UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to_____

Commission file number: 001-41031

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

Delaware	**47-3552922**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
360 Massachusetts Avenue, Suite 203, Acton, MA	**01720**
(Address of Principal Executive Offices)	(Zip Code)

(844) 327-7078
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller Reporting Company	☒
		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 Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	BJDX	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The registrant had 26,883,971 shares of common stock outstanding at November 4, 2024.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other sections of this Quarterly Report on Form 10-Q (this "Form 10-Q"). In some cases, you can identify these statements by forward-looking words such as "may," "might," "should," "would," "could," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or "continue," and the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to known and unknown risks, uncertainties and assumptions about us, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements.

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this Form 10-Q may describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this Form 10-Q to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this Form 10-Q in the case of forward-looking statements contained in this Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

EXPLANATORY NOTE

In this Form 10-Q, and unless the context otherwise requires, the "Company," "we," "us," and "our" refer to Bluejay Diagnostics, Inc. and its wholly owned subsidiary Bluejay SpinCo, LLC, taken as a whole.

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

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

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,755,741	$ 2,208,516
Prepaid expenses and other current assets	811,945	747,263
Deferred offering costs	-	265,081
Total current assets	6,567,686	3,220,860
Property and equipment, net	1,534,631	1,285,741
Operating lease right-of-use assets	227,495	333,267
Other non-current assets	23,598	28,663
Total assets	$ 8,353,410	$ 4,868,531
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 316,650	$ 491,474
Operating lease liability, current	111,453	162,990
Accrued expenses and other current liabilities	621,144	1,116,911
Notes payable, net	-	-
Total current liabilities	1,049,247	1,771,375
Operating lease liability, non-current	130,199	189,987
Other non-current liabilities	9,530	12,321
Total liabilities	1,188,976	1,973,683
Commitments and Contingencies (See Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 17,827,280 and 154,893 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	1,783	16
Additional paid-in capital	40,399,445	29,845,822
Accumulated deficit	(33,236,794)	(26,950,990)
Total stockholders' equity	7,164,434	2,894,848
Total liabilities and stockholders' equity	$ 8,353,410	$ 4,868,531

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-8 reverse stock split effective June 20, 2024

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 551,655	$ 1,397,318	$ 2,917,674	$ 4,428,123
General and administrative	809,199	963,534	2,759,817	3,213,614
Sales and marketing	753	(19,619)	7,481	282,756
Total operating expenses	1,361,607	2,341,233	5,684,972	7,924,493
Operating loss	(1,361,607)	(2,341,233)	(5,684,972)	(7,924,493)
Other income (expense):				
Interest expense	(190,610)	-	(822,299)	-
Other income	70,258	43,235	221,467	273,347
Total other income (expense), net	(120,352)	43,235	(600,832)	273,347
Net loss	$ (1,481,959)	$ (2,297,998)	$ (6,285,804)	$ (7,651,146)
Net loss per share – Basic and diluted	$ (0.16)	$ (16.67)	$ (1.82)	$ (58.38)
Weighted average common shares outstanding – Basic and diluted	9,555,855	137,871	3,444,646	131,054

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-8 reverse stock split effective June 20, 2024.

Bluejay Diagnostics, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

	Stockholders' Equity				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2023	154,893	$ 16	$ 29,845,822	$ (26,950,990)	$ 2,894,848
Stock-based compensation expense	-	-	11,874	-	11,874
Issuance of Common Stock and Prefunded Warrants net of issuance costs of $444,950	89,067	9	2,788,960	-	2,788,969
Exercise of January 2024 Prefunded Warrants	92,096	9	(9)	-	-
Net loss	-	-	-	(2,328,465)	(2,328,465)
Balance at March 31, 2024	**336,056**	**34**	**32,646,647**	**(29,279,455)**	**3,367,226**
Stock-based compensation expense	-	-	6,010	-	6,010
Exercise of January 2024 Prefunded Warrants	155,376	15	(15)	-	-
Issuance of Common Stock in connection with Bridge Note Financing	72,537	7	307,556	-	307,563
Issuance of Common Stock in connection with June 2024 Offering, net of issuance costs of $1,399,500	2,020,089	202	7,435,454	-	7,435,656
Net loss	-	-	-	(2,475,380)	(2,475,380)
Balance at June 30, 2024	**2,584,058**	**258**	**40,395,652**	**(31,754,835)**	**8,641,075**
Stock-based compensation expense	-	-	4,792	-	4,792
Exercise of June 2024 Prefunded Warrants	3,347,739	335	(335)	-	-
Exercise of Series D Warrants	11,895,483	1,190	(664)	-	526
Net loss	-	-	-	(1,481,959)	(1,481,959)
Balance at September 30, 2024	**17,827,280**	**$ 1,783**	**$ 40,399,445**	**$ (33,236,794)**	**$ 7,164,434**

	Stockholders' Equity				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2022	126,320	$ 13	$ 28,538,362	$ (16,997,102)	$ 11,541,273
Stock-based compensation expense	-	-	54,730	-	54,730
Grants of fully vested restricted stock units to settle accrued bonus, net of shares withheld	1,524	-	107,235	-	107,235
Net loss	-	-	-	(2,539,843)	(2,539,843)
Balance at March 31, 2023	**127,844**	**13**	**28,700,327**	**(19,536,945)**	**9,163,395**
Stock-based compensation expense	-	-	27,702	-	27,702
Issuance of Common Stock	94	-	-	-	-
RSU tax withholding	(45)		(1,453)	-	(1,453)
Net loss	-	-	-	(2,813,305)	(2,813,305)
Balance at June 30, 2023	**127,893**	**13**	**28,726,576**	**(22,350,250)**	**6,376,339**
Stock-based compensation expense	-	-	(42,482)	-	(42,482)
Issuance of common stock, net of issuance costs of $413,544	27,000	3	1,177,293	-	1,177,296
Net loss	-	-	-	(2,297,998)	(2,297,998)
Balance at September 30, 2023	**154,893**	**$ 16**	**$ 29,861,387**	**$ (24,648,248)**	**$ 5,213,155**

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-8 reverse stock split effective June 20, 2024

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

	Nine months ended September 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,285,804)	$ (7,651,146)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	55,843	626,366
Stock-based compensation expense	22,676	204,810
Amortization of right-of-use asset	105,772	98,266
Non-cash interest expense for finance lease	814	-
Non-cash interest expense for notes payable	807,797	-
Impairment of property and equipment	925	1,787
Changes in operating assets and liabilities:		
Deferred offering costs	265,081	-
Prepaid expenses and other current assets	(64,682)	222,675
Other non-current assets	5,065	5,304
Accounts payable	(387,478)	18,609
Other non-current liabilities	(59,788)	-
Accrued expenses and other current liabilities	(547,304)	936,936
Net cash used in operating activities	**(6,081,083)**	**(5,536,393)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(305,658)	(616,272)
Net cash used in investing activities	**(305,658)**	**(616,272)**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, gross	-	1,590,840
Payment for issuance of common stock	-	(413,544)
Proceeds from issuance of notes payable, net of discounts of $287,580	2,000,000	-
Repayment of notes payable	(2,287,580)	-
Proceeds from issuance of common stock and prefunded warrants	12,069,075	-
Issuance costs related to issuance or common stock	(1,844,450)	-
Proceeds from exercise of Class D warrants and prefunded warrants	526	-
Payment of Finance Lease	(3,605)	(3,605)
Payment of tax withholding obligations on restricted stock units	-	(59,079)
Net cash provided by financing activities	**9,933,966**	**1,114,612**
Increase (decrease) in cash and cash equivalents	3,547,225	(5,038,053)
Cash and cash equivalents, beginning of period	2,208,516	10,114,990
Cash and cash equivalents, end of period	$ 5,755,741	$ 5,076,937
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH INVESTING AND FINANCING ACTIVITIES		
Fair value of common stock issued in connection with notes payable	$ 307,563	-
Liabilities incurred for the purchase of property and equipment	-	$ 101,522

