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 March 31, 2025

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 1,494,182 shares of common stock outstanding at May 12, 2025.

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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 of 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 of 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)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,116,103	$ 4,301,945
Prepaid expenses and other current assets	456,079	596,938
Total current assets	3,572,182	4,898,883
Property and equipment, net	1,495,094	1,513,495
Operating lease right-of-use assets	176,296	209,788
Other non-current assets	34,435	35,257
Total assets	$ 5,278,007	$ 6,657,423
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 519,524	$ 145,122
Operating lease liability, current	100,002	113,260
Accrued expenses and other current liabilities	697,151	551,986
Total current liabilities	1,316,677	810,368
Operating lease liability, non-current	87,372	108,989
Other non-current liabilities	7,582	8,567
Total liabilities	1,411,631	927,924
Commitments and Contingencies (See Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 554,012 shares issued and outstanding at March 31, 2025 and December 31, 2024	55	55
Additional paid-in capital	40,399,540	40,398,228
Accumulated deficit	(36,533,219)	(34,668,784)
Total stockholders' equity	3,866,376	5,729,499
Total liabilities and stockholders' equity	$ 5,278,007	$ 6,657,423

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-50 reverse stock split effective November 18, 2024 and 1-for-8 reverse stock split effective June 20, 2024.

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

	Three Months Ended March 31	
	2025	**2024**
Operating expenses:		
Research and development	$ 784,800	$ 1,334,797
General and administrative	1,104,117	1,086,884
Sales and marketing	-	6,424
Total operating expenses	1,888,917	2,428,105
Operating loss	(1,888,917)	(2,428,105)
Other income (expense):		
Interest income	17,801	30,091
Other income, net	6,681	69,549
Total other income (expense), net	24,482	99,640
Net loss	$ (1,864,435)	$ (2,328,465)
Net loss per share - Basic and diluted	$ (3.37)	$ (394.76)
Weighted average common shares outstanding:		
Basic and diluted	554,012	5,898

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-50 reverse stock split effective November 18, 2024 and 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, 2024	554,012	$ 55	$ 40,398,228	$ (34,668,784)	$ 5,729,499
Stock-based compensation expense	-	-	1,312	-	1,312
Net loss	-	-	-	(1,864,435)	(1,864,435)
Balance at March 31, 2025	**554,012**	**$ 55**	**$ 40,399,540**	**$ (36,533,219)**	**$ 3,866,376**

	Stockholders' Equity				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2023	3,098	$ -	$ 29,845,838	$ (26,950,990)	$ 2,894,848
Stock-based compensation expense	-	-	11,874	-	11,874
Issuance of common stock in connection with January 2024 Offering	3,623	-	2,788,969	-	2,788,969
Net loss	-	-	-	(2,328,465)	(2,328,465)
Balance at March 31, 2024	**6,721**	**$ -**	**$ 32,646,681**	**$ (29,279,455)**	**$ 3,367,226**

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-50 reverse stock split effective November 18, 2024 and 1-for-8 reverse stock split effective June 20, 2024.

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

	Three Months Ended March 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (1,864,435)	$ (2,328,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	18,401	19,714
Stock-based compensation expense	1,312	11,874
Amortization of right-of-use asset	33,492	34,612
Changes in operating assets and liabilities:		
Deferred offering costs	-	265,081
Prepaid expenses and other current assets	140,859	(41,315)
Other non-current assets	822	3,448
Accounts payable	374,402	(219,649)
Accrued expenses and other current liabilities	110,290	(45,269)
Net cash used in operating activities	**(1,184,857)**	**(2,299,969)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	-	(35,433)
Net cash used in investing activities	**-**	**(35,433)**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, gross	-	3,500,000
Payment of issuance costs of common stock	-	(711,031)
Payment of finance lease	(985)	(914)
Net cash (used in) provided by financing activities	**(985)**	**2,788,055**
Increase (decrease) in cash and cash equivalents	(1,185,842)	452,653
Cash and cash equivalents, beginning of period	4,301,945	2,208,516
Cash and cash equivalents, end of period	$ 3,116,103	$ 2,661,169

See accompanying notes to condensed consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Bluejay Diagnostics, Inc. ("Bluejay" and/or the "Company") is a medical diagnostics company focused on improving patient outcomes in critical care settings. The Company is working on developing rapid tests using whole blood on its Symphony technology platform ("Symphony"), which consists of an analyzer and single-use protein detection cartridges that have a function of automatic stepwise feeding of reagent. The Company does not yet have regulatory clearance for Symphony, and it will need to receive regulatory authorization from the U.S. Food and Drug Administration (the "FDA") to be marketed as a diagnostic product in the United States. The Company has completed the development of the Symphony analyzer. The Company is planning to begin cartridge redevelopment either at an in-house facility or through a third-party contractor who would manage such redevelopment. Such redevelopment is intended to address several technical challenges to bring Symphony to a level consistent with necessary performance and quality requirements. After redevelopment, the Company plans to have manufacturing of the Symphony cartridges occur at a Contract Manufacturing Organization ("CMO"). To achieve its plan, the Company expects to need to raise at least $30 million of capital between the second quarter of 2025 and the end of the 2027 fiscal year, which the Company hopes to do in various tranches during this time period. The Company's current plan, subject to achieving necessary financing, is to begin testing of samples it is collecting as part of its ongoing SYMON-II clinical trial in mid-2027, with a goal of being in position to submit a 510(k) regulatory application to the FDA in the fourth quarter of 2027, with an objective of achieving FDA approval as early as the third quarter of 2028.

The Company's Symphony platform is a combination of Bluejay's intellectual property ("IP") and exclusively licensed and patented IP on the Symphony technology that the Company believes, if cleared, authorized, or approved by the FDA, can provide a solution to a significant market need in the United States. The Symphony device is designed to produce laboratory-quality results in 20 minutes in critical care settings, including Intensive Care Units ("ICUs") and Emergency Rooms ("ERs"), where rapid and reliable results are required.

The Company's first product candidate, the Symphony IL-6 test, is an immunoassay for the measurement of interleukin-6 (IL-6) to be used for the monitoring of disease progression in critical care settings. The Company is currently focused on pursuing the Symphony IL-6 test in the context of sepsis. IL-6 is a clinically established inflammatory biomarker, and is 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 Company believes that its Symphony IL-6 test, if ultimately successful and approved, could have the ability to consistently monitor this critical care biomarker with rapid results.

If the Company succeeds with the foregoing plan, in the future it hopes to develop additional tests for Symphony, including tests for myocardial infarction and congestive heart failure (cardiac biomarkers hsTNT and NT pro-BNP) as well as other tests using the Symphony platform.

The Company was incorporated under the laws of Delaware on March 20, 2015. Its headquarters are 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. The Company currently is not actively pursuing development of the ALLEREYE diagnostic test.

FDA Regulatory Strategy

The Company's current regulatory strategy is designed to support commercialization of Symphony in the United States pending marketing authorization from the FDA. In May 2023, the Company submitted a pre-submission application to the FDA presenting study designs to validate Symphony IL-6 for use with hospitalized sepsis patients. We participated in a pre-submission meeting with the FDA on August 11, 2023, and 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, the Company determined to proceed on this basis, which considers the FDA's feedback.

In the second quarter of 2024, the Company 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. 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. In the third quarter of 2024, we initiated SYMON-II pivotal clinical study to validate the findings of the SYMON-I pilot clinical study.

Using the data analysis from the SYMON-I pilot clinical study, the Company initiated the SYMON-II pivotal clinical study in the third quarter of 2024. 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. Patient enrollment started during the fourth quarter of 2024. The Company's goal is to use the Symphony IL-6 test to complete the testing in the SYMON-II clinical trial.

