

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): March 10, 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-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 2.02 Results of Operations and Financial Condition.

On March 10, 2022, Bluejay Diagnostics, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2021 and a corporate update. 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 March 10, 2022
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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

**IMMEDIATE RELEASE****Bluejay Diagnostics, Inc. Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update**

Testing program underway for lead product candidate, the Symphony IL-6 Test, in support of an FDA Marketing Application, planned for Q3 2022

2021 ended with approximately \$19 million in cash expected to fund operations beyond the date of our anticipated regulatory approval and initial commercialization of the IL-6 Test

Acton, Massachusetts, March 10, 2021 – Bluejay Diagnostics, Inc. (NASDAQ: BJDY) (“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 financial results for the fourth quarter and full year ended December 31, 2021 and provided a corporate update, including on the Company’s first product candidate, the IL-6 Test.

“Bluejay had a very productive 2021. We substantially advanced our lead product candidate, the Symphony IL-6 Test, into several clinical studies at highly respected study sites, completed an upsized IPO, and started to build out our team and the systems to support the company as we prepare for commercial launch in the U.S.,” said Neil Dey, Bluejay’s Chief Executive Officer.

“Bluejay’s Symphony platform was designed to provide rapid test results, using whole blood samples, in near-patient settings to aid in the care of patients with life-threatening diseases. Looking ahead in 2022, we plan to complete the clinical and analytical studies to support the company’s planned marketing application with the FDA and to continue our preparations for commercial launch of the Symphony IL-6 Test in the U.S.,” continued Neil.

Corporate Update:

- **Overview of the IL-6 test for sepsis triage.** Bluejay’s IL-6 Test was designed to measure IL-6 levels in whole blood samples in near-patient settings. 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.
 - **Clinical testing program underway.** Bluejay is conducting a comprehensive clinical testing program for its IL-6 Test product candidate. The program is expected to be complete in Q3:22. Results will form the basis of the Company’s planned marketing submission. The Company plans to incorporate any necessary feedback from the FDA, which may be received as part of the pre-submission process, to modify these studies and construct a potential FDA marketing authorization process.
 - **FDA Pre-Marketing Application planned for Q3:22.** Bluejay plans to complete and file its marketing submission for the Symphony IL-6 Test in Q3:22. While the specific type of submission has yet to be determined, it could be a 510(K) notice or *de novo* request, or an alternative path, such as an Emergency Use Authorization (EUA).
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Recent Corporate Highlights:

- **FDA Pre-submission Filing.** In January 2022, we presented a pre-submission briefing package to the FDA for the Symphony IL-6 Test.
- **Completed 90 Subjects in Multicenter Clinical Study for Symphony IL-6 Test.** In January 2022, we announced enrollment of 90 subjects at two study sites in Dallas, Texas.
- **Appointed Mark Feinberg M.D. as Chief Medical Advisor.** In January 2022, we announced the appointment of Mark Feinberg, a respected physician-scientist from the Brigham and Women's Hospital and Harvard Medical School, in Boston, as Chief Medical Advisor. Dr. Feinberg has been involved with several clinical trials and has served as an advisor to a number of global pharmaceutical companies.
- **Appointment of Gary Gemignani to the Board of Directors.** In November, Gary Gemignani joined Bluejay's Board of Directors. Mr. Gemignani brings extensive experience in life sciences, public companies, accounting and finance, based on a career of senior executive and leadership roles at Acacia Pharma Group plc, Synergy Pharmaceuticals Inc., Biondi Inc., Prudential Financial, Gentium, Novartis, Wyeth and Arthur Andersen & Co.
- **Completed an Upsized IPO with Gross Proceeds of \$21.6 million.** On November 10, 2021, Bluejay announced the pricing of an upsized \$21.6 million underwritten Initial Public Offering of 2,160,000 units, at a combined price per unit of \$10.00.

Financial Results for the Three Months Ended December 31, 2021 and Full Year 2021

Cash and cash equivalents. Cash and cash equivalents on December 31, 2021 were \$19,047,778 as compared to \$912,361 on December 31, 2020. The company expects its existing cash and cash equivalents to be sufficient to fund operations beyond the date of our anticipated regulatory approval and initial commercialization of the IL-6 Test.

Research and development expense. Research and development expenses for the three months ended December 31, 2021 were \$455,253 as compared to \$419,061 for the comparable period in 2020. Research and development expenses for 2021 were \$1,147,955 compared to \$527,253 for 2020.

