

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): May 10, 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 May 10, 2023, Bluejay Diagnostics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter end March 31, 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. Exhibit Description**

| | |
|------|---|
| 99.1 | Press release dated May 10, 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: May 10, 2023



Bluejay Diagnostics Reports First Quarter 2023 Financial Results

ACTON, Mass., May 10, 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 announced financial results for the quarter ended March 31, 2023.

“Our journey continues towards realizing Bluejay’s vision of improving patient outcomes by addressing time-sensitive, life-saving needs in critical care settings,” said Neil Dey, CEO of Bluejay Diagnostics. “Symphony’s potential to be a rapid near-patient testing platform providing laboratory quality results has already been affirmed by IL-6 data from our comprehensive clinical studies. More recently, all resources and efforts at Bluejay have been focused on aligning our expanded clinical study with FDA feedback to optimize the pathway to regulatory approval. We look forward to providing an update on our Symphony IL-6 clinical program during this quarter.”

Financial Results for the Three Months Ended March 31, 2023:

Cash and cash equivalents. Cash and cash equivalents on March 31, 2023 were \$6.8 million, as compared to \$10.1 million on December 31, 2022. The Company will limit its cash burn during the FDA submission process and continue to closely monitor the management of its liquidity.

Research and development expense. Research and development expenses for the three months ended March 31, 2023 was approximately \$1.4 million as compared to approximately \$695,000 for the same period in 2022. The increase in research and development expenses was primarily due to an increase in personnel costs and clinical trials expenses. We expect future research and development expenses to be focused on costs specifically associated with our clinical trial program supporting our regulatory strategy and any necessary manufacturing improvements.

General and administrative expense. General and administrative expenses for the three months ended March 31, 2023 was approximately \$1.2 million as compared to approximately \$1.3 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. We expect to monitor and continue to pare our general and administrative spend, as necessary, to optimize operational alignment.

Sales and marketing expense. Sales and marketing expenses for the three months ended March 31, 2023 was approximately \$148,000 as compared to approximately \$54,000 for the comparable period in 2022. We expect minimal sales and marketing efforts during 2023, appropriately corresponding our spend with bringing Symphony to market.

Net loss/Net loss per share. The net loss was \$2.5 million, or \$0.12 per share for the three months ended March 31, 2023, compared to \$2.0 million, or \$0.10 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)

| | March 31, 2023 | December 31, 2022 |
|--|---------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 6,781,911 | \$ 10,114,990 |
| Prepaid expenses and other current assets | 2,120,012 | 1,673,480 |
| Total current assets | <u>8,901,923</u> | <u>11,788,470</u> |
| Property and equipment, net | 1,519,722 | 1,232,070 |
| Operating lease right-of-use assets | 433,361 | 465,514 |
| Other non-current assets | 33,443 | 35,211 |
| Total assets | <u>\$ 10,888,449</u> | <u>\$ 13,521,265</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 388,045 | \$ 635,818 |
| Operating lease liability, current | 168,709 | 168,706 |
| Accrued expenses and other current liabilities | 863,397 | 835,730 |
| Total current liabilities | <u>1,420,151</u> | <u>1,640,254</u> |
| Operating lease liability, non-current | 289,910 | 323,915 |
| Other non-current liabilities | 14,970 | 15,823 |
| Total liabilities | <u>1,725,031</u> | <u>1,979,992</u> |
| Commitments and Contingencies (See Note 13) | | |
| Stockholders' equity: | | |
| Common stock, \$0.0001 par value; 100,000,000 shares authorized; 20,459,057 and 20,215,288 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively | 2,046 | 2,022 |
| Additional paid-in capital | 28,698,317 | 28,536,353 |
| Accumulated deficit | (19,536,945) | (16,997,102) |
| Total stockholders' equity | <u>9,163,418</u> | <u>11,541,273</u> |
| Total liabilities and stockholders' equity | <u>\$ 10,888,449</u> | <u>\$ 13,521,265</u> |

See notes to unaudited condensed consolidated financial statements.

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

| | Three Months Ended March 31, | |
|---|---|----------------|
| | 2023 | 2022 |
| Operating expenses: | | |
| Research and development | 1,354,549 | 694,757 |
| General and administrative | 1,176,977 | 1,319,819 |
| Sales and marketing | 148,046 | 53,685 |
| Total operating expenses | 2,679,572 | 2,068,261 |
| Operating loss | (2,679,572) | (2,068,261) |
| Other income: | | |
| Other income, net | 139,729 | 54,858 |
| Total other income | (139,729) | (54,858) |
| Net loss | \$ (2,539,843) | \$ (2,013,403) |
| Net loss per share - Basic and diluted | \$ (0.12) | \$ (0.10) |
| Weighted average common shares outstanding: | | |
| Basic and diluted | 20,375,092 | 20,142,300 |

See notes to unaudited condensed consolidated financial statements.