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

FORM 10-Q

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

For the quarterly period ended September 30, 2023

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 1,239,140 shares of common stock outstanding at November 7, 2023.

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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)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,076,937	$ 10,114,990
Prepaid expenses and other current assets	1,450,805	1,673,480
Total current assets	6,527,742	11,788,470
Property and equipment, net	1,321,711	1,232,070
Operating lease right-of-use assets	367,248	465,514
Other non-current assets	29,907	35,211
Total assets	$ 8,246,608	$ 13,521,265
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 755,949	$ 635,818
Operating lease liability, current	168,716	168,706
Accrued expenses and other current liabilities	1,875,475	835,730
Total current liabilities	2,800,140	1,640,254
Operating lease liability, non-current	220,093	323,915
Other non-current liabilities	13,220	15,823
Total liabilities	3,033,453	1,979,992
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.0001 par value; 7,500,000 shares authorized; 1,239,140 and 1,010,560 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	124	101
Additional paid-in capital	29,861,279	28,538,274
Accumulated deficit	(24,648,248)	(16,997,102)
Total stockholders' equity	5,213,155	11,541,273
Total liabilities and stockholders' equity	$ 8,246,608	$ 13,521,265

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-20 reverse stock split effective July 24, 2023.

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ -	$ -	$ -	$ 249,040
Cost of sales	-	-	-	200,129
Gross profit	-	-	-	48,911
Operating expenses:				
Research and development	1,397,318	1,379,665	4,428,123	2,830,705
General and administrative	963,534	1,284,411	3,213,614	3,801,226
Sales and marketing	(19,619)	146,102	282,756	281,144
Total operating expenses	2,341,233	2,810,178	7,924,493	6,913,075
Operating loss	(2,341,233)	(2,810,178)	(7,924,493)	(6,864,164)
Other income (expense):				
Impairment of property and equipment	-	(210,117)	-	(210,117)
Other income, net	43,235	60,406	273,347	163,587
Total other income (expense), net	43,235	(149,711)	273,347	(46,530)
Net loss	$ (2,297,998)	$ (2,959,889)	$ (7,651,146)	$ (6,910,694)
Net loss per share - Basic and diluted	$ (2.08)	$ (2.94)	$ (7.30)	$ (6.86)
Weighted average common shares outstanding:				
Basic and diluted	1,102,966	1,007,617	1,048,430	1,007,445

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-20 reverse stock split effective July 24, 2023.

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

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2022	1,010,560	$ 101	$ 28,538,274	$ (16,997,102)	11,541,273
Stock-based compensation expense	-	-	54,730	-	54,730
Grants of fully vested restricted stock units to settled accrued bonus, net of shares withheld	12,188	1	107,234	-	107,235
Net loss	-	-	-	(2,539,843)	(2,539,843)
Balance as of March 31, 2023	1,022,748	102	28,700,238	(19,536,945)	9,163,395
Stock-based compensation expense	-	-	27,702	-	27,702
Issuance of common stock	750	-	-	-	-
RSU tax withholding	(358)	-	(1,453)	-	(1,453)
Net loss	-	-	-	(2,813,305)	(2,813,305)
Balance as of June 30, 2023	1,023,140	102	28,726,487	(22,350,250)	6,376,339
Stock-based compensation expense	-	-	(42,482)	-	(42,482)
Issuance of common stock, net of issuance costs of $413,544	216,000	22	1,177,274	-	1,177,296
Net loss	-	-	-	(2,297,998)	(2,297,998)
Balance as of September 30, 2023	1,239,140	$ 124	$ 29,861,279	$ (24,648,248)	$ 5,213,155

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2021	1,005,612	$ 101	$ 28,076,394	$ (7,694,786)	$ 20,381,709
Impact of adoption of ASC 842	-	-	-	(5,368)	(5,368)
Stock-based compensation expense	-	-	126,086	-	126,086
Exercise of common stock Series B Warrants	1,950	-	-	-	-
Net loss	-	-	-	(2,013,403)	(2,013,403)
Balance as of March 31, 2022	1,007,562	101	28,202,480	(9,713,557)	18,489,024
Stock-based compensation expense	-	-	106,114	-	106,114
Exercise of common stock Series B Warrants	55	-	-	-	-
Net loss	-	-	-	(1,937,402)	(1,937,402)
Balance as of June 30, 2022	1,007,617	101	28,308,594	(11,650,959)	16,657,736
Stock-based compensation expense	-	-	113,218	-	113,218
Net loss	-	-	-	(2,959,889)	(2,959,889)
Balance as of September 30, 2022	1,007,617	$ 101	$ 28,421,812	$ (14,610,848)	$ 13,811,065

See notes to unaudited condensed consolidated financial statements.
Reflects a 1-for-20 reverse stock split effective July 24, 2023.

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

	Nine months ended September 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,651,146)	$ (6,910,694)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	626,366	125,916
Stock-based compensation expense	204,810	345,418
Amortization of right-of-use asset	98,266	111,527
Impairment of property and equipment	1,787	210,117
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	222,675	965,814
Other non-current assets	5,304	(12,460)
Accounts payable	18,609	(81,067)
Due to related party	-	(2,000)
Accrued expenses and other current liabilities	936,936	450,079
Net cash used in operating activities	(5,536,393)	(4,797,350)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(616,272)	(961,063)
Net cash used in investing activities	(616,272)	(961,063)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, gross	1,590,840	-
Payment for issuance costs of common stock	(413,544)	-
Payment of tax withholding on obligations on restricted stock units	(59,079)	-
Payment of finance lease	(3,605)	-
Net cash provided by financing activities	1,114,612	-
Net decrease in cash and cash equivalents	(5,038,053)	(5,758,413)
Cash and cash equivalents, beginning of period	10,114,990	19,047,778
Cash and cash equivalents, end of period	$ 5,076,937	$ 13,289,365
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH INVESTING ACTIVITIES		
Reclassification of goods previously classified as inventory to property and equipment	$ -	$ 615,313
Liabilities incurred for the purchase of property and equipment	$ 101,522	$ 228,324

See notes to unaudited condensed consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

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

Bluejay's first product, the Symphony IL-6 test, is for the monitoring of disease progression in critical care settings. IL-6 is a clinically established inflammatory biomarker, considered a 'first-responder' for the 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 with the determination of a patient's level of severity at triage and The Symphony IL-6 test has the ability to consistently monitor this critical care biomarker with rapid results.

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

Bluejay's operations to date have been funded primarily through the proceeds of the Company's initial public offering (the "IPO") in November 2021 (the "IPO Date").

On June 4, 2021, the Company formed Bluejay Spinco, LLC, a wholly owned subsidiary of the Company, for potential 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.

August 2023 Financing

On August 24, 2023, the Company entered into a securities purchase agreement with certain institutional and accredited investors (the "Purchase Agreement") relating to the registered direct offering and sale of 216,000 shares of the Company's common stock at a purchase price of $7.365 per share (the "Offering").

In a concurrent private placement, the Company also issued to such institutional and accredited investors unregistered warrants to purchase up to 216,000 shares of Common Stock (the "Warrants"). Pursuant to the terms of the Purchase Agreement, for each share of Common Stock issued in this offering an accompanying Warrant was issued to the purchaser thereof. Each Warrant is exercisable for one share of Common Stock (the "Warrant Shares") at an exercise price of $7.24 per share, will be immediately exercisable upon issuance and will expire five years from the date of issuance. The Warrants were offered and sold at a purchase price of $0.125 per underlying warrant share, which purchase price is included in the offering price per share of Common Stock issued in the Offering (the "Private Placement").