See accompanying notes to condensed consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Bluejay Diagnostics, Inc. ("Bluejay" or the "Company") is a medical diagnostics company developing rapid tests using whole blood on our Symphony technology platform ("Symphony") to improve patient outcomes in critical care settings. The Company's Symphony platform is an exclusively licensed and patented technology that consists of a mobile device and single-use test cartridges that if cleared, authorized, or approved by the U.S. Food and Drug Administration (the "FDA"), can provide a solution to a significant market need in the United States. Clinical trials indicate the Symphony device produces results in less than 20 minutes for intensive care units and emergency rooms, where rapid and reliable results are required.

Bluejay's first product, the Symphony IL-6 test, is for the monitoring of disease progression in critical care settings. IL-6 is a clinically established inflammatory biomarker, considered a 'first-responder,' for assessment of severity of infection and inflammation across many disease indications, including sepsis. A current challenge of healthcare professionals is the excessive time and cost associated determining a patient's level of severity at triage and the Symphony IL-6 test could consistently monitor this critical care biomarker with rapid results providing critical information to the physicians to improve patient care.

In the future Bluejay plans to develop additional tests for Symphony including two cardiac biomarkers (hsTNT and NT pro-BNP), as well as other tests using the Symphony platform. The Company does not yet have regulatory clearance for its Symphony products, and its Symphony products will need to receive regulatory authorization from the FDA in order to be marketed as a diagnostic product in the United States.

In the future, Bluejay also plans to explore new products to support Bluejay's biomarker detection program. Furthermore, Bluejay plans to explore strategic opportunities around the specimen biobanks generated from the SYMON I and SYMON II clinical studies.

We were incorporated under the laws of Delaware on March 20, 2015. Our headquarters is located in Acton, Massachusetts.

On June 4, 2021, the Company formed Bluejay Spinco, LLC, a wholly owned subsidiary of the Company, for purposes of further development of the Company's ALLEREYE diagnostic test. ALLEREYE is a point-of-care device offering healthcare providers a solution for diagnosing Allergic Conjunctivitis.

Risks and Uncertainties

Risks related to the Company's FDA regulatory and clinical trial, Nasdaq listing and going concern status are each described below. In addition, the Company is subject to several risks similar to other companies in its industry, including rapid technological change, competition from larger companies, availability of raw materials and device components, and dependence on key personnel.

FDA Regulatory and Clinical Trial Update

Our current regulatory strategy is designed to support commercialization of Symphony in the United States pending marketing authorization from the FDA. Previously, our regulatory strategy involved clinical studies involving COVID-19 patients. However, we have shifted our focus away from COVID-19 patients due to a significant decline in the number of COVID-19 related hospitalizations. Pursuant to this revised strategy, we have completed a pilot clinical study (SYMON-I) and plan to begin a clinical study (SYMON-II) to validate the results of the pilot study to support an FDA regulatory submission with an initial indication for risk stratification of hospitalized sepsis patients. We 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, we are determined to proceed on this basis, which considers the FDA's feedback.

In the second quarter of 2024, we completed a multicenter SYmphony IL-6 MONitoring Sepsis ("SYMON") clinical study investigating the role of interleukin-6 (IL-6) in patients diagnosed with sepsis and septic shock. This prospective study assessed the performance of IL-6 upon initial presentation to the intensive care unit (ICU). A primary analysis of the SYMON-I pilot clinical study (registered clinical trial number NCT06181604) highlighted that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU may predict patient mortality out to 28 days. We will seek to validate these findings in the SYMON-II pivotal study.

Furthermore, a secondary outcome of the SYMON-I study showed that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU is a predictor of patient mortality during their hospitalization. Other secondary outcomes showed that lactate and Sequential Organ Failure Assessment (SOFA), standard clinical tests used for sepsis and septic shock patients, were not predictors of patient mortality out to 28 days.

We believe that the findings underscore the potential importance of IL-6 as a predictor and provide new insights into the potential pathways for improving sepsis outcomes.

The SYMON II clinical study has three components: (1) collection, freezing, and biobanking of patient samples, (2) measuring IL-6 concentrations in the biobanked samples near the end of patient enrollment or after the patient enrollment has completed, and (3) analysis of the IL-6 data with the patient outcomes to see if the established IL-6 cutoff value has been validated for 28-day all-cause mortality.

We initiated the SYMON-II pivotal clinical study in the third quarter of 2024. We plan to start patient enrollment during the fourth quarter of 2024. Our goal is to use the Symphony IL-6 test to complete the testing in the SYMON-II clinical trial. We are experiencing several technical challenges related to the Symphony Cartridge product that we expect to delay our ability to complete such testing. In particular, several individual components in our product may need to be replaced and validated due to limited supply or discontinuation (including the antibody used in the product). In addition, we are working to correct several reliability issues with the Symphony Cartridge product. At this time, we anticipate these delays will prevent us from submitting an FDA application within the next 18 months.

If we are able to complete the SYMON-II clinical study and the results are positive, we intend to use the data generated from SYMON-II to support a 510(k) application to the FDA. This application will be based on the following intended use: "Symphony IL-6 is intended for use to determine the IL-6 concentration as an aid in assessing the cumulative 28-day risk of all-cause mortality in conjunction with other laboratory findings and clinical assessments for patients diagnosed with sepsis or septic shock in the ICU." We also plan to present the SYMON-I and SYMON-II results at future national scientific meetings and publish them in peer-reviewed journals.

For Symphony, we remain in the development phase of the overall product launch cycle. Currently are experiencing issues with critical materials and pilot production performance that could negatively affect our projected timeline for FDA submission. We are developing plans to improve product performance, ensure supply of these critical materials, and transfer production and all supply chain activities from the original developer and current supplier of cartridge intermediates (Toray) to an FDA-registered contract manufacturer (CMO). We expect that production lots for validation testing to support the FDA submission will be available once a transfer to an FDA registered CMO is completed.

If we are unable to meet the manufacturing requirements or analytical performance required for FDA clearance with Symphony, we may consider using an alternative IL-6 test for the SYMON-II study.

Our ability to engage in and complete the activities needed for an FDA submission, will be contingent upon us addressing these and other challenges, including possessing and/or raising sufficient capital, remaining a going concern, and producing product capable of supporting our product requirements and meeting analytical validation and clinical validation.

June 2024 Reverse Stock Split

On June 20, 2024, we effected a reverse stock split of our shares of common stock at a ratio of 1-for-8 (the "2024 Reverse Stock Split"). The Company's common stock continued trading on Nasdaq on a post-split basis under the Company's existing trading symbol, "BJDX."

All of the Company's historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect the Reverse Stock Split.

Nasdaq Minimum Bid Price Non-Compliance

Our common stock currently is listed for quotation on the Nasdaq Capital Market. We are required to meet specified financial requirements in order to maintain such listing, including a requirement that the bid price for our common stock remain above $1.00, and that the market value of our publicly held securities be at least $1 million.