If the Company is able to complete the SYMON-II clinical study and the results are positive, the Company intends to use the data generated from SYMON-II to support a 510(k) application to the FDA. This application is currently expected to 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." The Company also plans to present the SYMON-I and SYMON-II results at future national scientific meetings and publish them in peer-reviewed journals. Subject to achieving needed funding and successfully addressing the technical challenges that are described above, the Company's goal is to be in position to submit a 510(k) regulatory application to the FDA in the fourth quarter of 2027, with an objective of achieving FDA approval as early as the third quarter of 2028.

Product Manufacturing

The Company plans to manufacture its analyzers through Sanyoseiko Co. Ltd. ("Sanyoseiko"), as a contract manufacturing organizations ("CMO"), and the Company has a contract with Sanyoseiko for this purpose.

Once redeveloped, the Company also plans to manufacture its cartridges through Sanyoseiko or another suitable CMO. The Company currently does not have a contract in place for the re-development or manufacture of the cartridges.

Sanyoseiko had been selected as the Company's CMO for the analyzers due to their core competencies in manufacturing and quality system recognized by the FDA. Sanyoseiko's facilities are located in Japan. The Company currently licenses the technology for the Symphony cartridges from Toray Industries, Inc. ("Toray"). The Company's license grants it exclusive global marketing rights, with the exception of Japan. Bluejay holds the rights to manufacture the analyzers.

Risks and Uncertainties

As noted above, Bluejay will be reliant upon CMOs to provide analyzers and, if and once redeveloped, cartridges, in sufficient quantity and quality to complete the validations for our FDA application. Our FDA application submission could be delayed if the Company encounters any material supply interruptions. In addition, there can be no assurance that we will be able to obtain necessary regulatory authorization for the manufacturing or marketing of the Symphony in the United States or elsewhere. There also can be no assurance that we will successfully complete any clinical evaluations necessary to receive regulatory approvals, or that the clinical study will demonstrate sufficient safety and effectiveness of the Symphony IL-6 test. The failure to adequately demonstrate the clinical performance of the Symphony IL-6 test could delay or prevent regulatory approval, which could prevent or result in delays to market launch and could materially harm our business.

In addition to the FDA regulatory strategy risks and uncertainties, the Company is subject to a number of risks similar to other companies in its industry, including rapid technological change, competition from larger biotechnology companies and dependence on key personnel. The Company is also impacted by inflationary pressures and global supply chain disruptions currently impacting many companies. Additional risk and uncertainties regarding the Company are described in "Part I – Item 1A. Risk Factors" of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Reverse Stock Splits and Increase to Authorized Capital

On July 21, 2023, the Company effected a reverse stock split of its shares of common stock at a ratio of 1-for-20 (the "July 2023 Reverse Stock Split"). On June 20, 2024, the Company effected a second reverse stock split of its shares of common stock at a ratio of 1-for-8 (the "June 2024 Reverse Stock Split"). On November 18, 2024, the Company effected a third reverse stock split of its shares of common stock at a ratio of 1-for-50 (the "November 2024 Reverse Stock Split" and, together with the July 2023 Reverse Stock Split and June 2024 Reverse Stock Split, the "Reverse Stock Splits"). As such, collectively, the Company's common stock has undergone reverse stock splits that have combined the shares on a 1-for-8,000 aggregate basis since July 2023. 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 these reverse stock splits.

On October 23, 2024, the stockholders of the Company approved and adopted an amendment to the Company's amended and restated certificate of incorporation, to increase the number of authorized shares of the Company's Common Stock to 250,000,000.

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 financial statements and related footnotes for the year ended December 31, 2024 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 March 31, 2025, its results of operations and cash flows for the three months ended March 31, 2025 and 2024, in accordance with US GAAP. The unaudited condensed consolidated financial statements do not include all of 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 months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2025, or any other interim period within this fiscal year.

Going Concern

The accompanying unaudited condensed consolidated financial statements for the three months ended March 31, 2025 and 2024 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.

The Company had cash and cash equivalents of $3,116,103 and current liabilities of $1,316,677 as of March 31, 2025. The Company has incurred net losses since its inception, has incurred negative cash flows from operations and has an accumulated deficit of $36,533,219 as of March 31, 2025. The Company expects that its net cash used in operating activities will continue to be negative over at least the next several years as it attempts to redevelop aspects of the Symphony cartridges and conducts clinical trial work and, if such redevelopment and trials are successful, begin preparation of an FDA submission. These financial results and financial position, and the Company's expected forward-looking outwork of significant negative cash flow in the future, raise substantial doubt with respect to its ability to continue as a going concern. As a result of the Company's lack of cash, it has slowed the timeline of its clinical trial work to preserve cash resources in the near-term, and the Company expects that this will delay its Symphony platform regulatory submission timeline until the fourth quarter of 2027, at the earliest, if it is even able to generate sufficient clinical trial results to support such a submission. If the Company fails to obtain additional material financing in the near-term, its clinical trials and targeted FDA submission timeline could be delayed further, and it could be forced to abandon such activities entirely and cease operations, with the possible loss of such properties or assets. If the Company is unable to obtain additional financing as it continues to generate negative cash flow, its board of directors could determine to cause the Company to undertake a process of liquidation under Chapter 7 of applicable U.S. bankruptcy laws, or otherwise seek other protection under such laws. In such event, the Company expects that holders of shares of its common stock would recoup little if any material value in such process. The Company currently estimates that the cash resources it possesses as of the date of this filing will be sufficient to fund its operations up to the third quarter of 2025.

These accompanying financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. SIGNIFICANT ACCOUNTING POLICIES

During the three months ended March 31, 2025, there were no changes to the significant accounting policies as described in the 2024 Audited Financial Statements. Certain 2024 financial statement balances have been reclassified to correspond with current year presentation.

Use of estimates

The preparation of financial statements in conformity with US 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.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in the Financial Accounting Standards Board, or the FASB, ASC, 480, Distinguishing Liabilities from Equity, or ASC 480, and ASC 815, Derivatives and Hedging, or ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. Finally, the Company determines if the warrants meet the definition of a derivative based on their contractual terms. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and at each balance sheet date thereafter. Changes in the estimated fair value of liability-classified warrants are recognized as a non-cash gain or loss on the consolidated statements of operations. The Company also evaluates if changes in contractual terms or other considerations would result in the reclassification of outstanding warrants from liabilities to stockholders' equity (or vice versa).

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 options outstanding under the Company's stock option plan, restricted stock units, 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 anti -dilutive are as follows (in common stock equivalent shares):

	March 31,	
Potentially Dilutive Securities Listing:	**2025**	**2024**
Options to purchase common stock	72	74
Restricted stock units	1	2
Warrants for common stock	660	679
Class A warrants for common stock	310	310
Class B warrants for common stock	9	9
5-Year warrants for common stock	6,730	6,730
Prefunded warrants for common stock	-	3,107
Class C warrants for common stock	1,372,586	-
Placement agent warrants	471	-

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

The Company depends on Toray's intellectual property for the Symphony cartridges upon which the Symphony platform relies. On October 6, 2020, the Company entered into a License and Supply Agreement ("License Agreement") with Toray, providing the Company with an exclusive global license with Toray, excluding Japan, to use their patents and know-how related to the Symphony detection cartridges for the manufacturing, marketing and sale of the products (as defined in the License Agreement). In exchange for the license, the Company committed to make two payments of $120,000 each, both of which were made in 2021. In addition, following the first sale of the cartridges after regulatory approval, the Company is obligated make royalty payments to Toray based on the net sales of the cartridges for the period that any underlying patents exist or five years after the first sale. Following the first sale after obtaining regulatory approval, the Company will make minimum annual royalty payments of $60,000 for the first year and $100,000 for each year thereafter, which shall be creditable against any royalties owed to Toray in such calendar year.

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 the Company's Symphony analyzers 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 payment percentage payable by the Company to Toray was 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 three-month periods ended March 31, 2025 and 2024.