Pursuant to an engagement letter, dated as of August 7, 2023 (the "Engagement Letter"), between the Company and H.C. Wainwright & Co., LLC, or the placement agent, the Company agreed to pay the placement agent a total cash fee equal to 7.0% of the gross proceeds received in the Offering and the Private Placement. The Company also agreed to pay the placement agent in connection with the Offering and the Private Placement a management fee equal to 1.0% of the gross proceeds raised in the Offering and Private Placement, $45,000 for non-accountable expenses, and $15,950 for clearing fees. In addition, the Company agreed to issue to the placement agent, or its designees, warrants to purchase up to 15,120 shares of Common Stock (the "Placement Agent Warrants"), which represents 7.0% of the aggregate number of shares of Common Stock sold in the Offering. The Placement Agent Warrants have substantially the same terms as the Warrants, except that the Placement Agent Warrants have an exercise price equal to $ 9.2063, or 125% of the offering price per share of Common Stock sold in the Offering, and a term of five years from the commencement of the sales pursuant to the Offering.

The gross proceeds to the Company from the Offering and the Private Placement are $1,590,840. The Company incurred offering costs of $413,544.

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. Previously, the Company's regulatory strategy involved clinical studies involving COVID-19 patients. However, the Company has shifted its focus away from COVID-19 patients due to a significant decline in the number of COVID-19 related hospitalizations. Pursuant to this revised strategy, the Company plans to conduct a clinical study to support an FDA regulatory submission with an initial indication for risk stratification of hospitalized sepsis patients. The Company submitted a pre-submission application to the FDA presenting the new study design in May 2023 and participated in a pre-submission meeting on August 11, 2023. At the meeting, the FDA provided feedback on the new study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Based on this feedback, the Company intends to proceed as planned while taking into account the FDA's feedback. The Company believes that it will maintain the previously disclosed Symphony IL-6 regulatory submission timeline of the first half of 2024.

The Company has targeted certain medical institutions for its study, which the Company believes will also help support initial commercialization and market penetration. The Company believes that this clinical trial expansion could also support additional indications, but that any such expansion also could delay obtaining marketing authorization for the product. Based on the pre-submission meeting with the FDA, the focus of the clinical trial will be the risk stratification of hospitalized sepsis patients.

The Company maintains contracts with Sanyoseiko Co. Ltd ("Sanyoseiko") to manufacture our device and cartridges, and with Toray Industries, Inc ("Toray") to manufacture in the near-term (through its wholly owned subsidiary Kamakura Techno-Science, Inc.) certain product intermediary components for use in cartridges being manufactured for the Company by Sanyoseiko.

Risks and Uncertainties

As noted above, Bluejay is reliant upon Toray and Sanyoseiko to provide cartridges in sufficient quantity and quality to complete our clinical trials, and our clinical trials could be delayed if the Company encountered any material supply interruptions while the clinical trials are being conducted. 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 trial will demonstrate sufficient safety and efficacy of the Symphony. The failure to adequately demonstrate the clinical performance of the Symphony device could delay or prevent regulatory approval of the device, 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.

On October 25, 2022, the Company received a notification letter from the Nasdaq Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that the closing bid price for its common stock had been below $1.00 for the previous 30 consecutive business days and that the Company therefore is not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). On April 25, 2023, at the Company's request, Nasdaq's Listing Qualifications Staff notified the Company that it had extended the time for the Company to regain compliance with the Minimum Bid Requirement until October 23, 2023. To regain compliance, the closing bid price of the Company's common stock needed to be at least $1.00 or higher for a minimum of ten consecutive business days.

On July 24, 2023, the Company executed a reverse stock split of its shares of common stock at a ratio of 1-for-20 (the "Reverse Stock Split"), with a corresponding reduction in the number of authorized outstanding number of shares of common stock from 100,000,000 to 7,500,000. The Reverse Stock Split became effective on July 24, 2023, when the Company's common stock opened for trading on The Nasdaq Capital Market on a post-split basis under the Company's existing trading symbol, "BJDX." At such time, the Company's common stock also commenced trading with a new CUSIP number, 095633301.

On August 8, 2023, the Company received a letter from the Listing Qualifications Department of Nasdaq notifying the Company that, based on the closing bid price of the Company's common stock having been at least $1.00 per share for the required period, the Company has regained compliance with Nasdaq Listing Rule 5550(a)(2) and the minimum bid price deficiency matter previously disclosed by the Company on October 25, 2022 is now closed.

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 this 1-for-20 reverse stock split.

Going Concern

The Condensed Consolidated Financial Statements for the nine month periods ended September 30, 2023 and 2022 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 has incurred net losses since its inception, and has negative cash flows from operations and will need additional funding to complete planned development efforts. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company had cash and cash equivalents of $5,076,937, as of September 30, 2023. The Company continues to develop the Symphony device and its first test for the measurement of IL-6. The Company remains committed to obtaining FDA clearance and will conduct clinical trials to obtain sufficient data to support its FDA submission, while also continuing to build its manufacturing operations with its contract manufacturing organizations. Current cash resources and expected operating expenses are considered in determining its liquidity requirement; as well as $2,800,140 of current liabilities on its balance sheet as of September 30, 2023. The Company estimates cash resources will be sufficient to fund its operations into the first quarter of 2024. The Company will need additional capital to fund its planned operations for the next 12 months.

The Company expects that it will seek to raise such additional capital through public or private equity offerings, grant financing and support from governmental agencies, convertible debt, collaborations, strategic alliances and distribution arrangements. Additional funds may not be available when it needs them on terms that are acceptable to them, or at all. If adequate funds are not available, it may be required to delay its FDA regulatory strategy, and to delay or reduce the scope of its research or development programs, its commercialization efforts or its manufacturing commitments and capacity. In addition, if it raises additional funds through collaborations, strategic alliances or distribution arrangements with third parties, it may have to relinquish valuable rights to its technologies or future revenue streams.

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, 2022 included in the Company's Annual Report on Form 10-K. The unaudited condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2023 and December 31, 2022, its results of operations and cash flows for the three and nine months ended September 30, 2023 and 2022, 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 and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023, or any other interim period within this fiscal year.

2. SIGNIFICANT ACCOUNTING POLICIES

During the nine months ended September 30, 2023, there were no changes to the significant accounting policies as described in the 2022 Audited Financial Statements.

Use of estimates

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

Stock-based compensation

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

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

The Company recognizes forfeitures related to employee stock-based payments when they occur. Forfeited options are recorded as a reduction to stock compensation expense.

Research and development expenses

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

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

Segment Reporting

Management has determined that the Company has one operating segment, which is consistent with the Company's structure and how it manages the business.

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):

	September 30,	
	2023	**2022**
Options to purchase common stock	31,361	39,389
Restricted stock units	7,875	-
Warrants for common stock	271,714	40,594
Class A warrants for common stock	124,200	124,200
Class B warrants for common stock	3,770	3,770

Recently Adopted Accounting Standards

In October 2021, the FASB issued ASU No. 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers ("ASU 805")*, an amendment of the ASC. The amendments to ASU 805 address diversity and inconsistency related to the recognition and measurement of contract assets and contract liabilities acquired in a business combination and require that an acquirer recognize and measure contract assets and contract liabilities acquired in accordance with ASC 2014-09, *Revenue from Contracts with Customers (Topic 606) (*"ASC 606"). Under GAAP, an acquirer generally recognizes assets and liabilities assumed in a business combination, including contract assets and liabilities arising from revenue contracts with customers, at fair value on the acquisition date. ASU No. 2021-08 will result in the acquirer recording acquired contract assets and liabilities on the same basis that would have been recorded by the acquiree before the acquisition under ASC 606. The Company adopted this new standard on January 1, 2023. The new standard had no impact on the Company's consolidated statements of operations or cash flows.

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 condensed consolidated financial statements.

3. LICENSE AND SUPPLY AGREEMENT WITH TORAY INDUSTRIES

On October 6, 2020, the Company entered into a License and Supply Agreement ("License Agreement") with Toray Industries, Inc. ("Toray"). Under the License Agreement, the Company received the exclusive license (outside of Japan) to make and distribute protein detection cartridges that have a function of automatic stepwise feeding of reagent (the "Cartridges"). In addition, following the first sale of the Cartridges after regulatory approval, the Company will make royalty payments to Toray equal to 15% of 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. There were no sales of or revenues from the Cartridges during the nine-month periods ended September 30, 2023 and 2022.

As of September 30, 2023 and December 31, 2022, there were no amounts accrued related to the License Agreement.