On February 28, 2024, we received a notification letter from the Nasdaq Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") notifying us that the closing bid price for our common stock had been below $1.00 for the previous 30 consecutive business days and that we therefore are not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). The notification has no immediate effect on the listing of our common stock on the Nasdaq Capital Market.

On August 28, 2024, at the Company's request, Nasdaq's Listing Qualifications Staff notified the Company that it has extended the time for the Company to regain compliance with the minimum bid price requirement until February 24, 2025. To regain compliance, the closing bid price of our common stock must be at least $1.00 or higher for a minimum of ten consecutive business days, and in such case, Nasdaq will provide us with written confirmation of compliance. If we are not able to cure the deficiency during this compliance period, Nasdaq will provide written notice to us that our common stock will be subject to delisting. In the event of such delisting notification, we may appeal Nasdaq's determination to delist our securities, but there can be no assurance that Nasdaq would grant our request for continued listing**.**

We intend to take all reasonable measures available to us to achieve compliance to allow for continued listing on the Nasdaq Capital Market. However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise comply with other Nasdaq listing criteria. On June 20, 2024, we effected a reverse stock split of our shares of common stock at a ratio of 1-for-8, however, our common stock did not remain above a trading price of $1.00 following such reverse stock split. If our common stock does not regain compliance with the minimum price requirement during the remaining compliance period, we may need to effect a further reverse stock split, whereby shares of our common stock are further consolidated with the intent that the per-share trading price becomes greater than $1.00 per share on a sustained basis sufficient to regain compliance with the applicable Nasdaq requirements. On October 23, 2024, at a special meeting of stockholders, the Company's stockholders approved a proposed amendment to the Company's certificate of incorporation to effect a reverse stock split of the Company's outstanding shares of common stock by one of several fixed ratios (1-for-20, 1-for 25, 1-for-30, 1-for-35, 1-for-40, 1-for-45 and 1-for-50). The Company's board of directors is considering whether to proceed with implementation of the reverse stock split, including the timing and ratio thereof.

As of the close of business on November 4, 2024, the market value of our publicly held common stock (which is our only outstanding class of securities) was approximately $2.0 million, and the most recent closing price of our common stock on the Nasdaq Capital Market was $0.0729 per share. If the market value of our publicly held common stock declines below $1 million, or the closing price of our common stock declines to $0.10 per share or less for 10 consecutive trading days, we would also be subject to Nasdaq delisting proceedings on that basis. Nasdaq's staff also maintains discretionary authority under its listing rules to delist companies whose capital structure or public offerings raise public interest and investor protection concerns, including as a result of highly dilutive issuances, and it is possible that Nasdaq could assert that past offerings that we have consummated, or future offerings we may consummate, raise such concerns.

If our common stock is delisted, we may seek to have our common stock quoted on an over-the-counter marketplace, such as on the OTCQX. The OTCQX is not a stock exchange, and if our common stock trades on the OTCQX rather than a securities exchange, there may be significantly less trading volume and analyst coverage of, and significantly less investor interest in, our common stock, which may lead to lower trading prices for our common stock.

Any potential delisting of our common stock from the Nasdaq Capital Market may have materially adverse consequences to our stockholders, including:

- A reduced market price and liquidity with respect to our shares of common stock, which could make our ability to raise new investment capital more difficult;
- limited dissemination of the market price of our common stock;
- limited news coverage;
- limited interest by investors in our common stock;
- volatility of the prices of our common stock, due to low trading volume;
- our common stock being considered a "penny stock," which would result in broker-dealers participating in sales of our common stock being subject to the regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act;
- increased difficulty in selling our common stock in certain states due to "blue sky" restrictions; and
- limited ability to issue additional securities or to secure additional financing.

Going Concern Uncertainty

The accompanying unaudited condensed consolidated financial statements were prepared under the assumption that the Company will continue as a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business.

Our operations to date have been funded primarily through equity financings. As of September 30, 2024, the Company had cash and cash equivalents of approximately $5.8 million, and current liabilities of approximately $1.0 million. During the nine-month period ended September 30, 2024, the Company's net cash used in operating activities was approximately $6.1 million. The future viability of the Company is largely dependent on its ability to raise additional capital to finance its operations. The Company expects that it will need to raise additional capital within the next twelve months to continue its operations as the current cash resources will be sufficient to fund its operations through the first quarter of 2025. Although the Company has been able to raise capital in the past, there is no assurance that it will be successful in obtaining additional financing on terms acceptable to the Company, if at all. In addition, recent fundraising by the Company has resulted in significant ownership dilution to shareholders, and given the Company's current market capitalization and financing needs, it is likely that future fundraising may also be highly dilutive. If the Company is unable to obtain funding, it may be forced to delay, reduce or eliminate its research and development program, product development or commercialization efforts, which could adversely affect its business prospects.

Accordingly, based on the considerations discussed above, management has concluded there is substantial doubt as to the Company's ability to continue as a going concern within one year after the date these condensed consolidated financial statements are issued. The Company plans to continue to fundraise. If adequate funds are not available, the Company may require further steps to slow cash burn, extending the cash runway until financing can be secured. These condensed consolidated financial statements do not include any adjustments with respect to the carrying amounts of assets and liabilities and their classification that might result from the outcome of this uncertainty.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in conformity with generally accepted accounting principles in the United States ("US GAAP") consistent with those applied in, and should be read in conjunction with, the Company's audited consolidated financial statements and related footnotes for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K. The unaudited condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2024 and December 31, 2023, its results of operations and cash flows for the three- and nine-month periods ended September 30, 2024, and 2023, in accordance with US GAAP. The unaudited condensed consolidated financial statements do not include all the information and footnotes required by US GAAP for complete financial statements, as allowed by the relevant U.S. Securities and Exchange Commission ("SEC") rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading. The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

The results for the three- and nine-month periods ended September 30, 2024, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2024, or any other interim period within this fiscal year.

2. SIGNIFICANT ACCOUNTING POLICIES

During the nine months ended September 30, 2024, there were no changes to the significant accounting policies as described in the 2023 Audited Financial Statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in these condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. The Company believes judgment is involved in accounting for the fair value-based measurement of stock-based compensation, accruals, and warrants. The Company evaluates its estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the condensed consolidated financial statements.

Stock-based Compensation

Stock-based compensation expense for all stock-based payment awards made to employees, directors and non-employees is measured based on the grant-date fair value of the award. Stock-based compensation expense for awards granted to non-employees is determined using the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured.

The Company uses the Black-Scholes option pricing model to determine the fair value of options granted. The Company recognizes the compensation cost of stock-based awards on a straight-line basis over the requisite service period. For stock awards for which vesting is subject to performance-based milestones, the expense is recorded over the implied service period after the point when the achievement of the milestone is probable, or the performance condition has been achieved.

The Company recognizes forfeitures when they occur. Forfeited options are recorded as a reduction to stock compensation expense.

Research and Development Expenses

Costs incurred in the research and development of new products are expensed as incurred. Research and development costs include, but are not limited to, salaries, benefits, stock-based compensation, laboratory supplies, fees for professional service providers and costs associated with product development efforts, including preclinical studies and clinical trials.

The Company estimates preclinical study and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf.

