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, 2026

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 1,117,009 shares of common stock outstanding at November 03, 2026.

TABLE OF CONTENTS

		Page
PART I FINANCIAL INFORMATION		
Item 1.	Condensed Consolidated Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets as of September 30, 2026 and December 31, 2025	1
	Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2026 and 2025	2
	Condensed Consolidated Statements of Changes in Stockholders' Equity for the Three and Nine Months Ended September 30, 2026 and 2025	3
	Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2026 and 2025	4
	Notes to Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	30
Item 4.	Controls and Procedures	30
PART II OTHER INFORMATION		
Item 1.	Legal Proceedings	31
Item 1A.	Risk Factors	31
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	32
Item 3.	Defaults Upon Senior Securities	32
Item 4.	Mine Safety Disclosures	32
Item 5.	Other Information	32
Item 6.	Exhibits	33
Signatures		34

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

EXPLANATORY NOTE

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

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

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

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,379,983	$ 5,164,875
Prepaid expenses and other current assets	146,101	275,957
Assets held for sale	12,690	22,770
Total current assets	7,538,774	5,463,602
Property and equipment, net	1,778,293	1,534,441
Operating lease right-of-use assets	46,672	113,289
Other non-current assets	5,439	7,905
Total assets	$ 9,369,178	$ 7,119,237
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 445,843	$ 214,255
Operating lease liability, current	49,441	100,000
Accrued expenses and other current liabilities	1,432,036	804,942
Total current liabilities	1,927,320	1,119,197
Operating lease liability, non-current	-	20,211
Other non-current liabilities	1,331	4,540
Total liabilities	1,928,651	1,143,948
Commitments and Contingencies (See Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 1,117,009 and 151,133 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	112	15
Additional paid-in capital	55,212,779	47,492,541
Accumulated deficit	(47,772,364)	(41,517,267)
Total stockholders' equity	7,440,527	5,975,289
Total liabilities and stockholders' equity	$ 9,369,178	$ 7,119,237

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-4 reverse stock split effective January 29, 2026
and a 1-for-4 reverse stock split effective November 3, 2026

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 1,116,568	$ 785,608	$ 3,366,212	$ 2,460,304
General and administrative	944,845	831,339	2,983,157	3,030,921
Total operating expenses	2,061,413	1,616,947	6,349,369	5,491,225
Operating loss	(2,061,413)	(1,616,947)	(6,349,369)	(5,491,225)
Other income:				
Interest income	49,510	18,961	93,198	66,016
Other income (expense), net	60	354	1,074	6,538
Total other income, net	49,570	19,315	94,272	72,554
Net loss	$ (2,011,843)	$ (1,597,632)	$ (6,255,097)	$ (5,418,671)
Net loss per share – Basic and diluted	$ (1.72)	$ (16.92)	$ (9.68)	$ (73.98)
Weighted average common shares outstanding – Basic and diluted	1,172,658	94,408	646,219	73,243

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-4 reverse stock split effective January 29, 2026
and a 1-for-4 reverse stock split effective November 3, 2026

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

	Stockholders' Equity				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2025	151,133	$ 15	$ 47,492,541	$ (41,517,267)	$ 5,975,289
Exercise of October 2025 Pre-Funded Warrants	91,921	9	138	-	147
Issuance of common stock in connection with the March 2026 Private Placement	15,625	2	124,998	-	125,000
Net loss	-	-	-	(1,919,241)	(1,919,241)
Balance at March 31, 2026	258,679	26	47,617,677	(43,436,508)	4,181,195
Issuance of common stock in connection with June 2026 Private Placement, net of issuance costs of $942,262	-	-	7,557,827	-	7,557,827
Exercise of June 2026 Pre-Funded Warrants	237,242	24	(193)	-	(169)
Net loss	-	-	-	(2,324,013)	(2,324,013)
Balance at June 30, 2026	495,921	50	55,175,311	(45,760,521)	9,414,840
Stock-based compensation expense	-	-	55,972	-	55,972
Exercise of June 2026 Pre-Funded Warrants	621,088	62	56	-	118
Issuance costs in connection with the June 2026 Private Placement			(18,560)		(18,560)
Net loss	-	-	-	(2,011,843)	(2,011,843)
Balance at September 30, 2026	**1,117,009**	**$ 112**	**$ 55,212,779**	**$ (47,772,364)**	**$ 7,440,527**