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"). Please refer to Note 10 for further detail.

4. WARRANTS

The following table summarizes information with regard to warrants outstanding as of September 30, 2023:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
Common Stock Warrants	271,714	Common Stock	$ 15.94	4.5
Class A Warrants	124,200	Common Stock	$ 140.00	3.1
Class B Warrants	3,770	Common Stock	$ 200.00	3.1

As part of the Offering that occurred during the three- and nine- month periods ended September 30, 2023, the Company also issued 216,000 Warrants and 15,120 Placement Agent Warrants, which were accounted for as equity classified financial instruments under ASC 815, *Derivatives and Hedging*.

No warrants were issued during the three and nine months ended September 30, 2022.

Class A Warrants and Class B Warrants

In conjunction with the Company's IPO in November 2021 the Company issued 108,000 Class A Warrants and 108,000 Class B Warrants. Additionally, the underwriter of the IPO exercised their overallotment option, solely with respect to the Class A Warrants and Class B Warrants, shortly after the IPO Date resulting in an additional issuance of 16,200 Class A Warrants and 16,200 Class B Warrants.

Class A Warrants entitle the holder to purchase one share of common stock at an exercise price of $140.00 per share. As of September 30, 2023 all Class A Warrants were outstanding. As of September 30, 2023 and 2022, there remain 124,200 Class A Warrants outstanding.

Class B Warrants entitle the holder to purchase one share of common stock at an exercise price of $200.00 per share. Holders of Class B Warrants may also exercise such warrants on a "cashless" basis after the earlier of (i) 10 trading days from closing date of the offering or (ii) the time when $10.0 million of volume is traded in the Company's common stock, if the volume weighted average price of the Company's common stock on any trading day on or after the closing date of the offering fails to exceed the exercise price of the Class B Warrant (subject to adjustment as described in the warrant agreement). During the nine months ended September 30, 2023, no Class B Warrants were exercised, while during the nine months ended September 30, 2022, 40,100 Class B Warrants were exercised, all on a cashless basis. As of September 30, 2023 and 2022, there were 3,770 Class B Warrants outstanding.

5. 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, 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 units. The maximum number of shares reserved for issuance under the 2018 Plan is 31,472. As of September 30, 2023, there were 13,113 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 98,000 shares of common stock were approved to be initially reserved for issuance under the 2021 Stock Plan. As of September 30, 2023, there were 40,377 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 units for the nine months ended September 30, 2023:

Non-vested Restricted Stock Units		
	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2022	3,000	$ 25.80
Granted	25,609	8.80
Vested	(19,484)	9.45
Cancelled / forfeited	(1,250)	25.80
Outstanding at September 30, 2023	7,875	$ 10.96

In February 2023, the Company issued 18,734 fully vested restricted stock units to certain employees as a portion of their 2022 bonuses, for which, the Company incurred expenses of $164,860.

The following is a summary of stock option activity for the nine months ended September 30, 2023:

	Stock options			
	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2022	35,992	$ 39.25	6.5	$ 20,578
Granted	1,000	10.60		
Exercised	-	-		
Cancelled / forfeited	(5,631)	50.66		
Outstanding at September 30, 2023	31,361	$ 36.28	7.0	$ 5,141
Exercisable at September 30, 2023	26,405	$ 35.10	6.8	$ 5,141

The weighted average grant date fair value of options granted during the nine months ended September 30, 2023 and 2022 was $8.80 per share and $29.00 per share, respectively. The Company calculated the grant-date fair value of stock option awards granted during the nine months ended September 30, 2023 and 2022 using the Black-Scholes model with the following assumptions:

	Nine Months Ended September 30,	
	2023	2022
Risk-free interest rate	3.63%	1.58% – 3.06%
Expected dividend yield	0.00%	0.00%
Volatility factor	108.78%	102.03% - 140.40%
Expected life of option (in years)	6.00	5.37 – 6.00

Stock-Based Compensation Expense

For the three and nine months ended September 30, 2023 and 2022, the Company recorded stock-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 9,393	$ 20,528	$ 54,389	$ 54,231
General and administrative	(30,275)	92,531	157,971	290,397
Sales and marketing	(21,600)	160	(7,550)	790
Total stock-based compensation	$ (42,482)	$ 113,219	$ 204,810	$ 345,418

As of September 30, 2023, there was $46,083 of unrecognized compensation expense related to non-vested stock option awards that are expected to be recognized over a weighted-average period of 8.56 years. As of September 30, 2023, there was $31,872 of unrecognized compensation expense related to non-vested restricted stock units that are expected to be recognized over a weighted-average period of 9.11 years.

6. RELATED PARTY TRANSACTIONS

NanoHybrids Inc.

In December 2021, the Company entered into an agreement with NanoHybrids, Inc. (“NanoHybrids”) to utilize the Company’s research and development staff and laboratory facility when available to perform work for NanoHybrids. Any hours worked by Company employees for NanoHybrids is 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. The Company’s Chief Technology Officer is the majority shareholder of NanoHybrids. The table below summarizes the amounts earned and due from NanoHybrids as of and for the three and nine month periods ended September 30, 2023 and 2022, and balances due as of September 30, 2023 and December 31, 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Income from NanoHybrids included in Other Income	$ -	$ 42,649	$ 136,773	$ 118,575
Cash receipts from NanoHybrids	$ -	$ 35,040	$ 156,504	$ 75,926

	As of	
	September 30, 2023	December 31, 2022
Amounts receivable from NanoHybrids included in Prepaids and Other Current Assets	$ -	$ 19,731

7. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following at September 30, 2023 and December 31, 2022:

	Depreciable lives	September 30, 2023	December 31, 2022
Construction-in-process		$ 1,067,149	$ 375,466
Furniture, fixtures, and equipment	3-5 years	141,164	136,942
Software	3-5 years	4,457	4,457
Lab equipment	3-5 years	1,287,783	1,268,380
Leasehold improvements	Shorter of useful life or lease term	43,231	43,231
		2,543,784	1,828,476
Less: accumulated depreciation		(1,222,073)	(596,406)
Property and equipment, net		$ 1,321,711	$ 1,232,070

The Company reviews long-lived assets for impairment when events, expectations, or changes in circumstances indicate that the asset's carrying value may not be recoverable. As a result of this review in 2023, the Company revised the useful life of certain lab equipment in the first quarter of 2023 due to a change in expectations of the time the equipment will be used which resulted in approximately $431,740 of additional depreciation recorded in the nine months ended September 30, 2023.

8. LEASES

The Company primarily enters into lease arrangements for office and laboratory space. A summary of supplemental lease information is as follows:

	Nine Months Ended	
	September 30, 2023	September 30, 2022
Weighted average remaining lease term - operating leases (in years)	3.1	3.9
Weighted average remaining lease term - finance leases (in years)	4.3	5.3
Weighted average discount rate	7.0%	7.0%
Operating cash flows from operating leases	$ 130,692	$ 113,083
Operating cash flows from finance leases	$ 3,605	-

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

	As of	
	September 30, 2023	December 31, 2022
Operating lease right-of-use asset	$ 367,248	$ 465,514
Finance leases in Property and Equipment	21,067	21,067
Total lease assets	388,315	486,581
Current portion of operating lease liability	168,716	168,706
Current portion of finance lease liability included in accrued expenses	4,807	4,807
Noncurrent operating lease liabilities	220,093	323,915
Noncurrent finance lease liabilities	13,220	15,823
Total lease liabilities	$ 406,836	513,251

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

Year	Finance Leases	Operating Leases
2023*	$ 1,202	$ 42,177
2024	4,807	162,991
2025	4,807	100,000
2026	4,807	100,000
2027	5,207	25,000
Thereafter	-	-
Total future lease payments	20,830	430,168
Less: Imputed interest	2,803	41,359
Present value of lease liability	$ 18,027	$ 388,809

(*) Excludes the nine months ended September 30, 2023

9. COMMITMENTS AND CONTINGENCIES

Separation Agreement

Under the terms of a separation agreement with Mr. Kenneth Fisher, the Company's former Chief Financial Officer, the Company has agreed to compensate Mr. Fisher $240,000 (representing six months of base salary and the pro rata amount of Mr. Fisher's 2023 target bonus). The payment of such amounts are subject to the compliance by Mr. Fisher of certain ongoing covenants with respect to confidentiality, cooperation and other matters. Mr. Fisher departed from the Company on September 26, 2023, and the Company has recorded a severance liability of $240,000, which has been included in accrued expenses and other current liabilities on the Company's Condensed Consolidated Balance Sheets as of September 30, 2023.