Segment Reporting

Management has determined that the Company has one operating segment, which is consistent with the Company structure and how it manages the business. As of September 30, 2024 and December 31, 2023, the majority of the Company's assets were located in the United States.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury stock and if-converted methods. Dilutive common stock equivalents are comprised of convertible preferred stock, convertible notes, options outstanding under the Company's stock option plan and warrants. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be antidilutive are as follows (in common stock equivalent shares):

	September 30,	
Potentially Dilutive Securities Listing:	**2024**	**2023**
Options to purchase common stock	3,721	3,920
Restricted stock units (RSUs)	62	984
Warrants for common stock	33,240	33,964
Class A warrants for common stock	15,525	15,525
Class B warrants for common stock	471	471
5-Year warrants for common stock	336,539	-
Class C warrants for common stock	68,629,291	-
Class D warrants for common stock	9,883,000	-
Placement agent warrants	23,558	-

Recently Adopted Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This amends the ASC 815 Derivatives and Hedging—Contracts in Entity's Own Equity to simplify the guidance on (1) accounting for convertible instruments, and (2) the derivatives scope exception for contracts in an entity's own equity. The guidance on earnings per share ("EPS") has also been amended to simplify the calculations and make them more internally consistent. The Company adopted this new standard on January 1, 2024. The new standard had no impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Standards

The Company does not believe that any recently issued but not yet effective accounting pronouncements will have a material effect on the accompanying unaudited condensed consolidated financial statements.

3. LICENSE AND SUPPLY AGREEMENT WITH TORAY INDUSTRIES

On October 23, 2023, the Company and Toray entered into an Amended and Restated License Agreement (the "New Toray License Agreement") and a Master Supply Agreement (the "New Toray Supply Agreement"). Under the New Toray License Agreement, the Company continues to license from Toray intellectual property rights needed to manufacture single-use test cartridges, and the Company has received the right to sublicense certain Toray intellectual property to Sanyoseiko in connection with Sanyoseiko's ongoing agreement with the Company to manufacture its Symphony device and cartridges (including in connection with the Company's clinical trials). In addition, the New Toray License Agreement provides for the transfer of certain technology related to the cartridges to Sanyoseiko. The royalty payments payable by the Company to Toray have been reduced under the New Toray License Agreement from 15% to 7.5% (or less in certain circumstances) 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 Toray 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. There were no sales of or revenues from the cartridges during the nine-month periods ended September 30, 2024 and 2023.

Under the New Toray Supply Agreement, Toray is manufacturing (through its wholly owned subsidiary Kamakura Techno- Science, Inc.) certain product intermediate components for use in cartridges being manufactured for the Company by Sanyoseiko. These cartridges made using Toray intermediates are for the purpose of obtaining FDA approval and not for commercial sale. The New Toray Supply Agreement has a term ending on the earlier of October 23, 2025, or the date that the Company obtains FDA approval for its product and may be extended for up to six months by mutual agreements of the parties. If FDA approval is obtained, Sanyoseiko will be required to manufacture the intermediates and cartridges under a separate supply agreement between the Company and Sanyoseiko.

There were no amounts accrued related to the New Toray License Agreement at September 30, 2024 and December 31, 2023.

4. NOTES PAYABLE

On May 31, 2024, the Company entered into a Note Purchase Agreement with an accredited investor (the "NPA"), and a Securities Purchase Agreement with three accredited investors (the "SPA"). This transaction closed on June 3, 2024. Debt issuance costs related to the NPA and SPA totaled $212,654.

Under the terms of the NPA, the investor provided the Company with a $1,000,000 cash subscription in exchange for the issuance of a senior secured note. As of September 30, 2024, a total of $1,176,470 was repaid to the NPA investors. The difference between such note and the subscription amount, initially recorded as a discount on the notes, was the result of the discount factor included in the NPA of approximately 17.6%.

Under the terms of the SPA, the three investors agreed to collectively provide the Company with a separate $1,000,000 cash subscription in exchange for the issuance of senior secured notes ($333,333 each), and the collective issuance of 72,537 shares of the Company's common stock. The fair value of the common stock issued in connection with the SPA was $307,563.

As of September 30, 2024, a total of $1,111,110 was repaid to the SPA investors. The difference between such notes and the subscription amounts, initially recorded as a discount on the notes, was the result of the discount factor included in the SPA of 11.11%.

The interest expense recorded on the NPA and SPAs was $185,893 and $807,797 for the three- and nine-month periods ended September 30, 2024.

5. WARRANTS

The following table summarizes information with regard to warrants outstanding at September 30, 2024:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
June 2024 Class C Warrants	68,629,291	Common Stock	$ 0.326	4.7
June 2024 Class D Warrants	9,883,000	Common Stock	$ 0.0001	4.7
January 2024 Common Stock Warrants	336,538	Common Stock	$ 10.40	4.3
January 2024 Placement Agent Warrants	23,558	Common Stock	$ 13.00	4.3
August 2023 Common Stock Warrants	27,000	Common Stock	$ 57.92	3.9
August 2023 Placement Agent Warrants	1,888	Common Stock	$ 73.65	3.9
Class A Warrants	15,525	Common Stock	$ 1,120	2.1
Class B Warrants	471	Common Stock	$ 1,600	2.1
Other Pre-2024 Common Stock Warrants	4,352	Common Stock	$ 543.05	1.7

June 2024 Common Stock Warrants, June 2024 Underwriter Warrants and June 2024 Prefunded Warrants

On June 28, 2024, the Company sold in a public offering (the "June 2024 Offering"), (i) 577,073 common units (the "Common Units"), each consisting of one share of common stock, two Class C Warrants and one Class D Warrant and (ii) 4,791,025 prefunded warrants (the "Prefunded Units"), each consisting of one prefunded warrant to purchase one share of common stock (each, a "Prefunded Warrant"), two Class C Warrants and one Class D Warrant to purchase Common Shares. Aegis Capital Corp. (the "Underwriter") partially exercised its over-allotment option in respect to 678,674 Class C Warrants and 339,337 Class D Warrants (the "Over-Allotment Warrants").

The Common Units were sold at a price of $1.63 per unit and the Prefunded Warrants were sold at a price of $1.6299 per unit.

The Prefunded Warrants are immediately exercisable and may be exercised at any time until all the Prefunded Warrants are exercised in full. As of September 30, 2024, all of the prefunded Warrants have been exercised.

Upon stockholder approval of the issuance of Class C Warrants on August 21, 2024, the Class C Warrants, which had an initial exercise price of $1.96 per share of common stock, were adjusted to be exercisable at an exercise price of $0.326 per share (representing 20% of the Nasdaq Minimum Price), and the number of shares issuable upon exercise were proportionately adjusted to 68,629,291 shares such that the aggregate exercise price remained unchanged. The Class C Warrants may be exercised at any time for a period of five (5) years following the first exercisable date. In addition, subject to certain exemptions, if we sell, enter into an agreement to sell, or grant any option to purchase, or sell, enter into an agreement to sell, or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any shares of common stock, for a consideration per share less than the exercise price of the Class C Warrants then in effect, the exercise price of the Class C Warrants will be reduced to the lower of such price or the lowest volume weighted average price (VWAP) during the five (5) consecutive trading days immediately following such dilutive issuance or announcement thereof.

