

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): August 16, 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 2.02 Results of Operations and Financial Condition.

On August 16, 2023, Bluejay Diagnostics, Inc. (the “Company”) issued a press release announcing its financial results for the six months ended June 30, 2023 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.	Description
99.1	Press release dated August 16, 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: August 16, 2023



Bluejay Diagnostics Announces Clinical Update and Reports Second Quarter 2023 Financial Results

ACTON, Mass., August 16, 2023 – Bluejay Diagnostics, Inc. (NASDAQ: BJDJ) (“Bluejay” or the “Company”), a medical technology company developing rapid diagnostics on its Symphony platform to improve patient outcomes in critical care settings, announced financial results for the six months ended June 30, 2023.

“We continued to limit our cash burn during the quarter while executing our clinical strategy for the Symphony IL-6 test and are confident that our planned clinical and analytical studies may support a 510(k) FDA regulatory submission with an initial indication for risk stratification of hospitalized sepsis patients,” said Neil Dey, CEO of Bluejay Diagnostics. “We are excited to now have a clear pathway to obtain regulatory clearance of our Symphony IL-6 test, which will serve to demonstrate the vast capabilities of our rapid, near-patient Symphony technology platform.”

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 Company submitted a pre-submission application to the FDA presenting the new study design in May 2023 and participated in a pre-submission meeting on August 11, 2023. At the meeting, the FDA provided feedback on the new study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Based on this feedback, the Company intends to proceed as planned while taking into account the FDA’s feedback. The Company has targeted large, well-known medical and academic institutions for its study, which the Company believes will help support initial commercialization and market penetration. The Company believes that it will maintain the previously disclosed Symphony IL-6 regulatory submission timeline of the first half of 2024.

Financial Results for the Six Months Ended June 30, 2023:

Cash and cash equivalents. Cash and cash equivalents on June 30, 2023 were \$5.1 million, as compared to \$10.1 million on December 31, 2022. The Company closely monitors the management of its liquidity and expects to raise additional capital in the near-term to fund its planned operations.

Research and development expense. Research and development expenses for the six months ended June 30, 2023 were \$3.0 million, as compared \$1.5 million, for the same period in 2022. The increase in research and development expenses was primarily due to an increase in personnel costs and product development expenses. We expect future research and development expenses to be focused on our clinical trial program and any necessary manufacturing improvements.

General and administrative expense. General and administrative expenses for the six months ended June 30, 2023 were \$2.3 million, as compared to \$2.5 million for the comparable period in 2022. The minor decrease in general and administrative expenses is due to continued efforts to preserve capital by limiting our investment in infrastructure commensurate with our commercialization timeline.

Sales and marketing expense. Sales and marketing expenses for the six months ended June 30, 2023 were \$302,000, as compared to \$135,000 for the comparable period in 2022. The increase in sales and marketing expenses was primarily due to increased personnel costs.

Net loss/Net loss per share. The net loss for the six months ended June 30, 2023 was \$5.4 million, or \$5.24 per share, compared to \$4.0 million, or \$2.00 per share for the comparable period in 2022.

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 expansion, 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.

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

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,100,407	\$ 10,114,990
Prepaid expenses and other current assets	1,481,512	1,673,480
Total current assets	<u>6,581,919</u>	<u>11,788,470</u>
Property and equipment, net	1,464,125	1,232,070
Operating lease right-of-use assets	400,609	465,514
Other non-current assets	31,675	35,211
Total assets	<u>\$ 8,478,328</u>	<u>\$ 13,521,265</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 271,488	\$ 635,818
Operating lease liability, current	168,713	168,706
Accrued expenses and other current liabilities	1,392,378	835,730
Total current liabilities	<u>1,832,579</u>	<u>1,640,254</u>
Operating lease liability, non-current	255,306	323,915
Other non-current liabilities	14,104	15,823
Total liabilities	<u>2,101,989</u>	<u>1,979,992</u>
Commitments and Contingencies (See Note 13)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 7,500,000 shares authorized; 1,023,345 and 1,010,764 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	102	101
Additional paid-in capital	28,726,487	28,538,274
Accumulated deficit	(22,350,250)	(16,997,102)
Total stockholders' equity	<u>6,376,339</u>	<u>11,541,273</u>
Total liabilities and stockholders' equity	<u>\$ 8,478,328</u>	<u>\$ 13,521,265</u>

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-20 reverse stock split effective July 24, 2023.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Revenue	\$ -	\$ 249,040	\$ -	\$ 249,040
Cost of sales	-	200,129	-	200,129
Gross profit	-	48,911	-	48,911
Operating expenses:				
Research and development	1,676,256	756,283	3,030,805	1,451,040
General and administrative	1,073,103	1,196,996	2,250,080	2,516,815
Sales and marketing	154,329	81,357	302,375	135,042
Total operating expenses	<u>2,903,688</u>	<u>2,034,636</u>	<u>5,583,260</u>	<u>4,102,897</u>
Operating loss	<u>(2,903,688)</u>	<u>(1,985,725)</u>	<u>(5,583,260)</u>	<u>(4,053,986)</u>
Other income:				
Other income, net	90,383	48,323	230,112	103,181
Total other income, net	<u>90,383</u>	<u>48,323</u>	<u>230,112</u>	<u>103,181</u>
Net loss	<u>\$ (2,813,305)</u>	<u>\$ (1,937,402)</u>	<u>\$ (5,353,148)</u>	<u>\$ (3,950,805)</u>
Net loss per share - Basic and diluted	<u>\$ (2.75)</u>	<u>\$ (2.00)</u>	<u>\$ (5.24)</u>	<u>\$ (2.00)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>1,023,052</u>	<u>1,007,115</u>	<u>1,020,865</u>	<u>1,007,115</u>

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-20 reverse stock split effective July 24, 2023.