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 15% of the net sales of the Cartridges for the period that any underlying patents exist or for 5 years after the first sale. Following the first sale, the Company will pay a one-time minimum royalty of $60,000, which shall be creditable against any royalties owed to Toray in such calendar year. The Company will pay a minimum royalty of $100,000 in each year thereafter, which are creditable against any royalties owed to Toray in such calendar year. There were no sales of or revenues from the Cartridges through September 30, 2023.

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"). Please refer to Note 10 for further detail.

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.

10. SUBSEQUENT EVENTS

The Company did not identify any subsequent events that require adjustment or disclosure in the unaudited condensed consolidated financial statements other than discussed below.

On October 23, 2023, the Company and Toray entered into the New Toray License Agreement and the New Toray Supply Agreement. The New Toray License Agreement and the New Toray Supply Agreement amend and supersede the prior License and Supply Agreement entered into by the parties in October 2020 and amended in July 2021.

Under the New Toray License Agreement, the Company continues to license from Toray intellectual property rights needed to manufacture single-use test cartridges, and the Company has received the right to sublicense certain Toray intellectual property to Sanyoseiko in connection with Sanyoseiko's ongoing agreement with the Company to manufacture its Symphony device and cartridges (including in connection with the Company's clinical trials). In addition, the New Toray License Agreement provides for the transfer of certain technology related to the cartridges to Sanyoseiko. The royalty payments payable by the Company to Toray have been reduced under the New Toray License Agreement from 15% to 7.5% (or less in certain circumstances) of net sales of certain cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. The New Toray License Agreement contemplates that applicable royalty payment obligations from the Company to Toray for other products will be determined separately by the parties in the future.

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

Overview

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

Since inception, we have incurred net losses from operations each year and we expect to continue to incur losses for the foreseeable future. We incurred net losses of approximately $7.7 million and $6.9 million for the nine months ended September 30, 2023 and 2022, respectively. We had negative cash flow from operating activities of approximately $5.5 million and $4.8 million for the nine months ended September 30, 2023 and 2022, respectively, and had an accumulated deficit of approximately $24.6 million as of September 30, 2023.

Results of Operations

Comparison of the Three and Nine months Ended September 30, 2023 and 2022

The following table sets forth our results of operations for the three and nine months ended September 30, 2023 and 2022:

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ -	$ -	$ -	$ 249,040
Cost of sales	-	-	-	200,129
Gross profit	-	-	-	48,911
Operating expenses:				
Research and development	1,397,318	1,379,665	4,428,123	2,830,705
General and administrative	963,534	1,284,411	3,213,614	3,801,226
Sales and marketing	(19,619)	146,102	282,756	281,144
Total operating expenses	2,341,233	2,810,178	7,924,493	6,913,075
Operating loss	(2,341,233)	(2,810,178)	(7,924,493)	(6,864,164)
Other income (expense):				
Impairment of property and equipment	-	(210,117)	-	(210,117)
Other income, net	43,235	60,406	273,347	163,587
Total other income (expense), net	43,235	(149,711)	273,347	(46,530)
Net loss	$ (2,297,998)	$ (2,959,889)	$ (7,651,146)	$ (6,910,694)

Revenue and Gross Profit

Revenue and gross profit had no change for the three-month period ended September 30, 2023 and decreased approximately $0.2 million and $0.1 million respectively, for the nine-month period ended September 30, 2023, as compared to the same period in 2022. The decrease was due to a minor sale of five Symphony analyzers to our business partner, Toray, during 2022. Future sales to Toray after 2022 were not anticipated.

Research and Development

Research and development expenses for the three and nine months ended September 30, 2023 were approximately $1.4 million and $4.4 million, respectively, as compared to approximately $1.4 million and $2.8 million, respectively, for the comparable periods in 2022. The increase in research and development expenses was primarily due to an increase in personnel costs and product development expenses. We expect increases in our future research and development expenses which will be focused on our clinical trial program and any necessary manufacturing improvements.

General and Administrative

General and administrative expenses for the three and nine months ended September 30, 2023 were approximately $1.0 million and $3.2 million, respectively, as compared to approximately $1.3 million and $3.8 million, respectively, for the comparable periods in 2022. The decrease in general and administrative expenses is due to continued efforts to preserve capital by limiting our investment in infrastructure commensurate with our commercialization timeline, as well as reduction in our workforce. 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 and nine months ended September 30, 2023 were approximately zero, which was associated with the cancellation and forfeiture of equity awards by terminated personnel, and $0.3 million, respectively, as compared to approximately $0.1 million and $0.3 million, respectively, for the comparable periods in 2022. The decrease in sales and marketing expenses for the three months ended September 30, 2023 is primarily attributable to the Company’s cost savings efforts as the Company seeks to limit personnel costs.

Other Income, net

Other income, net for the three and nine months ended September 30, 2023 was approximately $0.1 million and $0.3 million as compared to approximately $0.1 million and $0.2 million for the same periods in 2022. While the net other income remained relatively unchanged for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022, the increase in net other income for the nine month period ended September 30, 2023 was primarily due to higher interest rates and an increase in related party income from NanoHybrids, as compared to the comparative nine-month period.

Liquidity and Going Concern

We have funded our operations primarily through the net proceeds from our IPO on November 10, 2021, and the Offering described within Note 1 of our Condensed Consolidated Financial Statements. We had cash and cash equivalents of approximately $5.1 million as of September 30, 2023. We continue to develop the Symphony device and its first cartridge for the measurement of IL-6. We remain committed to obtaining FDA clearance and will conduct clinical trials to obtain sufficient data to support our FDA submission, while also continuing to build our manufacturing operations with our contract manufacturing organizations. Current cash resources and expected operating expenses are considered in determining our liquidity requirement; as well as approximately $2.8 million of current liabilities on our condensed consolidated balance sheet as of September 30, 2023.As of the filing of this report, we expect to need additional capital to fund our planned operations for the next twelve months.

We expect that we will seek to raise such additional capital through public or private equity offerings, grant financing and support from governmental agencies, convertible debt, collaborations, strategic alliances and distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay our FDA regulatory strategy, and to delay or reduce the scope of our research or development programs, our commercialization efforts or our manufacturing commitments and capacity. In addition, if we raise additional funds through collaborations, strategic alliances or distribution arrangements with third parties, we may have to relinquish valuable rights to its technologies or future revenue streams.

If we are unsuccessful in our efforts to raise additional capital, based on our current and expected levels of operating expenses, our current capital will not be sufficient to fund our operations for the next twelve months. These conditions raise substantial doubt about our ability to continue as a going concern.

Summary Statement of Cash Flows

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

	Nine months Ended September 30,	
	2023	**2022**
Cash proceeds (used in) provided by:		
Operating activities	$ (5,536,393)	$ (4,797,350)
Investing activities	(616,272)	(961,063)
Financing activities	1,114,612	-
Net decrease in cash and cash equivalents	$ (5,038,053)	$ (5,758,413)

Net cash used in operating activities

During the nine months ended September 30, 2023, we used approximately $5.5 million in cash for operating activities, an increase of approximately $0.7 million as compared to approximately $4.8 million for the same period in 2022. The increase in net cash used in operating activities was primarily due to increases in personnel and product development costs, which ultimately led to the reduction of personnel in the second and third quarters of 2023, which is offset by noncash items such as depreciation expense on our fixed assets and stock-based compensation expense associated with our equity awards.