The Company is planning to begin cartridge redevelopment either at an in-house facility or through a third-party contractor who would manage such redevelopment. Such redevelopment is intended to address several technical challenges to bring Symphony to a level consistent with necessary performance and quality requirements. After the cartridge redevelopment is completed, the Company plans to have the manufacturing process occur at an FDA-registered CMO, including for validation testing and commercial manufacturing. If Toray were to assert that the Company has not established a facility to manufacture the cartridges prior to the expiration of the supply agreement (which is currently expected to occur in October 2025), Toray could assert that the Company is in material breach of the license agreement and seek to terminate it as early as November 2025. If Toray sought to terminate the license, and was successful in doing so, the Company would lose access to certain technology required to produce the cartridges that the Symphony system relies on to function, which would likely result in a material adverse effect on the Company's commercialization efforts. The Company is in the process of negotiating an agreement with Toray to, among other things, clarify that Toray will not seek to terminate the license agreement in connection with the expiration of the supply agreement.

At March 31, 2025 and 2024, there were no amounts accrued related to the New Toray License Agreement or the License Agreement.

4. FINANCINGS

June 2024 Offering

On June 28, 2024, the Company sold in a public offering (the "June 2024 Offering"), (i) 11,541 common units (the "Common Units"), each consisting of one share of common stock, two Class C Warrants and one Class D Warrant and (ii) 95,815 prefunded units (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. The Common Units were sold at a price of $81.50 per unit and the Prefunded Warrants were sold at a price of $81.495 per unit. Aegis Capital Corp. ("Aegis" or, the "Underwriter") partially exercised its over-allotment option in respect to 13,573 Class C Warrants and 6,787 Class D Warrants (the "Over-Allotment Warrants"). As of December 31, 2024, all Prefunded Warrants had been exercised in full.

Pursuant to an engagement letter dated June 6, 2024, by and between the Company and 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.

The gross proceeds to the Company from the June 2024 Offering were $8,569,075. The Company incurred offering costs of $1,133,419.

May 2024 Bridge Note Financing

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 (the "Bridge Note"). As of December 31, 2024, a total of $1,176,470 was repaid to the NPA investor in full satisfaction of the Bridge Note. The difference between the Bridge 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 (the "SPA Notes"), and the collective issuance of 1,451 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 December 31, 2024, a total of $1,111,110 had been repaid to the SPA investors, in full satisfaction of the SPA Notes. The difference between the SPA Notes and the subscription amounts, initially recorded as a discount on the SPA 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 $807,797 for the year ended December 31, 2024, including debt issuance costs related to the NPA and SPA totaling $212,654.

January 2024 Offering

On January 2, 2024, the Company sold in a public offering (such transaction, the "January 2024 Offering") (i) 1,344 shares of the Company's Common stock, par value $0.0001 per share, and (ii) prefunded warrants to purchase up to an aggregate 5,386 shares of Common Stock (the "Prefunded Warrants"). The Shares and Prefunded Warrants were sold together with warrants to purchase up to an aggregate of 6,730 shares of Common Stock at an exercise price of $520.00 per share (the "January 2024 Warrants"). The combined public offering price was $520.00 per share of Common Stock and related January 2024 Warrant and $519.96 per Prefunded Warrant and related January 2024 Warrant.

As of December 31, 2024, all Prefunded Warrants had been exercised in full. The January 2024 Warrants were exercisable immediately and remain exercisable 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 "Amended Engagement Letter"), by and between the Company and 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 471 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 $650.00, 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.

The gross proceeds to the Company from the January 2024 Offering were $3,500,000. The Company incurred offering costs of $711,031.

5. WARRANTS

The following table summarizes information with regard to warrants outstanding at March 31, 2025:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
June 2024 Class C Warrants	1,372,586	Common Stock	$ 16.30	4.2
January 2024 Common Stock Warrants	6,730	Common Stock	$ 520.00	3.8
January 2024 Placement Agent Warrants	471	Common Stock	$ 650.00	3.8
August 2023 Common Stock Warrants	540	Common Stock	$ 2,896.00	3.4
August 2023 Placement Agent Warrants	36	Common Stock	$ 3,684.00	3.4
Class A Warrants	310	Common Stock	$ 56,000.00	1.6
Class B Warrants	9	Common Stock	$ 80,000.00	1.6
Other Pre-2024 Common Stock Warrants	84	Common Stock	$ 27,327.00	1.1

June 2024 Common Stock Warrants and June 2024 Underwriter Warrants

As a part of the June 2024 Offering, the Company issued 214,724 Class C Warrants and 107,362 Class D Warrants. The Underwriter partially exercised its over-allotment option with respect to 13,573 Class C Warrants and 6,787 Class D Warrants (the "Over-Allotment Warrants").

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 $98.00 per share of common stock, were adjusted to be exercisable at an exercise price of $16.30 per share (the "floor" price, which represented 20% of the "minimum price" under Nasdaq's listing rules on the date of pricing of the June 2024 Offering), and the number of shares of common stock issuable upon exercise were proportionately increased to 1,372,586 shares. In connection with the reset in the exercise price and number of shares issuable pursuant to the Class C Warrants, we recorded a deemed dividend of $9,282,075 based on the excess of the fair value of the modified Class C Warrants over the fair value of the Class C Warrants before the modification, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the three-months ended September 30, 2024. The Class C Warrants may be exercised at any time for a period of five (5) years following the date of stockholder approval in August 2024.

The Class D Warrants were immediately exercisable at an exercise price of $0.0001 per share of common stock for a period of five (5) years following the date of issuance. Upon stockholder approval of the issuance of the Class D Warrants on August 21, 2024, the number of shares of common stock issuable upon exercise 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 $16.30 per share (the "floor" price, which represented 20% of the "minimum price" under Nasdaq's listing rules on the date of pricing of the June 2024 Offering) following the issuance date. In connection with the reset in the number of shares issuable pursuant to the Class D Warrants, we recorded a deemed dividend of $3,940,978 based on the excess of the fair value of the modified Class D Warrants over the fair value of the Class D Warrants before the modification, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the three months ended September 30, 2024. As of December 31, 2024, all Class D Warrants had been exercised and none currently remain outstanding.

During 2024, the Company issued 435,377 shares of common stock upon exercise of the June 2024 Class D Warrants. The Class D Warrants were exercised on either a cash basis at $0.0001 per share exercise price or on a proportional cashless basis.

January 2024 Common Stock Warrants and January 2024 Placement Agent Warrants

As part of the January 2024 Offering, the Company issued 6,730 Common Stock Warrants with an exercise price of $520.00 per share and 471 Placement Agent Warrants with an exercise price of $650.00 per share. The January 2024 Warrants became exercisable immediately upon issuance for a period of five years following the date of issuance.

The Company's warrants were accounted for as equity classified financial instruments as they meet the requirements for equity classification under ASC 815, *Derivatives and Hedging*.

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 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 79. At March 31, 2025, there were 35 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 245 shares of common stock were approved to be initially reserved for issuance under the 2021 Stock Plan. At March 31, 2025, there were 101 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 three months ended March 31, 2025:

	Non-vested Restricted Stock Awards	
	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2024	1	$ 10,320
Granted	-	-
Vested	-	-
Forfeited	-	-
Outstanding at March 31, 2025	1	$ 10,320

The following is a summary of stock option activity for the three months ended March 31, 2025:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2024	72	$ 14,966	5.8	$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Cancelled and forfeited	-	-	-	-
Outstanding at March 31, 2025	72	$ 14,966	5.5	$ -
Exercisable at March 31, 2025	67	$ 14,966	5.4	$ -

There were no options granted during the three months periods ended March 31, 2025 and 2024.

