bluejay Diagnostics. “The new indication expedites clinical enrollment by broadening patient eligibility and provides expanded utility of Symphony. We are excited to demonstrate Symphony’s value and be closer to achieving our mission of improving patient outcomes in critical care settings.”

The Company believes that Symphony IL-6 has the potential to be an influential tool for the prediction of clinical deterioration in sepsis patients. Symphony IL-6 testing, in conjunction with clinical and other diagnostic findings, may enable healthcare providers to better prioritize appropriate care for those at high risk to help prevent adverse outcomes, and potentially avoid unnecessary investigations and treatments in those at low risk.

IL-6 appears as a ‘first responder’ biomarker in the blood during early stages of inflammations and/or infection. A current unmet challenge for healthcare professionals to overcome is the amount of time it takes to identify sepsis in patients and determine disease severity. Existing technologies typically take several hours to deliver IL-6 results, which can delay critical treatment decisions that could improve patient outcomes. The significance of IL-6 testing was highlighted during the COVID-19 pandemic, where elevated IL-6 levels in critically ill patients served as a predictive prognosis biomarker for disease severity.

About the Symphony™ System:

Bluejay's Symphony System (the "Symphony System") is designed to address the need for simple, reliable, rapid, near-patient testing by providing quantitative measurements of specific biomarkers to determine the need for additional patient care and monitoring. The user-friendly Symphony System will not require any sample preparation or dedicated staff and was shown in published clinical studies to deliver results in approximately 20 minutes.

The Symphony IL-6 Test is a development stage product candidate for investigational use only. It is limited by United States law to investigational use.

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 triage and monitoring of disease progression. Bluejay's first product candidate, an IL-6 Test for sepsis triage, 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, the expected nature and timing of the Company's planned FDA submission and related plans for clinical study amendment, whether the Company's cash position will be sufficient to fund operations needed to achieve regulatory approval and initial commercialization of the Symphony IL-6 Test, and whether such regulatory approval will actually occur. 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 those discussed under item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. 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. 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.

Investor Contact:

Alexandra Schuman
LifeSci Advisors
alex@lifesciadvisors.com
t: 646-876-3647