Net cash used in investing activities

During the nine months ended September 30, 2023, we used approximately $0.6 million in cash for investing activities, a decrease of approximately $0.3 million as compared to the same period in 2022. The decrease in net cash used in investing activities was primarily due to a shift in the Company's focus away from COVID-19 patients, which decreased the Company's need for purchases of equipment during the nine months ended September 30, 2023.

Net cash provided by financing activities

During the nine months ended September 30, 2023, financing activities provided approximately $1.1 million in cash. The increase in net cash provided by financing activities was primarily due to the Company's Offering during the nine months ended September 30, 2023.

Recently Adopted Accounting Standards

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

Emerging Growth Company and Smaller Reporting Company Status

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

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenues of at least $1.235 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

Section 107 of 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 for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we remain an emerging growth company under the recently-enacted JOBS Act, we will, among other things:

- be permitted to have only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial condition and results of operations disclosure;
- be entitled to rely on an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- be entitled to reduced disclosure obligations about executive compensation arrangements in our periodic reports, registration statements and proxy statements; and
- be exempt from the requirements to seek non-binding advisory votes on executive compensation or golden parachute arrangements.

We currently intend to take advantage of some or all of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company." Among other things, this means that our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an emerging growth company, which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected.

Likewise, so long as we qualify as an emerging growth company, we may elect not to provide certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. As a result, investor confidence in our company and the market price of our common stock may be materially and adversely affected.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

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

We conducted an evaluation under the supervision and with the participation of our management, including the Chief Executive Officer and Interim Chief Financial Officer (our principal executive officer and principal financial officer, respectively), regarding the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Interim Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2023. We continue to review our disclosure controls and procedures and may from time to time make changes aimed at enhancing their effectiveness and ensuring that our systems evolve with our Company's business. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

(b) Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2023 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 2022 annual report on Form 10-K on file with the SEC. Except as set forth below, there have been no material changes to the risk factors disclosed in such annual report.

Risks Related to Our Business

The New License Agreement with Toray, which covers the license of the core technology used in our Symphony Cartridges, and the New Supply Agreement with Toray, which covers the supply of cartridge intermediates from Toray to SanyoSeiko for SanyoSeiko to manufacture cartridges for Bluejay, contain significant risks that may threaten our viability or otherwise have a material adverse effect on us and our business, assets and its prospects.

We have an exclusive license with Toray for the entire world, excluding Japan, to use their patents and know-how related to our Symphony test cartridges for the manufacturing, marketing and sale of such products. We also have a nonexclusive license for manufacturing purposes in Japan. We have a right to sublicense these Toray patents and know-how (upon either (a) obtaining consent from Toray prior to obtaining FDA approval or (b) giving notice to Toray after obtaining FDA approval), and for the purpose of obtaining FDA approval, we will need to exercise this sublicence to have the cartridges manufactured for Bluejay by a Japanese manufacturer, SanyoSeiko, Inc. (“SanyoSeiko”). We have no contractual rights to the intellectual property covered in the New License Agreement other than as expressly set forth therein. Our plans, business, prospects and viability are substantially dependent on that intellectual property and subject to the limitations relating thereto as set forth in the New License Agreement. Some of the risks this may give rise to are described below.

- After the receipt of regulatory approval in a country, we are required to pay Toray a minimum royalty of $60,000 for the initial year that royalties are payable increasing to a minimum of $100,000 thereafter, regardless of the actual amount of sales by us of licensed products. Accordingly, we could be obligated to pay royalties even though we have generated no or limited revenue. Such payments could materially and adversely affect our profitability and could limit our investment in our business.

- Toray is only required to supply cartridge intermediates for a period of in principle two years ending in October 2025, and with extension for a maximum of six months thereafter. If Sanyoseiko is unable to manufacture intermediates within that period or we are unable to extend that period further, we could be without any cartridge supply in the future.

- Toray may not be able to provide all necessary know-how related to the test cartridges, which may increase the time and cost of remediating product defects, or impair our ability to timely scale up cartridge manufacturing.

- The license and regulatory approvals (once obtained) are non-assignable. These restrictions may limit our flexibility to structure our operations in the most advantageous manner.

- At our sole expense, we must file for, prosecute the application for, and obtain all regulatory approvals for the licensed products and obtain all legal permits necessary for promoting, marketing, offering or selling each licensed product. The regulatory approval process can be expensive and time consuming, and there can be no assurances that we will be able to obtain or maintain any or all required permits.

- We are required to use reasonable efforts to obtain market approval for the products in the United States or the European Union by October 2026 or the License Agreement could be terminated by Toray.

- Toray has the right to terminate the New License Agreement or make it non-exclusive if we do not generate commercial sales by October 2028, or by October 2030 if the lack of commercial sales is due to events within our control and not due to Toray's failure to perform its obligations in a timely manner.

- Except with respect to (a) Toray's ownership of, or rights to license, all intellectual property rights in respect of the licensed property and (b) Toray's applicable patents being duly maintained and in effect, Toray provides no, and disclaims all, representations, warranties or covenants relating to the licensed intellectual property or any other matters under the New License Agreement and in particular disclaims any fitness of the intellectual property for any purpose or any warranty against infringement of any third-party patent. These provisions limit our recourse in the event that the licensed intellectual property is flawed, defective, inadequate, incomplete, uncommercial, wrongly described or otherwise not useful for our purposes. We have not independently verified any of the technical, scientific, commercial, legal, medical or other circumstances or nature of the licensed intellectual property and therefore there can be no assurances that any of the foregoing risks have been reduced or eliminated. These provisions represent a significant risk of a material adverse impact on us, our business and our prospects.

- While Bluejay is in principle permitted, even after the New License Agreement expires or is terminated, to continue manufacturing and selling products that incorporate Toray intellectual property and the royalties for which are fully paid up, if Bluejay commits certain material breaches of the agreement, Bluejay may be obligated to use reasonable efforts to arrange for the transfer to Toray of FDA or any other regulatory approvals for any products the royalties for which are not fully paid up. Where any such transfer is possible and approved by the regulator (if necessary), then depending on the nature of the material breach, Bluejay may be required to undertake the transfer at no cost to Toray or on reasonable terms and conditions. The loss of any such market approvals, especially if we are unable to receive any consideration for them, could have a material adverse impact on us, our business and our prospects, and depending on the timing and extent of the loss, it could even threaten our viability.

In addition, see the risks in "*Risks Related to Our Intellectual Property*" below. These risks are not the only risks inherent in the New License Agreement. You are encouraged to read the complete text of the New License Agreement, which was filed as an exhibit to our Form 8-K filed on October 26, 2023.

We depend on, and are liable for, SanyoSeiko as our primary contract manufacturing organization (CMO), so its inability or failure to perform appropriately in that capacity may threaten our viability or have a material adverse effect on us and our business, assets and its prospects.

We are dependent on SanyoSeiko not only to appropriately utilize Toray's know-how and other intellectual property, but also to continuously manufacture and supply us with our Symphony cartridges. If SanyoSeiko is unable to do so for any reason and we are unable to activate a new CMO to produce cartridges, we may be unable to obtain FDA approval and commence any commercial sales or unable to supply products to our customers in a timely manner or at all, either of which could threaten our viability.

We are also liable for SanyoSeiko's performance and actions as our CMO, and any breach by SanyoSeiko of the New License Agreement or the New Supply Agreement may have a material adverse effect on us and our business.

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from Toray, and any dispute over the license would significantly harm our business.

We are dependent on the intellectual property licensed from Toray. Disputes may arise between us and Toray regarding intellectual property subject to the New License Agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and launch our Symphony platform and our other product candidates. If we or Toray fail to adequately protect this intellectual property, our ability to launch our products in the market could be limited. For so long as we are dependent on the intellectual property covered by the New License Agreement for the pursuit of our business, any such disputes relating to the New License Agreement or failure to protect the intellectual property could threaten our viability.

We will depend primarily on Toray to file, prosecute, maintain, defend and enforce intellectual property that we license from it and that is material to our business.

