

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): November 8, 2022

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 2.02 Results of Operations and Financial Condition.

On November 8, 2022, Bluejay Diagnostics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2022 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 November 8, 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/ Kenneth Fisher

Kenneth Fisher
Chief Financial Officer

Dated: November 8, 2022



Bluejay Diagnostics, Inc. Reports Third Quarter 2022 Financial Results

Acton, Massachusetts, October 25, 2022 – Bluejay Diagnostics, Inc. (NASDAQ: BJDY) (“Bluejay” or the “Company”), a clinical-stage medical diagnostics company developing rapid, near-patient tests using whole blood on its Symphony platform to improve patient outcomes in critical care settings, today reported its financial results for the quarter and nine months ended September 30, 2022.

“The last quarter focused on increasing awareness of Bluejay’s Symphony IL-6 test by directly engaging the medical community to build a network of champions that will direct product development and drive initial commercialization,” said Neil Dey, CEO. “In August, Bluejay held a KOL event with clinicians in emergency and critical care who shared their perspectives on Symphony’s potential to guide patient care and acute intervention through monitoring of quantitative IL-6 measurements on a simple, reliable, efficient platform.”

“During July, the Company published positive clinical results for its Symphony IL-6 test presented at AACC, which demonstrated 98% NPV to identify COVID-19 patients at risk for severe illness,” continued Dey. “We are also currently expanding our clinical program, adding additional test sites in support of the Company’s planned De Novo marketing application with the FDA for our Symphony IL-6 test, with an anticipated submission during the first half of 2023.”

Financial Results for the Three and Nine Months Ended September 30, 2022

Cash and cash equivalents. Cash and cash equivalents on September 30, 2022 were \$13.3 million, as compared to \$19.0 million on December 31, 2021. The Company has maintained a slow cash burn during its FDA submission process and currently expects that its cash position will be sufficient to fund operations for the next 12 months.

Revenue and Gross Profit. Revenue and gross profit increased approximately \$250,000 and \$49,000 respectively, for the nine month periods ended September 30, 2022, as compared to the same period in 2021. We recognized a small, non-recurring sale to a foreign development partner in the second quarter of 2022, which it does not consider an entry to the market or indicative of expected margins. As expected, there were no sales in the third quarter.

Research and Development. Research and development expenses for the three and nine months ended September 30, 2022 were \$1.4 million and \$2.8 million, respectively, as compared to \$443,000 and \$693,000, respectively, for the comparable periods in 2021. The increase in research and development expenses was due to the expansion of our clinical program and supporting scale-up manufacturing of the Symphony technology platform and IL-6 test.

General and Administrative. General and administrative expenses for the three and nine months ended September 2022 were \$1.3 million and \$3.8 million, respectively, as compared to \$445,000 and \$975,000, respectively, for the comparable periods in 2021. The increase in general and administrative expenses reflects our investment in scalable infrastructure, as well as expenses to support public company operations due to the completion of our initial public offering in November 2021.

Sales and Marketing. Sales and marketing expenses for the three and nine months ended September 30, 2022 were \$146,000 and \$281,000, respectively, as compared to \$70,000 and \$190,000, respectively, for the comparable periods in 2021. While these expenses have been limited to date, we expect to increase these efforts when appropriate to support its commercial growth.

Net loss/Net loss per share. The net loss for the three and nine months ended September 30, 2022 was \$3.0 million and \$6.9 million, or \$0.15 and \$0.34 per share, respectively, compared to \$1.2 million and \$2.0 million, or \$0.11 and \$0.32 per share, respectively, for the comparable periods in 2021.

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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 does not require any sample preparation or dedicated staff and has been 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 ability of the Company to submit a marketing application with the FDA in the fourth quarter of 2022, whether the Company's cash position will be sufficient to fund operations beyond the date of its anticipated regulatory approval and initial commercialization of the Symphony IL-6 Test, and whether such anticipated 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 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.

Bluejay Diagnostics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 13,289,365	\$ 19,047,778
Prepaid expenses and other current assets	646,894	1,612,708
Total current assets	<u>13,936,259</u>	<u>20,660,486</u>
Property and equipment, net	1,238,352	337,366
Operating lease right-of-use assets	497,618	-
Other non-current assets	33,479	21,019
Total assets	<u>\$ 15,705,708</u>	<u>\$ 21,018,871</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 443,035	\$ 295,778
Accrued expenses	1,079,665	341,384
Total current liabilities	<u>1,522,700</u>	<u>637,162</u>
Non-current liabilities:		
Operating lease liability, non-current	356,523	-
Other non-current liabilities	15,420	-
Total liabilities	<u>371,943</u>	<u>637,162</u>
Commitments and Contingencies (See Note 9)		
Stockholders' equity		
Common stock, \$0.0001 par value; 30,000,000 shares authorized; 20,152,344 and 20,112,244 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	2,015	2,011
Additional paid-in capital	28,419,898	28,074,484
Accumulated deficit	(14,610,848)	(7,694,786)
Total stockholders' equity	<u>13,811,065</u>	<u>20,381,709</u>
Total liabilities, redeemable and stockholders' equity	<u>\$ 15,705,708</u>	<u>\$ 21,018,871</u>

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-3.15 stock dividend effective June 7, 2021.

Bluejay Diagnostics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Revenue	\$ -	\$ -	\$ 249,040	\$ -
Cost of sales	-	-	200,129	-
Gross profit	-	-	48,911	-
Operating expenses:				
Research and development	1,379,665	442,527	2,830,705	692,702
General and administrative	1,284,411	445,050	3,801,226	974,791
Sales and marketing	146,102	70,411	281,144	189,765
Total operating expenses	<u>2,810,178</u>	<u>957,988</u>	<u>6,913,075</u>	<u>1,857,258</u>
Operating loss	<u>(2,810,178)</u>	<u>(957,988)</u>	<u>(6,864,164)</u>	<u>(1,857,258)</u>
Other income (expenses):				
Interest income (expense), net of amortization of premium	-	(237,429)	-	(269,545)
Grant income	-	-	-	75,000
Impairment of property and equipment	(210,117)	-	(210,117)	-
Other income, net	60,406	2,036	163,587	24,001
Total other expenses, net	<u>(149,711)</u>	<u>(235,393)</u>	<u>(46,530)</u>	<u>(170,544)</u>
Net loss	<u>\$ (2,959,889)</u>	<u>\$ (1,193,381)</u>	<u>\$ (6,910,694)</u>	<u>\$ (2,027,802)</u>
Net loss per share - Basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.11)</u>	<u>\$ (0.34)</u>	<u>\$ (0.32)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>20,152,344</u>	<u>10,491,978</u>	<u>20,148,908</u>	<u>6,321,493</u>

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-3.15 stock dividend effective June 7, 2021.