The Class D Warrants are immediately exercisable at an exercise price of $0.0001 per share of common stock and may be exercised at any time for a period of five (5) years following the date of issuance. Upon stockholder approval of issuance of Class D Warrants on August 21, 2021, the number of shares of common stock issuable under the Class D Warrants increased to four shares per warrant for the remaining unexercised Class D Warrants as the weighted average price of our common stock over a rolling five (5)-trading day period fell below $0.326 per share (representing 20% of the Nasdaq Minimum Price) following the issuance date. As of November 4, 2024, Class D Warrants to purchase 821,250 shares of common stock at an exercise price of $0.0001 per share remained outstanding.

Pursuant to an engagement letter dated June 6, 2024, (the "Engagement Letter") by and between the Company and Aegis Capital Corp. (the "Aegis"), the Company paid Aegis a total cash fee of $743,750 equal to 8.5% of the gross proceeds received in the June 2024 Offering.

January 2024 Common Stock Warrants, January 2024 Placement Agent Warrants and January 2024 Prefunded Warrants

On January 2, 2024, the Company sold in a public offering (such transaction, the "January 2024 Offering") (i) 67,221 shares of the Company's common stock, and (ii) prefunded warrants to purchase up to an aggregate 269,318 shares of common stock (the January 2024, "Prefunded Warrants"). The shares and January 2024 Prefunded Warrants were sold together with warrants to purchase up to an aggregate of 336,539 shares of common stock at an exercise price of $10.40 per share (the "January 2024 Warrants"). The combined public offering price was $10.40 per share of common stock and related January 2024 Warrant and $10.3992 per January Prefunded Warrant and related January 2024 Warrant.

The January 2024 Prefunded Warrants were immediately exercisable and could be exercised at any time until all of the Prefunded Warrants are exercised in full. As of September 30, 2024, all of the January 2024 Prefunded Warrants had been exercised, and none remained outstanding.

The January 2024 Warrants became exercisable immediately upon issuance for a period of five years following the date of issuance.

Pursuant to an engagement letter, dated as of August 7, 2023, as amended October 11, 2023 (the "Placement Agent Engagement Letter"), by and between the Company and the H.C. Wainwright & Co., LLC, or the placement agent, the Company paid the placement agent a total cash fee of $245,000 equal to 7.0% of the gross proceeds received in the January 2024 Offering. The Company also paid the placement agent in connection with the January Offering a management fee of $35,000 equal to 1.0% of the gross proceeds raised in the January 2024 Offering and certain expenses incurred in connection with the January Offering. In addition, the Company issued to the placement agent, warrants to purchase up to an aggregate 23,558 shares of common stock (the "January 2024 Placement Agent Warrants"), which represents 7.0% of the aggregate number of shares of common stock and Prefunded Warrants sold in the January 2024 Offering. The January 2024 Placement Agent Warrants have substantially the same terms as the January 2024 Warrants, except that the January 2024 Placement Agent Warrants have an exercise price equal to $13.00, or 125% of the offering price per share of common stock and related January 2024 Warrant sold in the January Offering and expire on the fifth anniversary from the date of the commencement of sales in the January 2024 Offering.

6. STOCK COMPENSATION

Stock Incentive Plans

In 2018, the Company adopted the 2018 Stock Incentive Plan (the "2018 Plan") for employees, consultants, and directors. The 2018 Plan, which is administered by the Company's board of directors, permits the Company to grant incentive and nonqualified stock options for the purchase of common stock, and restricted stock awards. The maximum number of shares reserved for issuance under the 2018 Plan is 3,934. At September 30, 2024, there were 1,639 shares available for grant under the 2018 Plan.

On July 6, 2021, the Company's board of directors and stockholders approved and adopted the Bluejay Diagnostics, Inc. 2021 Stock Plan (the "2021 Plan"). A total of 12,250 shares of common stock were approved to be initially reserved for issuance under the 2021 Stock Plan. At September 30, 2024, there were 5,047 shares available for grant under the 2021 Plan.

Stock Award Activity

The following table summarizes the status of the Company's non-vested restricted stock awards for the nine months ended September 30, 2024:

	Non-vested Restricted Stock Awards	
	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2023	984	$ 87.68
Granted	-	-
Vested	922	79.62
Forfeited	-	-
Outstanding at September 30, 2024	62	$ 206.40

In February 2023, the Company issued 2,342 fully vested restricted stock units to certain employees in lieu of cash to satisfy their 2022 accrued bonuses of $164,860. Of the 2,342 restricted stock units issued, 818 shares were withheld for tax liabilities with a fair value of $57,588. The number of restricted stock unit awards issued was determined based on the approved bonus amount divided by the market price of the Company's common stock on the date of grant.

Stock Option Plan Summary

The following is a summary of stock option activity for the nine months ended September 30, 2024:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2023	3,721	$ 292.08	6.5	$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Cancelled and forfeited	-	-	-	-
Outstanding at September 30, 2024	3,721	$ 292.08	6.0	$ -
Exercisable at September 30, 2024	3,276	$ 292.08	5.8	$ -

There were no options granted during the nine months ended September 30, 2024

The weighted average grant date fair value of options granted during the nine months ended September 30, 2023 was $70.40 per share. The Company calculated the grant-date fair value of stock option awards granted during the nine months ended September 30, 2023 using the Black-Scholes model with the following assumptions:

Risk-free interest rate	3.63%
Expected dividend yield	0.00%
Volatility factor	108.78%
Expected life of option (in years)	6.0

Stock-Based Compensation Expense

For the three- and nine-months ended September 30, 2024 and 2023, the Company recorded stock-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 3,911	$ 9,393	$ 13,276	$ 54,389
General and administrative	881	(30,275)	9,400	157,971
Sales and marketing	-	(21,600)	-	(7,550)
Total stock-based compensation	$ 4,792	$ (42,482)	$ 22,676	$ 204,810

At September 30, 2024, there was approximately $5,200 of unrecognized compensation expense related to non-vested stock option awards that are expected to be recognized over a weighted-average period of 0.65 years. At September 30, 2024, there was approximately $3,000 of unrecognized compensation expense related to non-vested restricted stock awards that are expected to be recognized over a weighted-average period of 0.69 years.

7. RELATED PARTY TRANSACTIONS

NanoHybrids, LLC

In December 2021, the Company entered into an agreement with NanoHybrids, LLC ("NanoHybrids") to utilize the Company's research and development staff and laboratory facility when available to perform work for NanoHybrids. Any hours worked by Company employees for NanoHybrids are billed to NanoHybrids at a bill rate of the respective employee's fully burdened personnel cost plus 10%. Additionally, the Company may purchase certain lab supplies for NanoHybrids and rebill these costs to NanoHybrids. NanoHybrids is majority owned by the Company's Chief Technology Officer. The table below summarizes the amounts earned and received from NanoHybrids as of and for the three and nine month periods ended September 30, 2024 and 2023, and balances due as of September 30, 2024 and December 31, 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Income from NanoHybrids included in other income	$ 8,315	-	$ 112,515	$ 136,773
Cash receipts from NanoHybrids	$ 30,609	-	$ 145,469	$ 156,504

	As of	
	September 30, 2024	December 31, 2023
Amounts receivable from NanoHybrids included in Prepaid expenses and other current assets	$ 8,315	$ 41,269

8. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at September 30, 2024 and December 31, 2023:

	Depreciable lives	September 30, 2024	December 31, 2023
Construction-in-process		$ 1,358,253	$ 1,052,822
Furniture, fixtures, and equipment	3-5 years	141,164	141,164
Software	3-5 years	4,457	4,457
Lab equipment	3-5 years	1,287,783	1,287,783
Leasehold improvements	Shorter of useful life or life of lease	43,231	43,231
		2,834,888	2,529,457
Less: accumulated depreciation		(1,300,257)	(1,243,716)
Property and equipment, net		$ 1,534,631	$ 1,285,741

The Company reviews long-lived assets for impairment when events, expectations, or changes in circumstances indicate that the asset's carrying value may not be recoverable. As a result of this review in 2023, the Company revised the useful life of certain lab equipment in the first quarter of 2023 due to a change in expectations of the time the equipment will be used which resulted in approximately $382,795 of additional depreciation recorded in the twelve months ended December 31, 2023.