The key underlying intellectual property relating to our Symphony platform is owned by Toray. Under the New License Agreement, Toray generally has the right to file, prosecute, maintain and defend the intellectual property we have licensed from Toray. If Toray fails to conduct these activities for intellectual property protection covering any of our product candidates, our ability to develop and launch those product candidates may be adversely affected and we may not be able to prevent competitors from making, using or selling competing products. In addition, pursuant to the terms of the New License Agreement, Toray generally has the right to control the enforcement of our licensed intellectual property and the defense of any claims asserting the invalidity of that intellectual property. We cannot be certain that Toray will allocate sufficient resources to and otherwise prioritize the enforcement of such intellectual property or the defense of such claims to protect our interests in the licensed intellectual property. In the absence of action by Toray, we may be unable to protect and enforce the proprietary rights on which our business relies. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent or impede us from continuing to use the licensed intellectual property that we need to operate our business or from realizing the full commercial benefit contemplated by the agreement. In addition, even if we take control of the prosecution of licensed intellectual property and related applications, enforcement of licensed intellectual property, or defense of claims asserting the invalidity of that intellectual property, we may still be adversely affected or prejudiced by actions or inactions of Toray and its counsel that took place prior to or after our assuming control, and we cannot ensure the cooperation of Toray in any such action. Furthermore, if we take action to protect, enforce or defend the licensed intellectual property, we may incur significant costs and the attention of our management may be diverted from our normal business operations. As a result, our business, results of operations and financial condition could be materially and adversely affected.

We and Toray may be unable to protect or enforce the intellectual property rights licensed to us, which could impair our competitive position.

In order for our business to be viable and to compete effectively, the proprietary rights with respect to the technologies and intellectual property used in our products must be developed and maintained. Toray relies primarily on patent protection and trade secrets to protect its technology and intellectual property rights. There are significant risks associated with Toray's ability (or our ability, in the absence of action by Toray) to protect the intellectual property licensed to us, including:

- pending intellectual property applications may not be approved or may take longer than expected to result in approval in one or more of the countries in which we operate;
- Toray's intellectual property rights may not provide meaningful protection;
- other companies may challenge the validity or extent of Toray's patents and other proprietary intellectual property rights through litigation, oppositions and other proceedings. These proceedings can be protracted as well as unpredictable;
- other companies may have independently developed (or may in the future independently develop) similar or alternative technologies, may duplicate Toray's technologies or may design their technologies around Toray's technologies;
- enforcement of intellectual property rights is complex, uncertain and expensive, and may be subject to lengthy delays. In the event we take control of any such action under the New License Agreement, our ability to enforce our intellectual property protection could be limited by our financial resources; and
- the other risks described in "— Risks Related to Our Intellectual Property."

If any of Toray's patents or other intellectual property rights fail to protect the technology licensed by us, it would make it easier for our competitors to offer similar products. Any inability on Toray's part (or on our part, in the absence of action by Toray) to adequately protect its intellectual property may have a material adverse effect on our business, financial condition and results of operations.

We and/or Toray may be subject to claims alleging the violation of the intellectual property rights of others.

We may face significant expense and liability as a result of litigation or other proceedings relating to intellectual property rights of others. In the event that another party has intellectual property protection relating to an invention or technology licensed by us from Toray, we and/or Toray may be required to participate in an interference proceeding declared by the regulatory authorities to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome was favorable to us. We and/or Toray also could be required to participate in interference proceedings involving intellectual property of another entity. An adverse outcome in an interference proceeding could require us and/or Toray to cease using the technology, to substantially modify it or to license rights from prevailing third parties, which could delay or prevent the launch of our products in the market or adversely affect our profitability.

The cost to us of any intellectual property litigation or other proceeding relating the intellectual property licensed by us from Toray, even if resolved in our favor, could be substantial, especially given our early stage of development. A third party may claim that we and/or Toray are using inventions claimed by their intellectual property and may go to court to stop us and/or Toray from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume significant time and other resources. There is a risk that a court will decide that we and/or Toray are infringing the third party's intellectual property and will order us to stop the activities claimed by the intellectual property. In addition, there is a risk that a court will order us and/or Toray to pay the other party damages for having infringed their intellectual property. Moreover, there is no guarantee that any prevailing intellectual property owner would offer us a license so that we could continue to engage in activities claimed by the intellectual property, or that such a license, if made available to us, could be acquired on commercially acceptable terms.

We and Toray may be subject to claims challenging the invention of the intellectual property that we license from Toray.

We and Toray may be subject to claims that former employees, collaborators or other third parties have an interest in intellectual property as an inventor or co-inventor. For example, we and Toray may have inventorship disputes arising from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we and Toray fail in defending any such claims, in addition to paying monetary damages, we and Toray may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. As a result, it is unclear whether and, if so, to what extent employees of ours and Toray may be able to claim compensation with respect to our future revenue. We may receive less revenue from future products if any of the employees of Toray or us successfully claim compensation for their work in developing our intellectual property, which in turn could impact our future profitability.

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

None

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, filed with the Delaware Secretary of State on July 21, 2023 (initially filed as Exhibit 3.1 on Form 8-K (File No. 001-41031) on July 21, 2023, and incorporated by reference herein).
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.1	Form of Warrant, dated August 28, 2023 (initially filed as Exhibit 4.1 on Form 8-K (File No. 001-41031) on August 28, 2023, and incorporated by reference herein).F
10.1	Form of Securities Purchase Agreement, dated August 24, 2023, by and between the Company and each of the Purchasers signatory thereto (initially filed as Exhibit 10.1 on Form 8-K (File No. 001-41031) on August 28, 2023, and incorporated by reference herein).
10.2*	Separation Agreement and General Release, dated October 6, 2023, by and between the Company and Kenneth Fisher.
10.3	Amended and Restated License Agreement, entered into on October 23, 2023, by and between Bluejay Diagnostics, Inc. and Toray Industries, Inc. (initially filed as Exhibit 10.1 on Form 8-K (File No. 001-41031) on October 26, 2023, and incorporated by reference herein).
10.4	Master Supply Agreement, entered into on October 23, 2023, by and between Bluejay Diagnostics, Inc. and Toray Industries, Inc. (initially filed as Exhibit 10.2 on Form 8-K (File No. 001-41031) on October 26, 2023, and incorporated by reference herein).
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	Chief Executive Officer and Director (on behalf of the registrant)	November 9, 2023
/s/ Frances Scally Frances Scally	Interim Chief Financial Officer (principal financial and accounting officer)	November 9, 2023

SEPARATION AGREEMENT AND GENERAL RELEASE

This Separation Agreement and General Release (the "Agreement") is being entered into by and between Bluejay Diagnostic, Inc. (the "Company") and Kenneth R. Fisher ("Executive"). The Company and Executive may hereafter be referred to individually as a "Party" or collectively as the "Parties." Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Employment Agreement by and between the Parties entered into as of March 23, 2022 (the "Employment Agreement").

WHEREAS, Executive's last day of employment is or was September 26, 2023 the "Separation Date");

WHEREAS, Executive wishes to enter into this Agreement, and accordingly, the Company and Executive have agreed to the following terms in connection with termination of Executive's employment;

NOW, THEREFORE, for and in consideration of the mutual promises contained herein, and for other good and sufficient consideration, receipt of which is hereby acknowledged, and intending to be legally bound, the Parties agree as follows:

1. **Separation Date and Related Matters**.

(a) Executive acknowledges that as of the Separation Date, Executive's employment with the Company and all of the offices, directorships, appointments, and other positions Executive holds with the Company and all of its direct and indirect parents, subsidiaries, affiliates or related entities have terminated. After the Separation Date, Executive shall not represent that Executive is an employee, officer, agent, or representative of the Company or any of its direct or indirect parents, subsidiaries, affiliates, or related entities for any purpose.

(b) Whether or not Executive executes this Agreement, the Company will pay or provide to Executive: (i) any unpaid Base Salary through the Separation Date, (ii) any accrued but unused vacation or paid time off in accordance with the Company's policy, (iii) reimbursement for any unreimbursed business expenses incurred through the termination date, to the extent reimbursable in accordance with Section 3 of the Employment Agreement, and (iv) all other payments or benefits (if any) to which Executive is entitled under the terms of any benefit plan or arrangement.