The increase relates to initiation of testing and manufacturing of the Symphony IL-6 Test.

General and administrative expense. General and administrative expenses for the three months ended December 31, 2021 were \$817,688 as compared to \$143,270 for the comparable period in 2020. General and administrative expenses for 2021 were \$1,792,482 compared to \$596,116 for 2020.

The increase is attributable to the transition from a private to a public company, including the accounting, legal and audit related expenses. Compensation and benefit costs also increased as a result of increased headcount.

Marketing and business development expense. Marketing and business development expenses for the three months ended December 31, 2021 were \$99,961 as compared to \$19,448 for the comparable period in 2020. Marketing and business development expenses for 2021 were \$289,726 compared to \$73,022 for 2020.

The increase is attributable to increased employee/consultant headcount to facilitate commercialization of the Symphony IL-6 Test.

Net loss/Net loss per share. The Net loss and Net loss per share for the three months ended December 31, 2021 was \$1,460,493 and \$0.09 compared to \$544,025 and \$0.17 for the comparable period in 2020. The Net loss and Net loss per share for 2021 was \$3,488.298 and \$0.41 compared to \$1,158.285 and \$0.37 for 2020.

Full financial tables are included below. For further details on Bluejay's financials, refer to its Form 10K, filed March 10, 2022 with the S.E.C.

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 process with the FDA, with the Company's initial pre-submission submitted in January 2022, and the overall product development program. This testing program includes multiple studies, all intended to establish the performance and safety of the IL-6 Test. This clinical program is continuing in anticipation of the company's planned marketing application.

About the SymphonyTM System:

Bluejay's Symphony System (the Symphony System) is designed 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 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 planned clinical studies and the planned 510(k) marketing application submission and expectation that the Company's existing cash, cash equivalents and marketable securities will be sufficient to fund operations beyond the date of our anticipated regulatory approval and initial commercialization of the IL-6 Test. 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 under item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC"), 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:

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Bluejay Diagnostics, Inc.
Condensed Consolidated Balance Sheets

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,047,778	\$ 912,361
Inventory	-	84,762
Prepaid expenses and other current assets	1,612,708	61,071
Total current assets	20,660,486	1,058,194
Property and equipment, net	337,366	459,138
Other non-current assets	21,019	-
Total assets	\$ 21,018,871	\$ 1,517,332
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 295,778	\$ 374,928
Due to related party	2,000	125,102
Accrued expenses and other current liabilities	339,384	133,820
Notes payable, net	-	1,041,186
Note payable, Paycheck Protection Program	-	14,725
Derivative warrant liability	-	155,629
Total liabilities	637,162	1,845,390
Commitments and Contingencies		
Series A redeemable, convertible preferred stock, \$0.0001 par value; 10,600 shares authorized; 0 and 10,600 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	1,077,303
Series B redeemable, convertible preferred stock, \$0.0001 par value; 5,918 shares authorized; 0 and 5,187 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	1,800,347
Series C redeemable, convertible preferred stock, \$0.0001 par value; 636 shares authorized; 0 and 636 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	1,000,465
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 20,112,244 and 3,147,200 shares issued and outstanding at December 31, 2021 and 2020, respectively	2,011	315
Additional paid-in capital	28,074,484	-
Accumulated deficit	(7,694,786)	(4,206,488)
Total stockholders' equity (deficit)	20,381,709	(4,206,173)
Total liabilities, redeemable, convertible preferred stocks and stockholders' equity (deficit)	\$ 21,018,871	\$ 1,517,332



Bluejay Diagnostics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss

	For the Years Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 1,147,955	\$ 527,253
General and administrative	1,792,482	596,116
Marketing and business development	289,726	73,022
Total operating expenses	<u>3,230,163</u>	<u>1,196,391</u>
Operating loss	<u>(3,230,163)</u>	<u>(1,196,391)</u>
Other income (expense):		
Gain on forgiveness of note payable, Paycheck Protection Program	5,000	102,000
Derivative warrant liability gain (loss)	9,676	(42,434)
Interest expense, net of amortization of premium	(367,459)	(26,997)
State grant income	75,000	-
Other income	19,648	5,537
Total other income (expense), net	<u>(258,135)</u>	<u>38,106</u>
Net loss	<u>\$ (3,488,298)</u>	<u>\$ (1,158,285)</u>
Net loss per share - Basic and diluted	\$ (0.41)	\$ (0.37)
Weighted average common shares outstanding:		
Basic and diluted	8,522,422	3,147,200