9. LEASES

The Company has lease arrangements for office, laboratory space and copiers. A summary of supplemental lease information is as follows:

	Nine Months Ended	
	September 30, 2024	September 30, 2023
Weighted average remaining lease term – operating leases (in years)	2.4	3.1
Weighted average remaining lease term – finance leases (in years)	3.3	4.3
Weighted average discount rate	7.0%	7.0%
Operating cash flows from operating leases	$ 132,642	$ 130,692
Operating cash flows from finance leases	$ 3,605	$ 3,605

A summary of the Company's lease assets and liabilities are as follows (1):

	September 30, 2024	December 31, 2023
Operating lease right-of-use asset	$ 227,495	$ 333,267
Finance lease asset – property & equipment, net	11,604	15,152
Total lease assets	$ 239,099	$ 348,419
Current portion of operating lease liability	$ 111,453	$ 162,990
Current portion of finance lease liability included in accrued expenses	4,807	4,807
Non-current portion of operating lease liabilities	130,199	189,987
Non-current portion of finance lease liabilities included in other non-current liabilities	9,530	12,321
Total lease liabilities	$ 255,989	$ 370,105

(1) Excludes an operating lease extension entered into on October 7, 2024 covering the period December 1, 2024 through February 28, 2025 with minimum lease payments totaling $19,886.

A summary of the Company's estimated operating lease payments are as follows:

Year	
2024 (1)	$ 36,453
2025	100,000
2026	100,000
2027	25,000
2028	-
Thereafter	-
Total future lease payments	261,453
Less: Imputed interest	19,801
Present value of lease liability	$ 241,652

(1) Excludes the nine months ended September 30, 2024.

10. COMMITMENTS AND CONTINGENCIES

Minimum Royalties

As required under the License Agreement (see Note 3), following the first sale of Cartridges, the Company will make royalty payments to Toray equal to 7.5% of the net sales of the 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. There were no sales of or revenues from the Cartridges through September 30, 2024.

Indemnification

The Company has certain agreements with service providers with which it does business that contain indemnification provisions pursuant to which the Company typically agrees to indemnify the party against certain types of third-party claims. The Company accrues for known indemnification issues when a loss is probable and can be reasonably estimated. The Company would also accrue for estimated incurred but unidentified indemnification issues based on historical activity. As the Company has not incurred any indemnification losses to date, there were no accruals for or expenses related to indemnification issues for any period presented.

11. SUPPLEMENTAL BALANCE SHEET INFORMATION

Prepaid expenses and other current assets consist of the following:

	September 30, 2024	December 31, 2023
Prepaid insurance	$ 591,935	$ 136,342
Vendor prepayments	193,708	558,959
Prepaid other	26,302	51,962
Total prepaid expenses and other current assets	$ 811,945	$ 747,263

Accrued expenses and other current liabilities consist of the following:

	September 30, 2024	December 31, 2023
Accrued personnel costs	$ 143,449	$ 566,087
Goods received but unpaid	-	78,579
Accrued expenses for CFO separation agreement	-	160,000
Accrued legal fees	83,269	157,670
Accrued clinical trial expenses	162,791	-
Accrued board of director fees and other	231,635	154,575
Total accrued expenses and other current liabilities	$ 621,144	$ 1,116,911

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Form 10-Q. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Form 10-Q.

Overview

We are a clinical-stage medical diagnostics company developing rapid tests using whole blood on our Symphony platform ("Symphony") to improve patient outcomes in critical care settings. Our Symphony technology platform is an exclusively licensed, patented system that consists of a mobile device and single-use test cartridges that if cleared, authorized, or approved by the U.S. Food and Drug Administration ("FDA"), can provide a solution to a significant market need in the United States. Clinical trials indicate Symphony produces results in less than 20 minutes for intensive care units and emergency rooms, where rapid and reliable results are required.

Since inception we have incurred net losses from operations each year and we expect to continue to incur losses for the foreseeable future. We incurred net losses of approximately $1.5 million and $6.3 million for the three and nine months ended September 30, 2024. We had an accumulated deficit of approximately $33.2 million as of September 30, 2024.

As further described below under "Liquidity and Going Concern Uncertainty" as of September 30, 2024, the Company possessed cash and cash equivalents of approximately $5.8 million, while having current liabilities of approximately $1.0 million. During the nine months ended September 30, 2024, the Company's net cash used in operating activities was approximately $6.1 million. The Company expects that it will need to raise additional capital in the next twelve months to continue as a going concern, and absent such funding, cash resources will be sufficient to fund its operations only through the first quarter of 2025.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 551,655	$ 1,397,318	$ 2,917,674	$ 4,428,123
General and administration	809,199	963,534	2,759,817	3,213,614
Sales and marketing	753	(19,619)	7,481	282,756
Total operating expenses	1,361,607	2,341,233	5,684,972	7,924,493
Operating loss	(1,361,607)	(2,341,233)	(5,684,972)	(7,924,493)
Interest expense	(190,610)	-	(822,299)	-
Other income	70,258	43,235	221,467	273,347
Other income (expense), net	(120,352)	43,235	(600,832)	273,347
Net loss	$ (1,481,959)	$ (2,297,998)	$ (6,285,804)	$ (7,651,146)

Research and Development

Research and development expenses for the three months ended September 30, 2024 were approximately $0.6 million as compared to approximately $1.4 million for the same period in 2023. The decrease in research and development expenses was primarily due to a reduction in technology transfer efforts which offset increased clinical trial expenses. We expect future research and development expenses to be focused on costs specifically associated with our clinical trial program supporting our regulatory strategy, technology transfer efforts and any necessary manufacturing improvements.

General and Administrative

General and administrative expenses for the three months ended September 30, 2024, were approximately $0.8 million as compared to approximately $1.0 million for the comparable period in 2023. The minor decrease in general and administrative expenses is due to continued efforts to preserve capital by limiting our investment in infrastructure and reducing professional services 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

Sales and marketing expenses for the three months ended September 30, 2024 were $753 as compared to $(19,619) for the comparable period in 2023. The low sales and marketing expenses in 2024 are due to a reduction in spending in all sales and marketing efforts and the negative 2023 amount is related to the cancellation and forfeiture of equity awards by terminated personnel.

Other Income (expense), net

Other income (expense), net for the three months ended September 30, 2024, was $(120,352) of expense as compared to $43,235 of income for the same periods in 2023. The decrease in other income (expense), was primarily due to higher interest expense incurred associated with our notes payable under the Bridge Note Financing.

