

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): July 26, 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 July 26, 2022, Bluejay Diagnostics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 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 July 26, 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: July 26, 2022

**IMMEDIATE RELEASE****Bluejay Diagnostics, Inc. Reports Second Quarter 2022 Financial Results**

Acton, Massachusetts, July 26, 2022 – Bluejay Diagnostics, Inc. (NASDAQ: BJDY) (“Bluejay” or the “Company”), a medical diagnostics company focused on developing cost-effective, rapid, near-patient tests for triage and monitoring of disease progression, today announced financial results for the quarter and six months ended June 30, 2022.

Neil Dey, Chief Executive Officer, said, “This quarter was very exciting for Bluejay, announcing our plan to pursue a *de Novo* regulatory pathway and completion of our initial clinical studies for the Symphony IL-6 Test. In addition, we reported that results of our clinical studies will be published at the 2022 AACC Annual Scientific Meeting being held July 26th to 28th in Chicago.”

Mr. Dey concluded, “Achievement of these milestones highlights Bluejay’s progression towards our goal of bringing to the market rapid, near-patient tests, using whole blood samples, to aid in the care of patients with life-threatening diseases. We have continued to invest in our manufacturing infrastructure as we prepare our FDA marketing application for submission, expected in the fourth quarter of 2022.”

Financial Results for the Three Months Ended June 30, 2022

Cash and cash equivalents. Cash and cash equivalents on June 30, 2022 were \$15.3 million, as compared to \$19.0 million on December 31, 2021. The Company expects that its cash position will be sufficient to fund operations beyond the date of our anticipated regulatory approval and initial commercialization of the Symphony IL-6 Test.

Revenue/Gross Profit. Bluejay recognized a small sale to a foreign development partner, which we do not consider an entry to the market or indicative of expected margins.

Research and development expense. Research and development expenses for the three and six months ended June 30, 2022 were \$756,000 and \$1.5 million, respectively, as compared to \$226,000 and \$250,000, respectively, for the comparable periods in 2021. The increase in research and development expenses is due to the advancement of our clinical studies and to support scale-up manufacturing of the Symphony IL-6 Test.

General and administrative expense. General and administrative expenses for the three and six months ended June 30, 2022 were \$1.2 million and \$2.5 million, respectively, as compared to \$390,000 and \$530,000, respectively, for the comparable periods in 2021. The increase in general and administrative expenses reflects the Company’s 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 expense. Sales and marketing expenses for the three and six months ended June 30, 2022 were \$81,000 and \$135,000, respectively, as compared to \$50,000 and \$119,000, 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 our commercial growth.

Net loss/Net loss per share. The net loss for the three and six months ended June 30, 2022 was \$1.9 million and \$4.0 million, or \$0.10 and \$0.20 per share, respectively, compared to \$640,000 and \$834,000, or \$0.15 and \$0.20 per share, respectively, for the comparable periods in 2021.

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:

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.

Investor Contact:

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

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,341,862	\$ 19,047,778
Inventories	671,250	-
Prepaid expenses and other current assets	1,037,145	1,612,708
Total current assets	<u>17,050,257</u>	<u>20,660,486</u>
Property and equipment, net	409,070	337,366
Operating lease right-of-use assets	573,040	-
Other non-current assets	35,075	21,019
Total assets	<u>\$ 18,067,442</u>	<u>\$ 21,018,871</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 196,108	\$ 295,778
Accrued expenses	783,482	341,384
Total current liabilities	<u>979,590</u>	<u>637,162</u>
Non-current liabilities:		
Operating lease liability, non-current	430,116	-
Total liabilities	<u>1,409,706</u>	<u>637,162</u>
Commitments and Contingencies		
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 June 30, 2022 and December 31, 2021, respectively	2,015	2,011
Additional paid-in capital	28,306,680	28,074,484
Accumulated deficit	(11,650,959)	(7,694,786)
Total stockholders' equity	<u>16,657,736</u>	<u>20,381,709</u>
Total liabilities and stockholders' equity	<u>\$ 18,067,442</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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	\$ 249,040	\$ -	\$ 249,040	\$ -
Cost of sales	200,129	-	200,129	-
Gross profit	48,911	-	48,911	-
Operating expenses:				
Research and development	756,283	225,992	1,451,040	250,175
General and administrative	1,196,996	389,830	2,516,815	529,741
Sales and marketing	81,357	50,250	135,042	119,354
Total operating expenses	2,034,636	666,072	4,102,897	899,270
Operating loss	(1,985,725)	(666,072)	(4,053,986)	(899,270)
Other income:				
Interest expense, net	-	(59,167)	-	(32,116)
Grant income	-	75,000	-	75,000
Other income, net	48,323	10,006	103,181	21,965
Total other income, net	48,323	25,839	103,181	64,849
Net loss	\$ (1,937,402)	\$ (640,233)	\$ (3,950,805)	\$ (834,421)
Net loss per share - Basic and diluted	\$ (0.10)	\$ (0.15)	\$ (0.20)	\$ (0.20)
Weighted average common shares outstanding:				
Basic and diluted	20,151,969	4,201,688	20,151,969	4,201,688

See notes to unaudited condensed consolidated financial statements.

Reflects a 1-for-3.15 stock dividend effective June 7, 2021.