Stock-Based Compensation Expense

For the three months ended March 31, 2025 and 2024, the Company recorded stock-based compensation expense as follows:

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 1,113	$ 4,845
General and administrative	199	7,029
Total stock-based compensation	$ 1,312	$ 11,874

At March 31, 2025, there was approximately $1,221 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 March 31, 2025, there was approximately $406 of unrecognized compensation expense related to non-vested restricted stock awards that are expected to be recognized over a weighted-average period of 0.44 years.

7. RELATED PARTY TRANSACTIONS

NanoHybrids, LLC

In December 2021, the Company entered into an agreement with NanoHybrids, LLC (“NanoHybrids”), an entity in which the Company’s Chief Technology Officer, Jason Cook, served as Chief Executive Officer of prior to joining Bluejay, to utilize the Company’s research and development staff and laboratory facility when available to perform work for NanoHybrids (the “Sharing and Services Agreement”). 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. Dr. Cook is the majority shareholder of NanoHybrids. The table below summarizes the amounts earned and due from NanoHybrids as of and for the three-month periods’ ended March 31, 2025 and 2024, and balances due as of March 31, 2025 and December 31, 2024:

	Three Months Ended March 31,	
	2025	2024
Income from NanoHybrids included in Other Income	$ 6,873	$ 73,591
Cash receipts from NanoHybrids	$ 14,564	$ 41,269

	As of	
	March 31, 2025	December 31, 2024
Amounts receivable from NanoHybrids included in Prepaids and Other Current Assets	$ 6,873	$ 14,564

On May 8, 2025, the Company entered into a settlement and release agreement with Nanohybrids that terminated the respective parties' obligations under the Sharing and Services Agreement, and memorialized that prior discussions between the parties regarding a potential sale of Nanohybrids to the Company (the "Strategic Transaction Discussions") were terminated. Under the terms of such agreement, the Company agreed to make payment of $50,000 to Nanohybrids and reimburse Nanohybrids for up to $30,000 in reasonable and documented attorneys' fees that Nanohybrids had previously incurred in connection with the Strategic Transaction Discussions. The Company and Nanohybrids (including Dr. Cook for this limited purpose) each also provided the other with releases related to the Sharing and Services Agreement and the Strategic Transaction Discussions.

Each of the foregoing agreements was approved in advance by the Audit Committee of the Company's Board of Directors.

8. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at March 31, 2025 and December 31, 2024:

	Depreciable lives	March 31, 2025	December 31, 2024
Construction-in-process		$ 1,351,179	$ 1,351,179
Furniture, fixtures, and equipment	3-5 years	135,785	136,312
Software	3-5 years	4,457	4,457
Lab equipment	3-5 years	173,268	173,268
Leasehold improvements	Shorter of useful life or life of lease	43,231	43,231
		1,707,920	1,708,447
Less: accumulated depreciation		(212,826)	(194,952)
Property and equipment, net		$ 1,495,094	$ 1,513,495

Construction in process consists of symphony cartridge manufacturing equipment. There are no commitments in place to complete construction in process as of March 31, 2025.

9. LEASES

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

	Three Months Ended	
	March 31, 2025	March 31, 2024
Weighted average remaining lease term – operating leases (in years)	2.0	2.7
Weighted average remaining lease term – finance leases (in years)	2.8	3.9
Weighted average discount rate – operating leases	7.0%	7.0%
Weighted average discount rate – finance leases	7.0%	7.0%
Operating cash flows from operating leases	$ 38,259	$ 44,214
Operating cash flows from finance leases	$ 217	$ 288

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

	March 31, 2025	December 31, 2024
Operating lease right-of-use asset	$ 176,296	$ 209,788
Finance lease asset – property & equipment, net	9,238	10,421
Total lease assets	$ 185,534	$ 220,209
Current portion of operating lease liability	$ 100,002	$ 113,260
Current portion of finance lease liability included in accrued expenses	4,807	4,807
Non-current portion of operating lease liabilities	87,372	108,989
Non-current portion of finance lease liabilities included in other non-current liabilities	7,582	8,567
Total lease liabilities	$ 199,763	$ 235,623

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

Year	Operating Lease
2025 (1)	$ 75,000
2026	100,000
2027	25,000
Thereafter	-
Total future lease payments	200,000
Less: Imputed interest	12,626
Present value of lease liability	$ 187,374

(1) Excludes the three months ended March 31, 2025

10. COMMITMENTS AND CONTINGENCIES

Minimum Royalties

As required under the License Agreement (see Note 3), following the first sale of cartridges, the Company will also 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 March 31, 2025.

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:

	March 31, 2025	December 31, 2024
Prepaid insurance	$ 353,071	$ 489,174
Vendor prepayments	-	21,946
Prepaid and other	103,008	85,818
Total prepaid expenses and other current assets	$ 456,079	$ 596,938

Accrued expenses and other current liabilities consist of the following:

	March 31, 2025	December 31, 2024
Accrued personnel costs	$ 147,148	$ 100,974
Accrued legal fees	143,350	48,860
Accrued clinical trial expenses	180,891	191,673
Accrued board of director fees	-	95,000
Accrued other	104,194	115,479
Accrued Delaware franchise tax	121,568	-
Total accrued expenses and other current liabilities	$ 697,151	$ 551,986

12. SUBSEQUENT EVENTS

April 2025 Private Placement

On April 7, 2025, the Company entered into inducement letter agreements (the "Inducement Letter Agreements") with certain existing holders (the "Holders") of the Company's Class C warrants, pursuant to which the Holders agreed to purchase an aggregate of 1,085,106 shares of the Company's common stock. The Class C warrants were originally issued to the Holders on June 28, 2024 for an exercise price of $98.00 per share and were subsequently reduced to $16.30 per share pursuant to stockholder approval on August 21, 2024. Pursuant to the Inducement Letter Agreements, the Holders agreed to exercise their Series C warrants at a reduced exercise price of $3.42 per share, and to purchase an equivalent number of new Class E warrants for an additional $0.125 per share. The Class E warrants have an exercise price of $3.42 per share and expire on April 8, 2030.

The transaction closed on April 8, 2025. The exercise of the Class C warrants resulted in the Company issuing 682,203 shares of Common Stock at closing and pre-funding of 402,903 shares of Common Stock. As of May 13, 2025, 144,951 of the shares subject to pre-funding have not been issued.

The New Warrants were issued and sold in a private placement pursuant to Section 4(a)(2) of the Securities Act of 1993, as amended (the "Securities Act"), and/or Rule 506 of Regulation D as promulgated by the Securities and Exchange Commission under the Securities Act. Pursuant to the Inducement Letter Agreements, the Company agreed to file a registration statement providing for the resale by the purchasers of the shares of Common Stock issuable upon exercise of the New Warrants.

The gross proceeds to the Company from the exercise of the Class C Warrants and the sale of the new Class E warrants were approximately $3.8 million. The Company incurred total offering costs of approximately $465,000, including a 10% financial advisory fee to Aegis Capital Corp. of approximately $385,000.

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

Bluejay Diagnostics, Inc. ("Bluejay," the "Company," "we" and/or "us")) is a medical diagnostics company focused on improving patient outcomes in critical care settings. The Company is working on developing rapid tests using whole blood on its Symphony technology platform ("Symphony"), which consists of an analyzer and single-use protein detection cartridges that have a function of automatic stepwise feeding of reagent. The Company does not yet have regulatory clearance for Symphony, and it will need to receive regulatory authorization from the U.S. Food and Drug Administration (the "FDA") to be marketed as a diagnostic product in the United States. The Company has completed the development of the Symphony analyzer. The Company is planning to begin cartridge redevelopment either at an in-house facility or through a third-party contractor who would manage such redevelopment. Such redevelopment is intended to address several technical challenges to bring Symphony to a level consistent with necessary performance and quality requirements. After redevelopment, the Company plans to have manufacturing of the Symphony cartridges occur at a Contract Manufacturing Organization ("CMO"). To achieve its plan, the Company expects to need to raise at least $30 million of capital between the second quarter of 2025 and the end of the 2027 fiscal year, which the Company hopes to do in various tranches during this time period. The Company's current plan, subject to achieving necessary financing, is to begin testing of samples it is collecting as part of its ongoing SYMON-II clinical trial in mid-2027, with a goal of being in position to submit a 510(k) regulatory application to the FDA in the fourth quarter of 2027, with an objective of achieving FDA approval as early as the third quarter of 2028.

