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): January 31, 2022

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 7.01 Regulation FD Disclosure

On January 31, 2022, Bluejay Diagnostics, Inc. (the "Company"), issued a press release to announce that it has filed a Pre-Submission package for the Symphony IL-6 Test with the U.S. Food and Drug Administration. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

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 ("Securities Act"), unless specifically identified therein as being incorporated by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Press release dated January 31, 2022
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/ Gordon Kinder
Gordon Kinder
Chief Financial Officer

Dated: January 31, 2022

IMMEDIATE RELEASE
Date: January 31, 2022

Bluejay Diagnostics, Inc. Announces its Pre-Submission Filing Package for the Symphony IL-6 Test is with the FDA

Acton, Massachusetts, January 31, 2022 – Bluejay Diagnostics, Inc. (NASDAQ: BJDX) ("Bluejay", "the Company") a late-stage, pre-revenue diagnostics company focused on developing cost-effective, rapid, near-patient products for triage and monitoring of disease progression, today announced that it has **filed a Pre-Submission package for the Symphony IL-6 Test with the U.S. Food and Drug Administration** ("FDA" or "the agency"). The purpose of this filing is to request feedback from the agency prior to submitting a medical device marketing application. The pre-submission package will allow the FDA to review and comment on the Company's plans for clinical trials and analytical testing.

Neil Dey, Bluejay's Chief Executive Officer commented "I am very pleased to announce that Bluejay successfully met its goal of filing the pre-submission package with the FDA for the Symphony IL-6 Test by the end of January, 2022. Bluejay is developing the Symphony IL-6 Test to rapidly measure IL-6 in whole blood in a near-patient setting that is intended to help healthcare professionals make better treatment decisions for patients with life threatening diseases. The pre-submission filing an important milestone for Bluejay as we will receive important feedback from the FDA for our planned marketing submission for the Symphony IL-6 Test, planned for Q3:22."

About Interleukin-6

Interleukin-6 (IL-6) is an established biomarker of immune system activation. It is elevated in infection, inflammation, and cancer. IL-6 presents as an early "first responder" and needs to be measured quickly and reliably.

About the Symphony IL-6 Test Program

Bluejay's initial testing program is proceeding as planned to support the Pre-Submission filing with the FDA, as announced today, and the overall product development program. This testing program includes multiple studies, all intended to demonstrate the performance and safety of the IL-6 test. This clinical program will continue in anticipation of the company's planned marketing application.

About the Symphony^{TM} System:

Bluejay's Symphony System (the Symphony System) is intended to address the need for simple, reliable, rapid near-patient testing. The Symphony System is designed to provide quantitative measurements of specific biomarkers to determine the need for additional patient care and monitoring, when used in combination with other test and laboratory measurements. The system does not require any sample prep and was shown in published clinical studies to deliver results in about 24 minutes.

This user-friendly system is expected to fit into ICU/near-patient settings without the need for dedicated staff to run a test. The system has been designed to measure test analytes using whole blood. Samples are collected and loaded into proprietary, test-specific cartridges.

The Symphony System is based on a well-accepted test method (ELISA, Enzyme-Linked Immunosorbent Assay) using advances in nanotechnology and new approaches to microfluidics. Bluejay has an exclusive license to the Symphony System from Toray Industries (Toray), a multinational company with more than 96 years of manufacturing experience, located in Japan. The product is manufactured by Toray and Sanyoseiko. Sanyoseiko is an FDA-registered manufacturer with more than 50 years of global experience in medical devices manufacturing, located in Japan.

The Symphony IL-6 Test ("Symphony IL-6 Test") is currently Bluejay's lead product candidate. The Company completed a Pre-submission filing for the Symphony IL-6 Test on January 31, 2022.

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 late-stage, pre-revenue diagnostics company focused on improving patient outcomes through the Symphony System, a more cost-effective, rapid, near-patient product candidate for triage and monitoring of disease progression in hospital and long-term acute care (LTAC) settings. Bluejay's first product candidate, an IL-6 test for sepsis triage, is designed to provide accurate, reliable results in approximately 24 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. These statements include, but are not limited to, statements relating to the expected timeline for the Pre-Submission application with the FDA, planned clinical studies and the planned 510(k) marketing application submission. Forward-looking statements are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "suggest", "will," and variations of such words or similar expressions or their negatives (as well as other words and expressions referencing future events, conditions, or circumstances). 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 in the Company's filings with the Securities and Exchange Commission, including as set forth in the "Risk Factors" section of the Company's final prospectus, which was filed with the Securities and Exchange Commission on November 11, 2021, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. You should not place undue reliance on these statements, as they are subject to risks and uncertainties, and actual results and performance in future periods 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 changes in the Company's expectations of results or any change in events.

Investor Contact:

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