

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 9, 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)).

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

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.

Item 2.02 Results of Operations and Financial Condition.

On November 9, 2023, Bluejay Diagnostics, Inc. (the “Company”) issued a press release announcing its financial results for the three and nine months ended September 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 November 9, 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/ Neil Dey
Neil Dey
Chief Executive Officer

Dated: November 9, 2023



Bluejay Diagnostics, Inc. Reports Third Quarter 2023 Financial Results

Acton, Massachusetts, November 9, 2023 – 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, 2023.

“Based on FDA’s feedback from the August 11, 2023, meeting, the Company focused on implementing the modified clinical strategy that puts us on the most efficient pathway and believes that it would submit for regulatory approval for Symphony IL-6 during the first half of 2024 as planned. Furthermore, we have re-negotiated our licensing agreement with Toray Industries, Inc. to include a reduced royalty payment from 15% to 7.5% of net sales of certain cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. The new license agreement contemplates that applicable royalty payment obligations from the Company to Toray for other products will be determined separately by the parties in the future. Overall, the re-negotiated licensing agreement provides Bluejay with more freedom to operate, and better secures long-term licensing of Toray’s patents and know-how around the Symphony technology. In addition, we have re-negotiated our supply agreement with Toray Industries, Inc. to ensure critical Symphony Cartridge component supply that will sustain us through clinical studies,” said Neil Dey, CEO of Bluejay Diagnostics.

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 to help improve outcomes for those at high risk, and potentially avoid unnecessary investigations and treatments in those at low risk. IL-6 appears as a ‘first responder’ inflammatory biomarker in blood during inflammation, which is common in diseases and infections. A current unmet challenge for healthcare professionals is the amount of time it takes to identify sepsis in patients and to 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.

“We 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. In order for us to realize this, we have continued to limit our cash burn while executing our clinical and regulatory strategy for the Symphony IL-6 test,” said Neil Dey, CEO of Bluejay Diagnostics.

Financial Results for the Three Months Ended September 30, 2023

Cash and cash equivalents. Cash and cash equivalents on September 30, 2023 were \$5.08 million, as compared to \$10.1 million on December 31, 2022. The Company has maintained a slow cash burn during its FDA submission process. The Company estimates cash resources will be sufficient to fund its operations into the first quarter of 2024. The Company will need additional capital to fund its planned operations for the next 12 months. The Company expects that it will seek to raise such additional capital through public or private equity offerings, grant financing and support from governmental agencies, convertible debt, collaborations, strategic alliances and distribution arrangements.

Research and development expense. Research and development expenses for the three and nine months ended September 30, 2023 were \$1.39 million and \$4.42 million, respectively, as compared to \$1.37 million and \$2.83 million, respectively, for the comparable periods in 2022. The increase in research and development expenses is due to the expansion of our clinical program and to support scale-up manufacturing of the Symphony technology platform and IL-6 Test.

General and administrative expense. General and administrative expenses for the three and nine months ended September 2023 were \$0.96 million and \$3.21 million, respectively, as compared to \$1.28 million and \$3.8 million, respectively, for the comparable periods in 2022. The decrease in general and administrative expenses reflects the Company’s focus on clinical program and manufacturing scale-up.

Sales and marketing expense. Sales and marketing expenses for the three and nine months ended September 30, 2023 were \$(19,619) and \$282,756, respectively, as compared to \$146,102 and \$281,144, respectively, for the comparable periods in 2022. 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 nine months ended September 30, 2023 was \$2.29 million and \$7.65 million, or \$2.08 and \$7.30 per share, respectively, compared to \$2.9 million and \$6.9 million, or \$2.94 and \$6.86 per share, respectively, for the comparable periods 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 ability of the Company to submit a marketing application with the FDA in the first-half of 2024 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>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,076,937	\$ 10,114,990
Prepaid expenses and other current assets	1,450,805	1,673,480
Total current assets	6,527,742	11,788,470
Property and equipment, net	1,321,711	1,232,070
Operating lease right-of-use assets	367,248	465,514
Other non-current assets	29,907	35,211
Total assets	\$ 8,246,608	\$ 13,521,265
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 755,949	\$ 635,818
Operating lease liability, current	168,716	168,706
Accrued expenses and other current liabilities	1,875,475	835,730
Total current liabilities	2,800,140	1,640,254
Operating lease liability, non-current	220,093	323,915
Other non-current liabilities	13,220	15,823
Total liabilities	3,033,453	1,979,992
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 7,500,000 shares authorized; 1,239,140 and 1,010,560 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	124	101
Additional paid-in capital	29,861,279	28,538,274
Accumulated deficit	(24,648,248)	(16,997,102)
Total stockholders' equity	5,213,155	11,541,273
Total liabilities and stockholders' equity	\$ 8,246,608	\$ 13,521,265

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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenue	\$ -	\$ -	\$ -	\$ 249,040
Cost of sales	-	-	-	200,129
Gross profit	-	-	-	48,911
Operating expenses:				
Research and development	1,397,318	1,379,665	4,428,123	2,830,705
General and administrative	963,534	1,284,411	3,213,614	3,801,226
Sales and marketing	(19,619)	146,102	282,756	281,144
Total operating expenses	<u>2,341,233</u>	<u>2,810,178</u>	<u>7,924,493</u>	<u>6,913,075</u>
Operating loss	<u>(2,341,233)</u>	<u>(2,810,178)</u>	<u>(7,924,493)</u>	<u>(6,864,164)</u>
Other income (expense):				
Impairment of property and equipment	-	(210,117)	-	(210,117)
Other income, net	43,235	60,406	273,347	163,587
Total other income (expense), net	<u>43,235</u>	<u>(149,711)</u>	<u>273,347</u>	<u>(46,530)</u>
Net loss	<u>\$ (2,297,998)</u>	<u>\$ (2,959,889)</u>	<u>\$ (7,651,146)</u>	<u>\$ (6,910,694)</u>
Net loss per share - Basic and diluted	<u>\$ (2.08)</u>	<u>\$ (2.94)</u>	<u>\$ (7.30)</u>	<u>\$ (6.86)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>1,102,966</u>	<u>1,007,617</u>	<u>1,048,430</u>	<u>1,007,445</u>

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