The Company's Symphony platform is a combination of Bluejay's intellectual property ("IP") and exclusively licensed and patented IP on the Symphony technology that the Company believes, if cleared, authorized, or approved by the FDA, can provide a solution to a significant market need in the United States. The Symphony device is designed to produce laboratory-quality results in 20 minutes in critical care settings, including Intensive Care Units ("ICUs") and Emergency Rooms ("ERs"), where rapid and reliable results are required.

The Company's first product candidate, the Symphony IL-6 test, is an immunoassay for the measurement of interleukin-6 (IL-6) to be used for the monitoring of disease progression in critical care settings. The Company is currently focused on pursuing the Symphony IL-6 test in the context of sepsis. IL-6 is a clinically established inflammatory biomarker, and is 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 Company believes that its Symphony IL-6 test, if ultimately successful and approved, could have the ability to consistently monitor this critical care biomarker with rapid results.

If the Company succeeds with the foregoing plan, in the future it hopes to develop additional tests for Symphony, including tests for myocardial infarction and congestive heart failure (cardiac biomarkers hsTNT and NT pro-BNP) as well as other tests using the Symphony platform.

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 $1.9 million and $2.3 million for the three months ended March 31, 2025 and 2024, respectively. We had negative cash flow from operating activities of approximately $1.2 million and $2.3 million for the three months ended March 31, 2025 and 2024, respectively, and had an accumulated deficit of approximately $36.5 million as of March 31, 2025.

As further described below under "Liquidity and Going Concern Uncertainty" as of March 31, 2025, the Company possessed cash and cash equivalents of approximately $3.1 million, while having current liabilities of approximately $1.3 million. The Company will need to raise a material amount of additional capital in the imminent near-term to continue as a going concern, and that absent such near-term funding, it will likely run out of available cash resources in the near-term. If we are unable to obtain financing in the near-term, or otherwise consummate strategic alternatives, we could determine to undertake a process of liquidation under U.S. bankruptcy laws.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

The following table sets forth our results of operations for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 784,800	$ 1,334,797
General and administrative	1,104,117	1,086,884
Sales and marketing	-	6,424
Total operating expenses	1,888,917	2,428,105
Operating loss	(1,888,917)	(2,428,105)
Other income (expense):		
Interest income	17,801	30,091
Other income, net	6,681	69,549
Total other income (expense), net	24,482	99,640
Net loss	$ (1,864,435)	$ (2,328,465)

Research and Development

Research and development expenses for the three months ended March 31, 2025 were approximately $0.8 million as compared to approximately $1.3 million for the same period in 2024. 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 March 31, 2025, were approximately $1.1 million as compared to approximately $1.1 million for the comparable period in 2024. The increase in general and administrative expenses is due to an increase in Delaware franchise tax expense of $0.1 million and largely offset by 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 March 31, 2025 were nil as compared to approximately $6,400 for the comparable period in 2024. The decrease in sales and marketing expenses was due to a reduction in spending in all sales and marketing efforts.

Other Income (Expense), net

Other income (expense), net for the three months ended March 31, 2025 was approximately $24,482 as compared to $99,640 for the same periods in 2024. The decrease in net other income (expense) was primarily due to lower interest income due to a reduction in our cash balance resulting in a decrease of approximately $12,000 and a decrease of approximately $67,000 in related party income from NanoHybrids.

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.

	Three Months Ended March 31,	
	2025	**2024**
Cash proceeds (used in) provided by:		
Operating activities	$ (1,184,857)	$ (2,299,969)
Investing activities	-	(35,433)
Financing activities	(985)	2,788,055
Net increase (decrease) in cash and cash equivalents	$ (1,185,842)	$ 452,653

Net cash used in operating activities

During the three months ended March 31, 2025, we used approximately $1.2 million in cash for operating activities, a decrease of approximately $1.1 million as compared to approximately $2.3 million for the same period in 2024. The decrease in net cash used in operating activities was primarily due to a decrease in working capital of approximately $664,000 and decreases in personnel and product development costs.

Net cash used in investing activities

During the three months ended March 31, 2025, we used no cash for investing activities, a decrease of approximately $35,000 as compared to the same period in 2024. The decrease in net cash used in investing activities was due to no purchasing of manufacturing equipment in 2025.

Net cash used in financing activities

During the three months ended March 31, 2025, we used $985 of cash in financing activities, a decrease of approximately $2.8 million as compared to the same period in 2024. The decrease in net cash generated by financing activities was due no fund raising in the first quarter of 2025 as compared to our public offering on January 2, 2024.

Liquidity and Going Concern Uncertainty

The Company had cash and cash equivalents of $3,116,103 and current liabilities of $1,316,677 on its balance sheet as of March 31, 2025. The Company has incurred net losses since its inception, and has negative cash flows from operations and had an accumulated deficit of $36,533,219 as of March 31, 2025. The Company expects that its net cash used in operating activities will continue to be negative over at least the next several years as it redevelops aspects of the Symphony cartridges and conducts clinical trial work and, if such redevelopment and trials are successful, begin preparation of an FDA submission. These financial results and financial position, and the Company's expected forward-looking outwork of significant negative cash flow in the future, raise substantial doubt with respect to its ability to continue as a going concern. As a result of the Company's lack of cash, it has slowed the timeline of its clinical trial work to preserve cash resources in the near-term, and the Company expects that this will delay its Symphony platform regulatory submission timeline until the fourth quarter of 2027, at the earliest, if it is even able to generate sufficient clinical trial results to support such a submission. If the Company fails to obtain additional material financing in the near-term, its clinical trials and targeted FDA submission timeline could be delayed further, and it could be forced to abandon such activities entirely and cease operations, with the possible loss of such properties or assets. If the Company is unable to obtain additional financing as it continues to generate negative cash flow, its board of directors could determine to cause the Company to undertake a process of liquidation under Chapter 7 of applicable U.S. bankruptcy laws, or otherwise seek other protection under such laws. In such event, the Company expects that holders of shares of its common stock would recoup little if any material value in such process. The Company currently estimates that the cash resources it possesses as of the date of this filing will be sufficient to fund its operations up to the third quarter of 2025.

The condensed consolidated financial statements for the three months ended March 31, 2025 and 2024 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.

Recent Offerings

January 2024 Offering

On January 2, 2024, the Company sold in a public offering (such transaction, the "January 2024 Offering") (i) 1,344 shares of the Company's common stock, par value $0.0001 per share and (ii) prefunded warrants to purchase up to an aggregate 5,386 shares of Common Stock (the "January Prefunded Warrants"). The Shares and January Prefunded Warrants were sold together with warrants to purchase up to an aggregate of 6,730 shares of Common Stock at an exercise price of $520.00 per share (the "January 2024 Warrants"). The combined public offering price was $520.00 per share of Common Stock and related January 2024 Warrant and $519.96 per January Prefunded Warrant and related January 2024 Warrant.

As of December 31, 2024, all January Prefunded Warrants had been exercised in full. The January 2024 Warrants are exercisable 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, by and between the Company and 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 471 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 $650.00, 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.

The gross proceeds to the Company from the January 2024 Offering were $3,500,000. The Company incurred offering costs of $711,031.

May 2024 Bridge Note Financing

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"). 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 December 31, 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 1,451 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 December 31, 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%.

Interest expense recorded on the NPA and SPAs was $807,797 for the year ended December 31, 2024, including debt issuance costs related to the NPA and SPA totaling $212,654.