Liquidity and Going Concern Uncertainty

Our operations to date have been funded primarily through equity financings. As of September 30, 2024, the Company had cash and cash equivalents of approximately $5.8 million and current liabilities of approximately $1.0 million. During the nine-month period ended September 30, 2024, the Company's net cash used in operating activities was approximately $6.1 million. The future viability of the Company is largely dependent on its ability to raise additional capital to finance its operations. The Company expects that it will need to raise additional capital within the next twelve months to continue its operations as the current, cash resources will be sufficient to fund its operations through the first quarter of 2025. Although the Company has been able to raise capital in the past, there is no assurance that it will be successful in obtaining additional financing on terms acceptable to the Company, if at all. In addition, recent fundraising by the Company has resulted in very high ownership dilution to shareholders, and given the Company's current market capitalization and financing needs, it is likely that future fundraising may also be highly dilutive. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development program, product development or commercialization efforts, which could adversely affect its business prospects.

We continue to develop the Symphony device and its first test for the measurement of IL-6, including conducting clinical trials to obtain additional data to support a submission to obtain FDA clearance of the Symphony device. However, our ability to continue these activities and continue operations (over the next twelve months) is dependent on the Company obtaining additional capital. If we fail to obtain additional financing within twelve months, we could be forced to abandon such activities entirely, with the possible loss of such properties or assets.

There can be no assurance that such additional capital will be available on a timely basis or on acceptable terms. We currently do not have any contracts or commitments for additional financing. In addition, any additional equity financing may involve substantial dilution to the Company's existing stockholders.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented.

	Nine Months Ended September 30,	
	2024	2023
Cash proceeds (used in) provided by:		
Operating activities	$ (6,081,083)	$ (5,536,393)
Investing activities	(305,658)	(616,272)
Financing activities	9,933,966	1,114,612
Net increase (decrease) in cash and cash equivalents	$ 3,547,225	$ (5,038,053)

Net cash used in operating activities

During the nine months ended September 30, 2024, we used approximately $6.1 million in cash for operating activities, an increase of approximately $545,000 as compared to the same period in 2023. The increase is primarily driven by the timing of payments made by the Company to their vendors when comparing the two periods.

Net cash used in investing activities

During the nine months ended September 30, 2024, we used approximately $306,000 in cash for investing activities, a decrease of approximately $311,000 as compared to the same period in 2023. The decrease in net cash used in investing activities was due to limited purchasing of manufacturing equipment.

Net cash provided by financing activities

During the nine months ended September 30, 2024, we raised approximately $9.9 million in cash through financing activities, an increase of approximately $8.8 million as compared to the same period in 2023. The increase in net cash generated by financing activities was due our public offering on January 2, 2024, the Bridge Note Financing in June 2024 and our public offering on June 28, 2024 as compared to our private placement of common stock in August 2023.

Recently Adopted Accounting Standards

See Note 2 to our condensed consolidated financial statements (under the caption “Recently Adopted Accounting Standards”).

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We are using the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of IPO (November 2021), (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (ii) the date on which we have issued more than $1 billion in non-convertible debt securities during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

JOBS Act Accounting Election

The JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We have implemented all new accounting pronouncements that are in effect and may impact our financial statements and we do not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on our financial position or results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as Amended (the "Exchange Act") and are not required to provide the information required under this item.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures and Changes in Internal Control over Financial Reporting

We conducted an evaluation under the supervision and with the participation of our management, including our President and Chief Executive Officer (who serves as our principal executive officer and principal financial officer), regarding the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on this evaluation, our President and Chief Executive Officer concluded that our disclosure controls and procedures were effective as of September 30, 2024. We continue to review our disclosure controls and procedures and may from time to time make changes aimed at enhancing their effectiveness and ensuring that our systems evolve with our Company's business. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

(b) Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. We are not able to estimate an aggregate amount or range of reasonably possible losses for those legal matters for which losses are not probable and estimable. We have insurance policies covering potential losses where such coverage is cost effective.

We are not at this time involved in any legal proceedings.

Item 1A. Risk Factors

For a discussion of potential risks or uncertainties, see "Risk Factors" in the Company's 2023 annual report on Form 10-K on file with the SEC. The following disclosures supplement such Risk Factors, and should be read in conjunction therewith:

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception, do not currently generate any operating income, and will continue to incur losses as we work to obtain product approval, and thus we may never achieve or maintain profitability.

We incurred substantial losses of approximately $10.0 million and $9.3 million for fiscal years 2023 and 2022, respectively, and approximately $6.3 million for the nine months ended September 30, 2024, and from our inception through September 30, 2024, we had an accumulated deficit of approximately $33.2 million. We do not currently generate any operating income. As of September 30, 2024, we had cash and cash equivalents of approximately $5.8 million, and current liabilities of approximately $1.0 million. We expect that our net cash used in operating activities will continue to be negative as we continue to conduct clinical trial work and, if such trials are successful, begin preparation of an FDA submission. These raise substantial doubt with respect to our ability to continue as a going concern. The Company expects that it will need to raise additional capital to continue to fund its operations, and absent such funding, it will likely run out of available cash resources in the first quarter of 2025. If we are unable to obtain such financing, or otherwise consummate strategic alternatives, we may be required to further delay our FDA regulatory strategy, and to delay or reduce the scope of our clinical trials, research or development programs, commercialization efforts or manufacturing commitments and capacity. Such inability to obtain additional financing when needed could have a material adverse effect on our business, results of operations, cash flow, financial condition and prospects.

Our failure to become and remain profitable could depress the value of our common stock and impair our ability to raise capital, expand our business, maintain our development efforts, or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2023, included an emphasis of matter paragraph stating that our recurring losses from operations and continued cash outflows from operating activities raised substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this going concern uncertainty and have been prepared under the assumption that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we are unable to continue as a going concern, we may be forced to liquidate our assets which would have an adverse impact on our business and developmental activities. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. The reaction of investors to the inclusion of a going concern statement by our independent registered public accounting firm and our potential inability to continue as a going concern may materially adversely affect our stock price and our ability to raise new capital.

We will need to raise additional funding to fund our working capital needs. Additional financing may not be available on acceptable terms, or at all.

Failure to obtain additional capital may force us to limit or terminate our operations.

We expect that the net proceeds of the public offering we consummated in June 2024 will not be sufficient for us to fund the working capital needs of our business beyond first quarter of 2025. We intend to continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Additional funding may not be available to us on acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, we may be required to further delay our FDA regulatory strategy, and to delay or reduce the scope of our clinical trials, research or development programs, commercialization efforts or manufacturing commitments and capacity. Such inability to obtain additional financing when needed could have a material adverse effect on our business, results of operations, cash flow, financial condition and prospects.

Risks Related to Product Development and Regulatory Approval

Ongoing materials, manufacturing and quality control issues could negatively affect our timeline for the FDA submission of Symphony.

We are experiencing a limited supply of critical materials, manufacturing and quality control issues for our test cartridges that, until addressed, will negatively affect our timeline for the FDA submission of Symphony. We are working with Toray, our licensing and cartridge intermediate supplier, to address these issues. In particular, several individual components in our product may need to be replaced or validated due to limited supply or discontinuation (including the antibody used in the product). In addition, we are working to correct several other accuracy and precision issues related to the manufacturing of the Symphony product (including related to shelf-life stability). At the present time, we expect that these issues will likely delay our ability to complete the testing, and that they will prevent us from submitting an FDA application within the next 18 months.

