

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 20, 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:

<b>Title of each class</b>	<b>Trading Symbol (s)</b>	<b>Name of each exchange on which registered</b>
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 20, 2023, Bluejay Diagnostics, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 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**

<b>Exhibit No.</b>	<b>Exhibit Description</b>
99.1	<a href="#">Press release dated March 20, 2023</a>
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: March 20, 2023



## Bluejay Diagnostics Reports 2022 Financial Results

ACTON, Mass., March 20, 2023 – Bluejay Diagnostics, Inc. (NASDAQ: BJDY) (“Bluejay” or the “Company”), a medical diagnostics company developing rapid tests using whole blood on its Symphony platform to improve patient outcomes in critical care settings, today reported its financial results for the year ended December 31, 2022.

“Significant developmental strides were made during 2022, with our IL-6 clinical study data affirming the potential of Bluejay’s Symphony System to be a rapid and precise testing platform for near-patient management in critical care settings,” said Neil Dey, CEO of Bluejay Diagnostics. “Recent positive feedback from the FDA indicated an expansion of our clinical study would be necessary to support our planned *de novo* submission, extending our anticipated submission timeline to the first half of 2024. While the impact of this delay will require additional funding to reach commercialization, it also presents opportunities to expand awareness of the utility of our Symphony IL-6 test beyond COVID-19. Additionally, this new timeline facilitates our ability to cultivate strategic relationships and commercial partnerships to enhance the impact of our market entry.”

### 2022 Corporate Highlights:

- FDA Pre-submission feedback accepted a *de novo* regulatory pathway for our Symphony IL-6 Test
- Completed initial multi-center clinical study, with results published at the 2022 annual meeting of the American Association for Clinical Chemistry (AACC)
- Initiated expanded clinical program to support *de novo* FDA Marketing Application
- Hosted KOL Event highlighting the clinical utilities of the Symphony IL-6 Test

### Financial Results for the Year Ended December 31, 2022:

**Cash and cash equivalents.** Cash and cash equivalents on December 31, 2022 were \$10.1 million, as compared to \$19.0 million on December 31, 2021. The Company has limited its cash burn during the FDA submission process to maximize its runway and intends to continue to closely monitor the management of its liquidity.

**Revenue/Gross Profit.** The Company 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 remainder of 2022.

**Research and development expense.** Research and development expenses increased approximately \$3.0 million, or 262%, for the year ended December 31, 2022, as compared to 2021. This was due primarily to an increase in personnel; costs incurred for clinical trials necessary to support the Company’s planned *de novo* FDA submission; and product design, testing, and manufacturing scale-up related to its Symphony device and cartridges.

---

**General and administrative expense.** General and administrative expenses increased approximately \$3.0 million, or 166%, for the year ended December 31, 2022, as compared to 2021. The increase was primarily attributable to administrative costs necessary to operate as a public company, totaling approximately \$1.6 million. In addition, employee compensation and benefits increased by \$1.3 million due to an increase in personnel.

**Marketing and business development expense.** Marketing and business development expenses increased approximately \$162,000, or 56%, for year ended December 31, 2022, as compared to 2021. The increase was primarily attributable to personnel costs and the attendance of various industry conferences in 2022, introducing the Symphony platform to the market.

**Net loss/Net loss per share.** The net loss for the year ended December 31, 2022 was \$9.3 million, or \$0.46 per share, compared to \$3.5 million, or \$0.41 per share, for 2021.

***About the De Novo Classification:***

If it is determined that there is not a legally marketed class I or class II device upon which to base a determination of substantial equivalence and a device is considered to be of low to moderate risk, the FDA may make a determination to classify the product candidate as a De Novo application, rather than the more conventional 510(k) marketing application.

***About the Symphony<sup>TM</sup> 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](http://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 *de novo* 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 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:**

Alexandra Schuman  
LifeSci Advisors  
[alex@lifesciadvisors.com](mailto:alex@lifesciadvisors.com)  
t: 646-876-3647

**Bluejay Diagnostics, Inc.**  
**Consolidated Balance Sheets**

		<b>December 31,</b>	
		<b>2022</b>	<b>2021</b>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$	10,114,990	\$ 19,047,778
Prepaid expenses and other current assets		1,673,480	1,612,708
Total current assets		11,788,470	20,660,486
Property and equipment, net		1,232,070	337,366
Operating lease right-of-use assets		465,514	-
Other non-current assets		35,211	21,019
Total assets	\$	13,521,265	\$ 21,018,871
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	\$	635,818	\$ 295,778
Operating lease liability, current		168,706	-
Accrued expenses and other current liabilities		835,730	341,384
Total current liabilities		1,640,254	637,162
Operating lease liability, non-current		323,915	-
Other non-current liabilities		15,823	-
Total liabilities		1,979,992	637,162
Commitments and Contingencies			
Stockholders' equity:			
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 20,215,288 and 20,112,244 shares issued and outstanding at December 31, 2022 and 2021, respectively		2,022	2,011
Additional paid-in capital		28,536,353	28,074,484
Accumulated deficit		(16,997,102)	(7,694,786)
Total stockholders' equity		11,541,273	20,381,709
Total liabilities and stockholders' equity	\$	13,521,265	\$ 21,018,871

See notes to consolidated financial statements.

**Bluejay Diagnostics, Inc.**  
**Consolidated Statements of Operations**

	<b>For the Years Ended</b>	
	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Revenue	\$ 249,040	\$ -
Cost of sales	200,129	-
Gross Profit	<u>48,911</u>	<u>-</u>
<b>Operating expenses:</b>		
Research and development	4,152,152	1,147,955
General and administrative	4,763,114	1,792,482
Marketing and business development	451,421	289,726
Total operating expenses	<u>9,366,687</u>	<u>3,230,163</u>
Operating loss	<u>(9,317,776)</u>	<u>(3,230,163)</u>
<b>Other income (expense):</b>		
Interest expense, net of amortization of premium	-	(367,459)
Impairment of property and equipment	(237,309)	-
State grant income	-	75,000
Other income, net	258,137	34,324
Total other income (expense), net	<u>20,828</u>	<u>(258,135)</u>
Net loss	<u>\$ (9,296,948)</u>	<u>\$ (3,488,298)</u>
Net loss per share - Basic and diluted	\$ (0.46)	\$ (0.41)
<b>Weighted average common shares outstanding:</b>		
Basic and diluted	20,163,915	8,522,422

See notes to consolidated financial statements.