June 2024 Offering

On June 28, 2024, the Company sold in a public offering (the "June 2024 Offering"), (i) 11,541 common units (the "Common Units"), each consisting of one share of common stock, two Class C Warrants and one Class D Warrant and (ii) 95,815 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. ("Aegis" or, the "Underwriter") partially exercised its over-allotment option in respect to 13,573 Class C Warrants and 6,787 Class D Warrants (the "Over-Allotment Warrants"). The Common Units were sold at a price of $81.50 per unit and the Prefunded Warrants were sold at a price of $81.495 per unit. As of December 31, 2024, all Prefunded Warrants had been exercised in full.

Pursuant to an engagement letter dated June 6, 2024, by and between the Company and 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.

The gross proceeds to the Company from the June 2024 Offering were $8,569,075. The Company incurred offering costs of $1,133,419.

April 2025 Private Placement

On April 7, 2025, the Company entered into inducement letter agreements (the "Inducement Letter Agreements") with certain existing holders (the "Holders") of the Company's Class C warrants, pursuant to which the Holders agreed to purchase an aggregate of 1,085,106 shares of the Company's common stock. The Class C warrants were originally issued to the Holders on June 28, 2024 for an exercise price of $98.00 per share and were subsequently reduced to $16.30 per share pursuant to stockholder approval on August 21, 2024. Pursuant to the Inducement Letter Agreements, the Holders agreed to exercise their Series C warrants at a reduced exercise price of $3.42 per share, and to purchase an equivalent number of new Class E warrants for an additional $0.125 per share. The Class E warrants have an exercise price of $3.42 per share and expire on April 8, 2030.

The transaction closed on April 8, 2025. The exercise of the Class C warrants resulted in the Company issuing 682,203 shares of Common Stock at closing and pre-funding of 402,903 shares of Common Stock.

The New Warrants were issued and sold in a private placement pursuant to Section 4(a)(2) of the Securities Act of 1993, as amended (the "Securities Act"), and/or Rule 506 of Regulation D as promulgated by the Securities and Exchange Commission under the Securities Act. Pursuant to the Inducement Letter Agreements, the Company agreed to file a registration statement providing for the resale by the purchasers of the shares of Common Stock issuable upon exercise of the New Warrants. Such registration statement was filed on April 29, 2025 and became effective on May 7, 2025.

The gross proceeds to the Company from the exercise of the Class C Warrants and the sale of the new Class E warrants were approximately $3.8 million. The Company incurred total offering costs of approximately $465,000, including a 10% financial advisory fee to Aegis Capital Corp. of approximately $385,000.

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

Pursuant to our evaluation of disclosure controls and procedures for the quarter ended December 31, 2024, the President and Chief Executive Officer (who serves as our principal executive officer and principal financial and accounting officer), concluded that our disclosure controls and procedures were not effective as of December 31, 2024. This determination was due to a material weakness in our internal control over financial reporting arising from a lack of sufficient internal accounting expertise at the Company, our President and Chief Executive Officer also concluded that our internal control over financial reporting was not effective as of December 31, 2024.

During the preparation of our Annual Report on Form 10-K for the fiscal year ended December 31. 2024 (the "2024 Form 10-K") in March 2025, our independent registered public accounting firm identified an issue with respect to our accounting and valuation of certain warrants. In particular, in June 2024, we issued Class C and Class D warrants that contained "reset" features that caused the exercise prices and number of shares of Company common stock issuable upon exercise of such warrants to increase following stockholder approval of such warrants in August 2024. Under applicable accounting guidance, upon reset, the Company should have recorded in its consolidated statement of operations a "deemed dividend on warrant modification" and "net loss applicable to common stockholders". In addition, these entries were not included in the Company's consolidated statement of operations for the three and nine months ended September 30, 2024 in the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2024.

Plan to Remediate Material Weakness

As a result of the material weakness determination that occurred in connection with the preparation of our 2024 Form 10-K, we plan to enhance our processes by designing and implementing controls to review and evaluate the complex financial instruments, including derivative securities such as warrants, that may be issued in subsequent financings, by engaging outside accounting experts to evaluate the terms and document the appropriate accounting for these complex instruments. When fully implemented and operational, we believe the measures described above will remediate the underlying causes of the control deficiencies that gave rise to the material weakness and will strengthen our internal control over financial reporting. However, remediation efforts are expected to continue into future fiscal quarters. Further, we will not be able to fully remediate this material weakness until these steps have been completed and have been operating effectively for a sufficient period of time. We may also identify additional measures that may be required to remediate the material weakness in our internal control over financial reporting, necessitating further action.

(a) Evaluation of Disclosure Controls and Procedures

We conducted an evaluation under the supervision and with the participation of our management, including our President and Chief Executive 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. As described above, during the preparation of 2024 Form 10-K in March 2025, our independent registered public accounting firm identified an issue that caused our management to conclude that a material weakness existed in our internal control over financial reporting, which is an integral component of our disclosure controls and procedures. Our remediation efforts with respect to this material weakness are continuing, and we have determined that this material weakness was continuing as of March 31, 2025. As a result, our President and Chief Executive Officer concluded that our other disclosure controls and procedures were not effective as of March 31, 2025.

(b) Changes in Internal Control Over Financial Reporting

Other than the material weakness determination described above and the commencement of the Company's remediation activities in connection therewith, 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 March 31, 2025 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 2024 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:

Additional Risks Related to Our Financial Condition and Capital Requirements

To remain a going concern, we are in need of imminent material additional capital and absent our ability to raise such material capital in the near-term, we may be required to undertake a process of liquidation under U.S. bankruptcy laws, which we expect would limit holders of our common stock from recouping any material value for their shares.

As of March 31, 2025, we possessed cash and cash equivalents of approximately $3.1 million, while having current liabilities of approximately $1.3 million. We incurred losses of approximately $7.7 million and $10.0 million for fiscal years 2024 and 2023, respectively, and $1.9 million for the fiscal quarter ended March 31, 2025. From our inception through March 31, 2025, we have an accumulated deficit of approximately $36.5 million, and we do not currently generate any operating income. To achieve our current strategic plan, which strives to be in position to submit a 510(k) regulatory application to the FDA in the fourth quarter of 2027 and achieve FDA approval as early as the third quarter of 2028, we expect to need to raise at least $30 million of capital between the second quarter of 2025 and the end of the 2027 fiscal year, which we hope to do in various tranches during this time period. In April 2025, we entered into a warrant inducement transaction with certain existing warrant holders that raised approximately $3.8 million of gross proceeds (less total offering costs of approximately $465,000, including a 10% financial advisory fee to Aegis Capital Corp. of approximately $385,000). We are exploring potential pathways to raise additional material capital, but there can be no assurance that such additional capital will be available on a timely basis or on terms that will be acceptable to us. If we are ultimately unable to obtain the needed financing to implement our business plans, our board of directors could determine to cause the Company to undertake a process of liquidation under Chapter 7 of applicable U.S. bankruptcy laws. In such event, we do not currently expect that holders of shares of our common stock would recoup any material value in such process.

Additional Risks Related to Our Business

To preserve cash resources, we have downsized our organization, which may reduce business continuity, affect our ability to apply for certain patents, and affect our product development and timelines, including our previously disclosed plan to transfer underlying production of our cartridges to an in-house facility for redevelopment.