Our ability to engage in and complete the activities needed for an FDA submission will be contingent upon us addressing these and other challenges, including possessing and/or raising sufficient capital, remaining a going concern, and producing product capable of supporting our product requirements and meeting analytical validation, clinical validation. The delays described above delay, coupled with our lack of cash resources, could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Common Stock and Our Recently Completed Public Offering

Sales of substantial amounts of our securities in the public market could depress the market price of our common stock.

Our common stock is listed for trading on the Nasdaq Capital Market. If our stockholders sell substantial amounts of our common stock in the public market, including the shares of common stock issuable upon the exercise of the June 2024 Prefunded Warrants, Class C Warrants and Class D Warrants issued in the public offering that we consummated in June 2024, and shares issued as consideration in any future acquisitions, or the market perceives that such sales may occur, the market price of our securities could fall and we may be unable to sell our securities in the future.

Although our common stock is listed on the Nasdaq Capital Market, the exchange could subsequently delist our common stock if we fail to comply with ongoing listing standards.

Our common stock currently is listed for quotation on the Nasdaq Capital Market. We are required to meet specified financial requirements in order to maintain such listing, including a requirement that the bid price for our common stock remain above $1.00, and that the market value of our publicly held securities be at least $1 million.

On February 28, 2024, we received a notification letter from the Nasdaq's Listing Qualifications Staff notifying us that the closing bid price for our common stock had been below $1.00 for the previous 30 consecutive business days and that we therefore are not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). The notification has no immediate effect on the listing of our common stock on the Nasdaq Capital Market.

On August 28, 2024, at the Company's request, Nasdaq's Listing Qualifications Staff notified the Company that it has extended the time for the Company to regain compliance with the minimum bid price requirement until February 24, 2025. To regain compliance, the closing bid price of our common stock must be at least $1.00 or higher for a minimum of ten consecutive business days, and in such case, Nasdaq will provide us with written confirmation of compliance. If we are not able to cure the deficiency during this compliance period, Nasdaq will provide written notice to us that our common stock will be subject to delisting. In the event of such notification, we may appeal Nasdaq's determination to delist its securities, but there can be no assurance that Nasdaq would grant our request for continued listing.

We intend to take all reasonable measures available to us to achieve compliance to allow for continued listing on the Nasdaq Capital Market. However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria. On June 20, 2024, we effected a reverse stock split of our shares of common stock at a ratio of 1-for-8, however, our common stock did not remain above a trading price of $1.00 following such reverse stock split. If our common stock does not regain compliance with the minimum price requirement during the remaining compliance period, we may need to affect a further reverse stock split with the intent that the per-share trading price becomes greater than $1.00 per share on a sustained basis sufficient to regain compliance with the applicable Nasdaq requirements. On October 23, 2024, at a special meeting of stockholders, the Company's stockholders approved a proposed amendment to the Company's certificate of incorporation to effect a reverse stock split of the Company's outstanding shares of common stock by one of several fixed ratios (1-for-20, 1-for 25, 1-for-30, 1-for-35, 1-for-40, 1-for-45 and 1-for-50). The Company's board of directors is considering whether to proceed with implementation of the reverse stock split, including the timing and ratio thereof.

As of the close of business on November 4, 2024, the market value of our publicly held common stock (which is our only outstanding class of capital stock) was approximately $2.0 million, and the most recent closing price of our common stock on the Nasdaq Capital Market was $0.729 per share. If the market value of our publicly held common stock declines below $1 million, or the closing price of our common stock declines to $0.10 per share or less for 10 consecutive trading days, we would also be subject to Nasdaq delisting proceedings on that basis. Nasdaq's staff also maintains discretionary authority under its listing rules to delist companies whose capital structure or public offerings raise public interest and investor protection concerns, including as a result of highly dilutive issuances, and it is possible that Nasdaq could assert that past offerings that we have consummated, or future offerings we may consummate, raise such concerns.

If our common stock is delisted, we may seek to have our common stock quoted on an over-the-counter marketplace, such as on the OTCQX. The OTCQX is not a stock exchange, and if our common stock trades on the OTCQX rather than a securities exchange, there may be significantly less trading volume and analyst coverage of, and significantly less investor interest in, our common stock, which may lead to lower trading prices for our common stock

Any potential delisting of our common stock from the Nasdaq Capital Market may have materially adverse consequences to our stockholders, including:

- a reduced market price and liquidity with respect to our shares of common stock, which could make our ability to raise new investment capital more difficult;
- limited dissemination of the market price of our common stock;
- limited news coverage;
- limited interest by investors in our common stock;
- volatility of the prices of our common stock, due to low trading volume;
- our common stock being considered a "penny stock," which would result in broker-dealers participating in sales of our common stock being subject to the regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act;
- increased difficulty in selling our common stock in certain states due to "blue sky" restrictions; and
- limited ability to issue additional securities or to secure additional financing.

Provisions of the Class C Warrants we sold in June 2024, as well as the previously issued August 2023 Warrants and January 2024 Warrants, could discourage an acquisition of us by a third-party.

Certain provisions of the Class C Warrants and Class D Warrants we sold in June 2024, as well as the August 2023 Warrants and January 2024 Warrants, could make it more difficult or expensive for a third-party to acquire us. The Class C Warrants, August 2023 Warrants and January 2024 Warrants each prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the applicable warrants. These and other provisions of the Class C Warrants, August 2023 Warrants and January 2024 Warrants could prevent or deter a third-party from acquiring us even where the acquisition could be beneficial to you.

The Class C Warrants may have an adverse effect on the market price of our common stock and make it more difficult to affect a business combination.

To the extent we issue shares of common stock to affect a future business combination, the potential for the issuance of a substantial number of additional shares of common stock upon exercise of the Class C Warrants could make us a less attractive acquisition vehicle in the eyes of a target business. Such Class C Warrants, when exercised, will increase the number of issued and outstanding shares of common stock and reduce the value of the shares issued to complete the business combination. Accordingly, the Class C Warrants may make it more difficult to effectuate a business combination or increase the cost of acquiring a target business. Additionally, the sale, or even the possibility of a sale, of the shares of common stock underlying the Class C Warrants could have an adverse effect on the market price for our securities or on our ability to obtain future financing. If and to the extent the Class C Warrants are exercised, you may experience dilution to your holdings.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on July 21, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on July 21, 2023).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on May 14, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on May 14, 2024).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on June 17, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on June 17, 2024).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on August 23, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on August 28, 2024).
3.6	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
3.7	Amendment No. 1 to Amended and Restated Bylaws of Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-41031) filed on October 16, 2024).
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*(1)	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*(1)	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

(1) The certifications on Exhibit 32 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Bluejay Diagnostics, Inc.

SIGNATURE	TITLE	DATE
/s/ Neil Dey Neil Dey	President, Chief Executive Officer and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	November 7, 2024

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, Neil Dey, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Bluejay Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 7, 2024

By: /s/ Neil Dey
Neil Dey
President and Chief Executive Officer
(Principal executive officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Neil Dey, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Bluejay Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 7, 2024

By: /s/ Neil Dey
Neil Dey
President and Chief Executive Officer
(Principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Bluejay Diagnostics, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The quarterly report on Form 10-Q for the quarter ended September 30, 2024 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 7, 2024

By: /s/ Neil Dey
Neil Dey
President and Chief Executive Officer
(Principal executive officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Bluejay Diagnostics, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The quarterly report on Form 10-Q for the quarter ended September 30, 2024 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 7, 2024

By: /s/ Neil Dey
Neil Dey
President and Chief Executive Officer
(Principal financial and accounting officer)