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): December 16, 2021

Bluejay Diagnostics, Inc.
(Exact Name of Registrant as Specified in its Charter)

DELAWARE	001-41031	47-3552922
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File No.)	(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-14(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 December 16, 2021, Bluejay Diagnostics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021 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 December 16, 2021
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/ Gordon Kinder
Gordon Kinder
Chief Financial Officer

Dated: December 16, 2021

Exhibit 99.1

IMMEDIATE RELEASE
Date: December 16, 2021

Bluejay Diagnostics, Inc. Reports Third Quarter 2021 Financial Results

IL-6 test for sepsis triage on Track for January 2022 FDA Pre-Submission Filing

Expanded Testing Program Planned for Q1-Q3 2022

Raised $21.6 million Gross Proceeds in an Upsized IPO

Acton, Massachusetts, Dec. 16, 2021 – Bluejay Diagnostics, Inc. (NASDAQ: BJDX) ("Bluejay") a late-stage, pre-revenue diagnostics/medical device company focused on developing cost-effective, rapid, near-patient products for triage, diagnosis and monitoring of disease progression, today announced financial results for the third quarter ended September 30, 2021 and provided a corporate update on the Company's first product candidate, the IL-6 test for sepsis triage.

"Bluejay has made substantial progress since our S-1 filing in July 2021. We completed an upsized $21.6 million Initial Public Offering and initiated the clinical testing program for the IL-6 test for sepsis triage," said Indranil "Neil" Dey, CEO. "These two important milestones will help to bring us closer to fulfilling Bluejay's mission of developing the first whole-blood, cost-effective, rapid, near-patient product to help medical professionals make earlier and better decisions in sepsis care."

Corporate Update: Overview, Initial Testing Plan and Next Steps for the IL-6 test for sepsis triage Product Candidate

- **Overview of the IL-6 test for sepsis triage.** Bluejay's IL-6 test for sepsis triage is intended to measure IL-6 levels in whole blood samples in near-patient settings. Interleukin-6 (IL-6) is an established biomarker of immune system activation. It is elevated in infection, inflammation, and cancer. IL-6 presents as an early "first responder" and needs to be measured quickly and reliably.

- **Initial Testing Program and Planned January 2022 FDA Pre-Submission Filing.** Bluejay initiated the initial clinical testing program for its IL-6 test for sepsis triage in October 2021 under a single protocol at three sites, two sites in the University of Texas Southwestern Medical Center (the William P. Clements Jr. University Hospital and the Zale Lipshy Pavilion Hospital) and the third site at the Parkland Memorial Hospital. Results from this program will form the basis of the FDA Pre-Submission application expected to be filed in January 2022.

- **Expanded Testing Program to be Conducted from Q1 to Q3 ’22**. Bluejay plans to conduct an expanded clinical testing program for its IL-6 test for sepsis triage product candidate. The program is expected to start in Q1 ’22 and an anticipated completion in Q3 ’22. The results from this program will form the basis of the Company’s planned 510(k) marketing application, intended to be filed in Q3 ’22. The Company plans to incorporate feedback from the FDA pre-submission to modify these studies to support premarket clearance (which could be through a traditional 510(k) or *de novo* application). The Company may also consider alternative regulatory paths including, for example, an Emergency Use Authorization (EUA).

Third Quarter 2021 Accomplishments:

- **Clinical Program Initiation**. Bluejay commenced the initial testing program for the IL-6 test for sepsis triage in October 2021 at the UT Southwestern Medical Center and at the Parkland Memorial Hospital. As noted above, results from this program will form the basis of the FDA Pre-Submission application filing, expected to be complete in January 2022.

- **November 10th IPO**. On November 10, 2021, Bluejay announced the pricing of an upsized $21.6 million underwritten Initial Public Offering of 2,160,000 units, at a unit price of $10.00.

- **Addition of Gary Gemignani to the Board.** As part of the closing of the offering, Mr. Gary Gemignani joined Bluejay’s Board of Directors. Mr. Gemignani brings extensive experience in life sciences, public companies, accounting and finance, based on a career of senior executive and leadership roles at Acacia Pharma Group plc, Synergy Pharmaceuticals Inc., Biodel Inc., Prudential Financial, Gentium, Novartis, and Wyeth and Arthur Andersen & Co.

Financial Results for the Three Months Ended September 30, 2021

Research and Development Expense. Research and development expenses for the three months ended September 30, 2021 were $442,527 as compared to $2,723 for the comparable period in 2020. The increase was primarily due to expenses in connection with clinical trial preparations and manufacturing costs.

General and Administrative Expense. General and administrative expenses for the three months ended September 30, 2021 were $445,050 as compared to $131,094 for the comparable period in 2020. The increase was attributable to increased operating expenses related to the Company’s transition to a public company, including accounting legal and audit related expenses as well as an increase in general and administration headcount.

Net Loss/Loss per share. The Net Loss and Net Loss per Share for the three months ended September 30, 2021 was $1,193,381 and $0.11 compared to $127,988 and $0.04 for the comparable period in 2020.