(c) Executive acknowledges that he was granted an Incentive Stock Option of 65,000 shares (the "Option") pursuant to the Bluejay Diagnostics, Inc. 2021 Stock Plan (the "Plan") Incentive Stock Option Agreement, effective as of March 23, 2022 (the "Option Agreement"). Executive acknowledges that, following a reverse stock split, 1,250 shares of the Option have vested and shall continue to be exercisable until the earlier of the 90th day after the Separation Date or the date the Option expires by its terms, and such shares remain subject to the terms and conditions of the Option Agreement and the Plan. The portion of the Option not vested as of the Separation Date shall expire as of such date and shall not be exercisable pursuant to the terms of the Option Agreement.

2. **Severance**.

(a) If Executive executes this Agreement, allows it to become effective, and complies with its terms, the Company shall pay Executive the gross sum of $150,000.00 (one hundred fifty thousand US dollars) in the amount of severance payment, which amount is the equivalent of six months of Executive's Base Salary *plus* the gross sum of $90,000.00 (ninety thousand US dollars) dollar amount of pro rata bonus, which amount is the equivalent of a pro rata portion of the Executive's 2023 target Annual Bonus (collectively, the "Severance Payments"). The Severance Payments shall be subject to withholding for applicable taxes and shall be paid in equal cash installments on the Company's normal payroll dates over a six month period, with the first such payment made on the first payroll date at least five (5) business days following the Effective Date (as defined below). The Severance Payments will be made by direct deposit to Executive's bank account currently on record with the Company.

(b) Executive acknowledges and agrees that the Severance Payments referred to in this Section 2 are consideration for Executive's promises contained in this Agreement, and that such Severance Payments are above and beyond any wages, salary, or other sums or benefits to which Executive is entitled from the Company or any of the other Company Releasees (defined below) under the terms of the Employment Agreement or any other source of entitlement. Executive agrees that once Executive receives the Severance Payments, Executive is not owed and will not seek any additional amounts or benefits from the Company or any of the other Company Releasees.

(c) For the avoidance of doubt, if the Effective Date (as defined below) does not occur, no Severance Payments shall be provided to Executive, and any Severance Payments that were previously provided to Executive must be returned or repaid.

3. **General Release**.

(a) Executive, on Executive's own behalf and on behalf of Executive's agents, heirs, executors, administrators, representatives, attorneys, successors and assigns, hereby releases and forever discharges the Company and any and all of the Company's past, present, or future parents, subsidiaries, affiliates, and related entities, and any and all of their past, present or future officers, directors, members, employees, agents, counsel, consultants, auditors, contractors, successors and assigns ("Company Releasees"), from any and all complaints, claims, demands, damages, lawsuits, and causes of action, whether known, unknown or unforeseen, arising out of or in connection with any event, transaction or matter occurring or existing on or before the date of Executive's execution of this Agreement, which Executive has or may have against any of them for any reason whatsoever in law or in equity, under federal, state, local or other law, whether the same be upon statutory claim, contract, tort or other basis, including but not limited to any and all claims arising from or relating to Executive's employment or the termination of employment; any and all claims relating to wages, salary, bonuses, commissions, other compensation, expenses, benefits, leave, discrimination, disabilities, accommodation, harassment, or retaliation or other wrongful conduct; and any and all claims relating to any employment contract, express or implied. Without limiting the generality of the foregoing, this release covers any and all claims under the Civil Rights Acts of 1866 and 1964, the Americans with Disabilities Act, the Equal Pay Act, the Age Discrimination in Employment Act ("ADEA"), the National Labor Relations Act, the Family and Medical Leave Act, the Fair Labor Standards Act, the Employee Retirement Income Security Act, all as amended, and any other federal, state or local statutes related to employment. Without limiting the foregoing, this release include claims relating to the Massachusetts Fair Employment Practices Law, the Massachusetts Civil Rights Act, the Massachusetts Equal Rights Act, the Minimum Fair Wage Act, the Massachusetts Wage Act, the Massachusetts Equal Pay Act, the Massachusetts Parental Leave Act, the Massachusetts Sexual Harassment Statute, all as amended and including all of their respective implementing regulations.

(b) This release covers claims Executive knows about and those Executive does not know about, but does not waive or release any claims or rights that arise after Executive executes this Agreement. Executive agrees, without limiting the generality of the above release, not to file any claim or lawsuit seeking monetary recovery or other relief for Executive based on any claims that are lawfully released in this Agreement. Executive further hereby irrevocably and unconditionally waives any and all rights to recover, and will not accept, any monetary or other relief for Executive concerning the claims that are lawfully released in this Section. Notwithstanding the foregoing, Executive is not releasing (a) any right to enforce this Agreement; or (b) any claims for unemployment compensation, workers' compensation benefits or other rights or claims that may not be released by this Agreement as a matter of law. Additionally, Executive is not releasing any rights Executive may have in the nature of indemnification or coverage under a directors and officers insurance policy, which shall apply in accordance with their terms. Executive represents and understands that the foregoing is a GENERAL RELEASE.

4. **No Admission**. The Parties agree that nothing contained in this Agreement shall constitute or be treated as an admission of liability or wrongdoing by the Company Releasees or Executive.

5. **Continuing Obligations**.

(a) Executive agrees to return and represents Executive has returned to the Company, and is no longer in possession of, all information, property, and supplies belonging to the Company and its Affiliated Entities and clients, including, without limitation, documents, records, files, notebooks, manuals, letters, notes, passwords/credentials, reports, customer and supplier lists, cost and profit data, e-mail, apparatus, computers, cell phones, tablets, hardware, software, drawings, and any other material, including all materials pertaining to Confidential Information developed by Executive or others, and all copies of such materials, whether of a technical, business or fiscal nature, whether on the hard drive of a laptop or desktop computer, in hard copy, disk, or any other format, which are in Executive's possession, custody, or control. Executive may, however, retain Executive's own personal compensation, financial, and benefits information.

(b) Executive reaffirms and agrees to comply with the restrictive covenants contained within the Employment Agreement and the Option Agreement, including (without limitation) under Sections 8 and 9 of the Employment Agreement and Section 5 of the Option Agreement (the "Reaffirmed Covenants"). The Reaffirmed Covenants are not superseded or limited by this Agreement (nor is this Agreement limited by such Reaffirmed Covenants), and continue to apply notwithstanding any other provisions in this Agreement.

(c) Executive acknowledges that during employment, Executive learned and came into contact with certain confidential and/or proprietary information and trade secrets of the Company and its Affiliated Entities, (collectively, "Confidential Information"). Executive acknowledges that Confidential Information includes without limitation trade secrets, financial information, future plans and projections, budgets, financing and credit-related information, business strategies and methods, costs, or other data and information concerning the Company, its Affiliated Entities, or their affairs, that the Company and/or its Affiliated Entities has not previously disclosed to the public, and any confidential information of others provided to the Company and its Affiliated Entities. Confidential Information includes information in any form, whether tangible or intangible, including without limitation all notes, records, drawings, handbooks, manuals, policies, contracts, memoranda, other documents, software, electronic files, data, drives, and cloud storage. Executive agrees that, as between Executive and the Company, Confidential Information is and shall remain the exclusive property of the Company, and Executive shall not disclose to any person or entity, use for Executive's own benefit, copy, or make notes of any Confidential Information, except as and only to the extent expressly authorized by the Company in writing.

(d) Executive agrees to keep confidential and not disclose the existence, terms, or circumstances relating to this Agreement (including, without limitation, the circumstances leading to Executive's separation from employment), except (i) as authorized in writing by the Company; (ii) to Executive's attorneys as may be necessary to secure advice concerning this Agreement; (iii) to Executive's tax advisors or accountants as may be necessary for the preparation of tax returns or other reports required by law; (iv) to members of Executive's immediate family; or (v) to enforce this Agreement. Executive further agrees that prior to disclosing such information under parts (ii), (iii) or (iv) of this subsection, Executive will inform the recipients that they are bound by these confidentiality limitations, and subsequent disclosure of such information by any such recipient shall be deemed to be a disclosure by Executive in breach of this Agreement.