To preserve cash resources, we have implemented a series of recent cost savings measures in our product development operations. As of the date of this filing, we have reduced our overall Company-wide full-time employee headcount to 6 persons, including recently separating with our VP of Operations, who was overseeing the process of redeveloping aspects of our Symphony cartridges. We are also currently negotiating an upcoming separation with our Chief Technology Officer, who is also significantly involved in these matters, our ongoing SYMON-II clinical studies, analytical studies, and certain intellectual property in connection with the prior development work of Symphony performed by Company. While we continue to explore conducting cartridge redevelopment at an in-house facility, we are now exploring other alternative pathways for how to pursue such redevelopment, including by outsourcing this work to third parties. In addition, these measures are expected to result in a loss of institutional knowledge that may make our product redevelopment work more difficult to successfully achieve, whether we ultimately attempt to undertake such work in-house or through a third party. To the extent we obtain sufficient funding, we may hire replacement personnel in these areas in the future, but there is no assurance that we will be able to do so. These circumstances may make it more difficult to succeed in meeting the technical challenges necessary to bring our Symphony product to a level consistent with necessary performance and quality requirements to support an FDA submission and ultimately be able to commercialize our product, as well as the timeline for completing this work.

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

Settlement and Release Agreement with Nanohybrids

On May 8, 2025, the Company entered into a settlement and release agreement (the "Settlement Agreement") with Nanohybrids that terminated the respective parties' obligations under the Sharing and Services Agreement, and memorialized that prior discussions between the parties regarding a potential sale of Nanohybrids to the Company (the "Strategic Transaction Discussions") were terminated. Under the terms of the Settlement Agreement, the Company agreed to make payment of $50,000 to Nanohybrids and reimburse Nanohybrids for up to $30,000 in reasonable and documented attorneys' fees that Nanohybrids had previously incurred in connection with the Strategic Transaction Discussions. The Company and Nanohybrids (including Dr. Cook for this limited purpose) each also provided the other with releases related to the Sharing and Services Agreement and the Strategic Transaction Discussions. The Settlement Agreement was approved in advance by the Audit Committee of the Company's Board of Directors. The foregoing description of the Settlement Agreement is qualified by reference to the text of such agreement, which is filed herewith as Exhibit 10.1 and incorporated herein by reference.

Upcoming Separation with Chief Technology Officer

On May 10, 2025, the Company informed its Chief Technology Officer, Jason Cook, that it intends to implement an upcoming separation from employment with Dr. Cook. As of the date of this filing, the Company and Dr. Cook are actively discussing the terms and timing of such separation. Under Dr. Cook's existing July 2021 employment agreement, upon a separation from employment instituted by the Company, and subject to Dr. Cook delivering and not revoking a standard release of claims, Dr. Cook would be entitled upon separation to severance amounts consisting of six-months' base salary and a pro rata target bonus for the 2025 calendar year based on the portion of the 2025 calendar year in which he is employed. Under the terms of his employment agreement, the payment of such amounts would occur in equal installments over the six-month period following his last day of employment and would be subject to compliance by Dr. Cook of certain ongoing covenants with respect to confidentiality, cooperation and other matters.

Insider Trading Arrangements and Policies

During the fiscal quarter ended March 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified or terminated any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Securities Exchange Act of 1934 or any "non-Rule 10b5-1 trading arrangement."

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit Number	Description
10.1*	Settlement Agreement and Release, dated as of May 8, 2025, by and among Bluejay Diagnostics, Inc. and Nanohybrids, Inc.
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)	May 13, 2025

Exhibit 10.1

SETTLEMENT AGREEMENT AND RELEASE

This Settlement Agreement and Release (this "**Agreement**"), dated as of May 8, 2025, is entered into by and between Bluejay Diagnostics, Inc., a Delaware corporation (the "**Company**"), and Nanohybrids, Inc., a Delaware corporation ("**Nanohybrids**"). Jason Cook (the "**Control Party**") joins this Agreement for the limited purposes set forth herein. Each of the parties to this Agreement may be referred to individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS, the Parties have previously engaged in oral and written discussions and negotiations regarding a potential strategic transaction involving the potential sale by the shareholders of Nanohybrids (the "**Shareholders**") a majority or all of the outstanding equity interests in Nanohybrids to the Company in exchange for one or more cash payments by the Company to the Shareholders (the "**Potential Strategic Transaction**");

WHEREAS, in addition, the Company and Nanohybrids have previously entered into a Facilities Sharing & Personnel Services Agreement, dated December 10, 2021 (the "**Sharing and Services Agreement**"), pursuant to which Nanohybrids is permitted to utilize the Company's research and development staff and laboratory facility when available to perform work for Nanohybrids, in each case, for the payment by Nanohybrids to the Company of fees and reimbursements provided for in such Sharing and Services Agreement;

WHEREAS, depending on the applicable service, either of the Company or Nanohybrids may terminate for convenience the services contemplated by the Sharing and Services Agreement upon either one (1) or three (3) months' notice to the other (the "**Notice Requirements**");

WHEREAS, the Parties desire to memorialize their mutual determination and agreement to (i) cease discussions regarding the Potential Strategic Transaction, and (ii) terminate the Sharing and Services Agreement and to waive the Notice Requirements in connection therewith, in each case effective as of the date of this Agreement;

WHEREAS, in connection with these matters, the Parties have agreed that the Company shall promptly (i) make payment of Fifty Thousand Dollars ($50,000) to Nanohybrids, and (ii) reimburse Nanohybrids for up to Thirty Thousand Dollars ($30,000) in reasonable and documented attorneys' fees that Nanohybrids previously incurred in connection with the Potential Strategic Transaction;

NOW THEREFORE, in consideration of the execution of this Agreement, the releases and agreements made herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged by each Party, it is hereby agreed as follows:

1. Releases.

(a) **Release by Nanohybrids and the Control Party.** Each of Nanohybrids and the Control Party, for itself and for each of its predecessors, successors, heirs, and past, present, and future subsidiaries, divisions, parents, alter egos, affiliates, and related entities, and its and their past, present, and future officers, directors, trustees, partners, employees, attorneys, assigns, agents, representatives, shareholders and stockholders hereby agrees to fully, finally, irrevocably, and forever release, quit claim, and discharge the Company Releasees (as defined below), any or all of them, from any and all claims, liabilities, demands, debts, accounts, obligations, actions, costs, expenses, losses, damages, judgments, lawsuits, causes of action, and other amounts of every kind, nature, or description, known or unknown, suspected or unsuspected at law or in equity that Nanohybrids and/or the Control Party may have had (or claim to have had) in the past, now have, or may have in the future, and that in any way arise out of or relate to the Potential Strategic Transaction or the Sharing and Services Agreement (including in each case the related diligence investigation and any communications or representations related thereto) (the "**Nanohybrids Released Matters**"). "**Nanohybrids Releasees**" include the Company and its subsidiaries, and any other person or entity charged or chargeable with responsibility or liability and as applicable, their predecessors, successors, heirs, and past, present, and future subsidiaries, divisions, parents, alter egos, affiliates, and related entities, and their past, present, and future officers, directors, trustees, partners, employees, attorneys, assigns, agents, representatives, shareholders, and stockholders.

(b) **Release by the Company.** The Company, for itself and for each of its predecessors, successors, heirs, and past, present, and future subsidiaries, divisions, parents, alter egos, affiliates, and related entities, and its past, present and future officers, directors, trustees, partners, employees, attorneys, assigns, agents, representatives, shareholders, and stockholders, hereby agree to fully, finally, irrevocably, and forever release, quit claim, and discharge the Company Releasees (as defined below), any or all of them, from any and all claims, liabilities, demands, debts, accounts, obligations, actions, costs, expenses, losses, damages, judgments, lawsuits, and causes of action, and other amounts of every kind, nature, or description, known or unknown, suspected or unsuspected at law or in equity that the Company may have had (or claim to have had) in the past, now have, or may have in the future, and that arise out of or relate to the Potential Strategic Transaction or the Sharing and Services Agreement (including in each case the related diligence investigation and any communications or representations related thereto) (the "**Company Released Matters**," and together with the Nanohybrids Released Matters, the "**Released Matters**"). "**Company Releasees**" include each of Nanohybrids, the Shareholders, and as applicable, their successors, assigns, heirs, and past, present, and future attorneys, advisors, trustees, agents and representatives.