Cash and Cash Equivalents and Marketable Securities. Cash, cash equivalents, and marketable securities on September 30, 2021 were $2,330,138 as compared to $912,361 on December 31, 2020. Subsequent to the end of the third quarter, the company completed a successful IPO, raising $18.8 million in net proceeds (after underwriters’ and other related expenses).

For further details on Bluejay's financials, refer to its Form 10Q filed December 16, 2021 with the S.E.C.

About the Symphony System:

Bluejay's Symphony Systemä is intended to address the need for simple, reliable, rapid near-patient testing. This user-friendly system is expected to fit into ICU/near-patient settings without the need for dedicated staff to run a test. The system has been designed to measure test analytes using whole blood. Samples are collected and loaded into proprietary, test-specific cartridges. The system does not require any sample prep and was shown in published clinical studies to deliver results in about 24 minutes.

The Symphony System is based on a well-accepted test method (ELISA, Enzyme-Linked Immunosorbent Assay) using advances in nanotechnology and new approaches to microfluidics. Bluejay has an exclusive license to the Symphony System from Toray Industries (Toray), a multinational company with more than 96 years of manufacturing experience, located in Japan. The product is manufactured by Toray and Sanyoseiko. Sanyoseiko is an FDA-registered manufacturer with more than 50 years of global experience in medical devices manufacturing, located in Japan.

About Bluejay Diagnostics:

Bluejay Diagnostics, Inc. is a late-stage, pre-revenue diagnostics/medical device company focused on improving patient outcomes through the Symphony System, a more cost-effective, rapid, near-patient product candidate for triage, diagnosis and monitoring of disease progression in hospital and long-term acute care (LTAC) settings. Bluejay's first product candidate, an IL-6 test for sepsis triage, is designed to provide accurate, reliable results in approximately 24 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. These statements include, but are not limited to, statements relating to the expected timeline for the completion of the Company's clinical studies and potential submissions to the FDA. Forward-looking statements are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "suggest", "will," and variations of such words or similar expressions or their negatives (as well as other words and expressions referencing future events, conditions, or circumstances). 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 in the Company's filings with the Securities and Exchange Commission, including as set forth in the "Risk Factors" section of the Company's final prospectus, which was filed with the Securities and Exchange Commission on November 11, 2021, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. You should not place undue reliance on these 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 changes in the Company's expectations of results or any change in events.

Investor Contact:

Alexandra Schuman
LifeSci Advisors
alex@lifesciadvisors.com
t: 646-876-3647

Bluejay Diagnostics, Inc.

Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,330,138	$ 912,361
Inventory	-	84,762
Deferred offering costs	482,308	-
Prepaid expenses and other current assets	451,407	61,071
Total current assets	3,263,853	1,058,194
Property and equipment, net	358,845	459,138
Total assets	$ 3,622,698	$ 1,517,332
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 242,856	$ 374,928
Due to related party	115,102	125,102
Accrued expenses	371,288	133,820
Notes payable, net	-	1,041,186
Convertible debentures	3,974,374	-
Note payable, Paycheck Protection Program	-	14,725
Derivative warrant liability	-	155,629
Total liabilities	4,703,620	1,845,390
Commitments and Contingencies (See Note 6)		
Series A redeemable, convertible preferred stock, $0.0001 par value; 10,600 shares authorized; 0 and 10,600 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	-	1,077,303
Series B redeemable, convertible preferred stock, $0.0001 par value; 5,918 shares authorized; 0 and 5,187 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	-	1,800,347
Series C redeemable, convertible preferred stock, $0.0001 par value; 636 shares authorized; 0 and 636 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	-	1,000,465
Stockholders' deficit:		
Common stock, $0.0001 par value; 30,000,000 shares authorized; 10,534,265 and 3,147,200 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1,054	315
Additional paid-in capital	5,152,314	-
Accumulated deficit	(6,234,290)	(4,206,488)
Total stockholders' deficit	(1,080,922)	(4,206,173)
Total liabilities, redeemable, convertible preferred stocks and stockholders' deficit	$ 3,622,698	$ 1,517,332

Bluejay Diagnostics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 442,527	$ 2,723	$ 692,702	$ 108,192
General and administrative	445,050	131,094	974,791	452,846
Marketing and business development	70,411	14,352	189,765	53,574
Total operating expenses	957,988	148,169	1,857,258	614,612
Operating loss	(957,988)	(148,169)	(1,857,258)	(614,612)
Other income (expense):				
Derivative warrant liability gain (loss)	-	4,344	9,676	(45,323)
Interest income (expense), net of amortization of premium	(237,429)	15,833	(269,545)	40,443
State grant revenue	-	-	75,000	-
Other income	2,036	4	14,325	5,232
Total other income (expense), net	(235,393)	20,181	(170,544)	352
Net loss	$ (1,193,381)	$ (127,988)	$ (2,027,802)	$ (614,260)
Net loss per share - Basic and diluted	$ (0.11)	$ (0.04)	$ (0.32)	$ (0.20)
Weighted average common shares outstanding:				
Basic and diluted	10,491,978	3,147,200	6,321,493	3,147,200