(e) Executive shall not, directly or indirectly, make any written or oral statements to any person or entity that reflect negatively upon or otherwise disparage the Company Releasees or their affairs, products, or services.

(f) Executive agrees to reasonably cooperate with and assist the Company at the Company's request in responding to any claims, litigation, proceeding, or inquiry involving the Company in matters which the Company reasonably deems Executive's participation to be necessary as a result of Executive's employment with the Company. The Company shall reimburse Execute for reasonable, out-of-pocket expenses (not including attorneys' fees) for cooperation provided under this paragraph.

(g) Executive shall, upon request of the Company, before and after the Separation Date, provide information and otherwise reasonably cooperate and assist in effectuating a smooth transition from Executive's employment and any other positions Executive held as a result of employment with the Company (including turnover of passwords and other login credentials). Executive shall not receive additional compensation for transition assistance provided under this paragraph.

(h) Executive waives any and all rights to employment, reinstatement, or re-employment with the Company and specifically agrees that Executive will not intentionally in the future seek to be re-employed in any position by the Company, nor will Executive seek or apply for any such employment position.

6. **Rights Not Subject to Limitation**.

(a) Notwithstanding any other provisions of this Agreement, this Agreement does not limit any right Executive or the Company may have that may not be limited by private agreement, including any right to:

(i) provide any information in response to a valid subpoena, court order, other legal process or as otherwise required to be provided by law;

(ii) challenge the validity or enforceability of this Agreement (including under the ADEA);

(iii) apply for unemployment compensation or workers' compensation benefits;

(iv) file a charge with, provide information to, or participate in an investigation or proceeding conducted by a government agency (such as the Equal Employment Opportunity Commission or National Labor Relations Board) authorized to enforce laws against unlawful conduct, provided that this Agreement does waive, to the maximum extent permitted by law, any right to seek, recover or accept any monetary payments or other individual relief for the Executive connected to any agency or other action related to claims that are lawfully released in this Agreement; or

(v) report possible violations of federal or state law or regulation to any governmental agency or entity or self-regulatory organization or to cooperate with such agency, entity, or organization, without notice to the Company (and to receive a whistleblower award provided by law for providing such information).

(b) The Parties acknowledge that pursuant to 18 U.S.C. § 1833(b), an individual may not be held liable under any criminal or civil federal or state trade secret law for disclosure of a trade secret: (i) made in confidence to a government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Additionally, an individual suing an employer for retaliation based on the reporting of a suspected violation of law may disclose a trade secret to his or her attorney and use the trade secret information in the court proceeding, so long as any document containing the trade secret is filed under seal and the individual does not disclose the trade secret except pursuant to court order.

(c) Executive agrees that in the event Executive receives a subpoena or similar request or demand by any person or entity (including a government agency) to give testimony or produce documents pertaining to Executive's employment with the Company, Executive will give prompt written notice of such subpoena, request, or demand to the Company, to allow the Company a reasonable opportunity to, if it elects, first contest the right of the requesting person or entity to such disclosure.

7. **Additional Provisions**.

(a) In the event of a breach or threatened breach by Executive of Sections 3 or 5 of this Agreement, Executive agrees that money damages would not afford an adequate remedy and that the Company shall be entitled to seek a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, without showing actual damages, and without posting bond. Any equitable relief will be in addition to, and not in lieu of, legal remedies, monetary damages, or other available relief.

(b) The Parties represent and acknowledge that in executing this Agreement they do not rely and have not relied upon any representation or statement, other than those contained in this Agreement, made by the other Party or the other Party's agents, representatives or attorneys with regard to the subject matter, basis or effect of this Agreement or otherwise. Executive acknowledges and agrees that Executive is solely responsible for payment of taxes owed by Executive as a consequence of this Agreement. This Agreement contains the entire agreement between the Parties relating to the subject matter of this Agreement, may not be altered or amended except by an instrument in writing signed by both Parties, and supersedes all prior agreements between the Parties relating to the subject matter of this Agreement except for the Option Agreement, the Plan, and the Reaffirmed Covenants.

(c) Neither the waiver by either Party of a breach of or default under any of the provisions of this Agreement, nor the failure of such Party, on one or more occasions, to enforce any of the provisions of this Agreement or to exercise any right or privilege hereunder shall be construed as a waiver of any subsequent breach or default of a similar nature, or as a waiver of any provisions, rights or privileges hereunder. If any part, term or provision of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, unenforceable or otherwise in conflict with law, the validity of the remaining parts, terms or provisions shall not be affected, provided that if a court finds that the release language is unenforceable, the Parties shall, in good faith, rewrite (or, if they cannot agree, ask the court to rewrite) the offending language to cure the defect in a reasonable manner that maintains the intended status quo as closely as possible. This Agreement shall extend to, be binding upon, and inure to the benefit of the Parties, and their respective successors, heirs, and assigns, provided that this Agreement may not be assigned by Executive without the Company's written consent.

(d) This Agreement shall be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts (excluding the choice of law rules thereof). The language of all parts of this Agreement shall in all cases be construed as a whole, according to its fair meaning, and not strictly for or against either Party. This Agreement may be executed electronically and may be executed in counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same written agreement, which shall be binding and effective as to all Parties.

(e) This Agreement is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"), or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under this Agreement upon a termination of employment that are "deferred compensation" for purposes of Section 409A shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by Executive on account of non-compliance with Section 409A.

8. **Acknowledgments; Effective Date**. Executive acknowledges and understands that Executive: (a) has read and understands this Agreement and executes it voluntarily and without coercion; (b) is being advised herein to consult an attorney prior to executing this Agreement and has had a full opportunity to do so; (c) has twenty-one (21) calendar days from the date Executive received this Agreement to consider, execute and return this Agreement to Gary Gemignani, 360 Massachusetts Avenue, Suite 203, Acton, MA 01720 (email:gary.gemignani@gmail.com) and if Executive signs this Agreement prior to the end of the twenty-one (21) day period, Executive has done so voluntarily; and (d) has seven (7) calendar days after executing this Agreement to revoke it by providing written notice of revocation to Gary Gemignani at the contact information stated above, no later than 11:59 p.m. on the seventh calendar date after Executive signed this Agreement. Executive further understands that if Executive revokes this Agreement, it shall be null and void and of no force or effect on either Executive or the Company. This Agreement is not effective or enforceable until after the seven (7) day period expires without revocation (the "Effective Date"), and the Company's promises under this Agreement, including but not limited to its obligation to provide Executive with the Severance Payments, will arise only after this time.

[*Signature page follows.*]

In witness hereof, the Parties have agreed and affixed their signatures below. If Executive has signed this Agreement before the expiration of any consideration period provided above, Executive acknowledges that the Executive has done so knowingly and voluntarily.

KENNETH R. FISHER:

/s/ Kenneth Fisher

Date: October 6, 2023

BLUEJAY DIAGNOSTIC, INC.:

By: /s/ Gary Gemignani
Name: Gary Gemignani
Title: Member of the Board, Chair, Audit Committee

Date: September 26, 2023

[*Signature Page to Separation Agreement and General Release*]

Exhibit 31.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER

I, Neil Dey, certify that:

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

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

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

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

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

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

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

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

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

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

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

November 9, 2023

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

Exhibit 31.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER

I, Frances Scally, certify that:

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

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

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

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

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

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

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

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

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

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

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

November 9, 2023

By: /s/ Frances Scally
Frances Scally
Interim Chief Financial Officer
(Principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION OF CHIEF 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)

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

The quarterly report on Form 10-Q for the quarter ended September 30, 2023 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2023

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

Exhibit 32.2

CERTIFICATION OF CHIEF 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)

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

The quarterly report on Form 10-Q for the quarter ended September 30, 2023 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2023

By: /s/ Frances Scally
Frances Scally
Interim Chief Financial Officer
(Principal financial and accounting officer)