(c) Each of the Company, Nanohybrids and the Control Party agree that this Agreement constitutes a full, complete, final, and binding compromise of potentially disputed matters, regardless of the adequacy of consideration paid. Each of the Company, Nanohybrids and the Control Party agree and understand that one or more of such Parties may have suffered or may in the future suffer damages that are unknown at present, which, if known, may have affected the decision to execute this Agreement. Each of the Company, Nanohybrids and the Control Party acknowledge that the consideration received under this Agreement is intended to and does release and discharge any liabilities in regard to such unknown or future damages, including effects or consequences thereof, and regardless of mistake of fact or law; and each Party hereby waives any rights to assert in the future any such liabilities not now known or suspected. Notwithstanding the foregoing, nothing in this Agreement shall be a waiver of any rights or claims with respect to the payment of amounts under this Agreement, claims arising after the date of this Agreement, or any claims that cannot be waived by law.

2. Termination of Discussions Regarding Potential Strategic Transaction. The Parties mutually agree all discussions and negotiations regarding the Potential Strategic Transaction are terminated as of the date hereof, and that none of the Parties shall have any further obligations in connection with the Potential Strategic Transaction.

3. Termination of Sharing and Services Agreement. The Parties mutually agree that the Sharing and Services Agreement is terminated effective as of the date of this Agreement and all services provided for thereunder are ended, in each case effective as of the date of this Agreement, and the Notice Requirements are hereby waived in connection therewith. Notwithstanding the foregoing or anything to the contrary herein, Nanohybrids shall have sixty (60) days from the date of this Agreement to vacate the Company's laboratory facility or other Company space occupied by Nanohybrids as of the date of this Agreement and shall have the right to continue to occupy and use such facilities for such period without the payment of any fees or reimbursements therefor.

4. Payment Agreements. As consideration for the Parties entering into this Agreement, the Company shall (i) promptly make payment of Fifty Thousand Dollars ($50,000) to Nanohybrids, and (ii) reimburse Nanohybrids, promptly upon receipt by the Company of a reasonably detailed invoice therefor, for up to Thirty Thousand Dollars ($30,000) in reasonable and documented attorneys' fees that Nanohybrids incurred in connection with or related to the Potential Strategic Transaction, including this Agreement.

5. Further Agreements. The Company hereby acknowledges and agrees that, with the Company's consent, the Control Party has rendered services to Nanohybrids in the past and shall continue to render services to Nanobybrids after the date of this Agreement. The Company acknowledges and agrees that such services do not interfere with the Control Party's responsibilities to the Company or violate any policy of the Company or any agreement between the Control Party and the Company, including any provision of the Control Party's Employment Agreement with the Company, and, in each case, have not done so in the past.

6. Related Parties; Successors in Interest. The Parties hereby agree that this Agreement shall be binding upon the Parties and each of them, and, as applicable, upon their predecessors, successors, heirs, and their past, present, and future affiliates, subsidiaries, divisions, alter egos, and related entities, and their past, present, and future officers, directors, trustees, partners, parents, stockholders, shareholders, employees, attorneys, assigns, agents, representatives, and any or all of them.

7. No Admission of Liability. The Parties acknowledge and agree that this Agreement is a compromise and settlement of the Released Matters and that neither the execution nor the terms hereof may be construed as an admission of liability on the part of any party with respect to the disputed matters.

8. No Assignment.

(a) Each of the Company, Nanohybrids and the Control Party represents and warrants that it has not assigned or transferred, voluntarily or involuntarily, by operation of law or otherwise, any of its interest in any of the claims, causes of action, or other matters that are released by this Agreement.

(b) This Agreement, and any and all rights, duties and obligations hereunder, shall not be assigned, transferred, delegated or sublicensed by any Party without the prior written consent of the other Parties. Any attempt by a Party without such permission to assign, transfer, delegate or sublicense any rights, duties or obligations that arise under this Agreement shall be void. Subject to the foregoing and except as otherwise provided herein, the provisions of this Agreement shall inure to the benefit of the successors, assigns, heirs, executors and administrators of the Parties.

9. Advice of Counsel. Each Party represents that it has been represented, or has had the opportunity to be represented, by independent legal counsel of its own choice throughout all of the negotiations which preceded the execution of this Agreement and that it has executed this Agreement with the consent and upon the advice of such independent legal counsel, or that it has had the opportunity to seek such consent and advice. Each Party acknowledges that it has read this Agreement and assents to all the terms and conditions contained herein without any reservation whatsoever and that it has had the opportunity to have the same explained to it by its own counsel, who have answered any and all questions which have been asked of them, with regard to the meaning of any provision hereof.

10. Entire Agreement. This Agreement contains the entire agreement and understanding of the Parties concerning the subject matter hereof, and supersede and replace all prior negotiations, proposed agreements, representations, and agreements. Each of the Parties acknowledges that it is not executing this Agreement in reliance on any promise, representation, or warranty not contained in this Agreement.

11. Severability. If any word, clause, phrase, sentence, or paragraph of this Agreement is declared void or unenforceable, such portion shall be considered independent of, and severable from the remainder, the validity of which shall remain unaffected.

12. Governing Law. This Agreement shall in all respects be interpreted, enforced, and governed by and under the laws of the State of Delaware, without regards to its conflict of laws provisions.

13. Waiver of Trial by Jury. To the extent now or hereafter permitted by law, each of the parties hereto hereby irrevocably waives any and all right to trial by jury in any legal proceeding (whether sounding in contract, tort or otherwise) arising out of or related to this Agreement.

14. Waivers and Amendments. A provision of this Agreement may be waived only by a writing signed by the waiving Party. A provision may be amended or modified only by a writing signed by all Parties.

15. Construction.

(a) The headings of sections herein are for convenience of reference only and shall not affect the meaning and interpretation of this Agreement.

(b) It is understood and acknowledged that this Agreement shall not be construed in favor of or against any Party by reason of the extent to which any Party or its counsel has participated in the drafting of this Agreement.

(c) The word "including" and words of similar import when used in this Agreement will mean "including without limitation", unless otherwise specified.

(d) When a reference is made to any agreement, instrument, document, statute, rule or regulation herein, such reference shall be to such agreement, instrument, document, statute, rule or regulation as amended or supplemented (and, in the case of a statute, rule or regulation, to any successor provision) unless otherwise specified.

(e) The use of "or" is not intended to be exclusive unless expressly indicated otherwise.

16. Authorization to Execute Agreement. Each individual who executes this Agreement on behalf of any Party hereby represents and warrants that he or she does so with the knowledge and express approval of the Party on whose behalf he or she executes this Agreement.

17. Enforcement Costs. In the event of any litigation or arbitration arising out of or relating to the enforcement of this Agreement, the prevailing Party shall be entitled to recover its attorneys' fees incurred, plus expenses and costs of the litigation or arbitration, including expert witness fees incurred from the losing Parties.

18. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be an original as against any Party who signs it, and all of which shall constitute one and the same document.

19. Telecopy Execution and Delivery. Signatures transmitted by email, facsimile, or other means of electronic communication shall be deemed original signatures and shall be binding as if they were original signatures.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, this Agreement is executed as of the date first written above.

COMPANY:

BLUEJAY DIAGNOSTICS, INC.

By: /s/ Neil Dey
Name: Neil Dey
Title: President and Chief Executive Officer

NANOHYBRIDS:

NANOHYBRIDS, INC.

By: /s/ Jason Cook
Name: Jason Cook
Title: CEO

CONTROL PARTY:

/s/ Jason Cook
Jason Cook

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.

Date: May 13, 2025

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.

Date: May 13, 2025

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 March 31, 2025 (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.

Date: May 13, 2025

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 March 31, 2025 (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.

Date: May 13, 2025

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