	Stockholders' Equity				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2024	34,626	$ 3	$ 40,398,280	$ (34,668,784)	$ 5,729,499
Stock-based compensation expense	-	-	1,312	-	1,312
Net loss	-	-	-	(1,864,435)	(1,864,435)
Balance at March 31, 2025	34,626	3	40,399,592	(36,533,219)	3,866,376
Stock-based compensation expense	-	-	(1,563)	-	(1,563)
Issuance of common stock for vested restricted stock units	1	-	-	-	-
Issuance of common stock in connection with April 2025 Warrant Inducement, net of issuance costs of $464,670 and warrant inducement costs of $2,706,645	58,760	6	675,371	-	675,377
Warrant inducement cost	-	-	2,706,645	-	2,706,645
Net loss	-	-	-	(1,956,604)	(1,956,604)
Balance at June 30, 2025	93,987	9	43,780,045	(38,489,823)	5,290,231
Stock-based compensation expense	-	-	183	-	183
Exercise of April 2025 Prefunded Warrants	9,060	1	(1)	-	-
Net loss	-	-	-	(1,597,632)	(1,597,632)
Balance at September 30, 2025	102,447	$ 10	$ 43,780,227	$ (40,087,455)	$ 3,692,782

See accompanying notes to condensed consolidated financial statements.
Reflects a 1-for-4 reverse stock split effective January 29, 2026
and a 1-for-4 reverse stock split effective November 3, 2026

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

	Nine Months Ended September 30,	
	2026	**2025**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,255,097)	$ (5,418,671)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	117,878	46,767
Stock-based compensation expense	55,972	(68)
Amortization of right-of-use asset	66,617	75,105
Write-off and impairment of property and equipment	2,880	37,069
Changes in operating assets and liabilities:		
Deferred offering costs	-	(101,170)
Prepaid expenses and other current assets	129,856	463,187
Other non-current assets	2,466	26,530
Accounts payable	231,588	16,040
Accrued expenses and other current liabilities	556,324	256,506
Net cash used in operating activities	**(5,091,516)**	**(4,598,705)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(358,580)	-
Proceeds from sale of property and equipment	4,050	-
Net cash used in investing activities	**(354,530)**	**-**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and pre-funded warrants, gross	8,624,835	3,846,692
Issuance costs related to issuance of common stock	(960,822)	(464,670)
Proceeds from exercise of prefunded warrants	350	-
Payment of finance lease	(3,209)	(2,994)
Net cash provided by financing activities	**7,661,154**	**3,379,028**
Increase (decrease) in cash and cash equivalents	2,215,108	(1,219,677)
Cash and cash equivalents, beginning of period	5,164,875	4,301,945
Cash and cash equivalents, end of period	$ 7,379,983	$ 3,082,268

See accompanying notes to condensed consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Bluejay Diagnostics, Inc. ("Bluejay" and/or the "Company") is a medical diagnostics company focused on improving patient outcomes in critical care settings, with a focus on sepsis. The Company is working on developing rapid, near-patient tests using whole blood on its Symphony™ technology platform ("Symphony"), which consists of an analyzer and single-use protein detection cartridges. The Company does not yet have regulatory clearance for Symphony, and it will need to receive regulatory authorization from the U.S. Food and Drug Administration (the "FDA") before Symphony can be marketed as a diagnostic product in the United States. The Company has completed the development of the Symphony analyzer. During 2025, the Company transferred the intellectual property underlying the production of the Symphony cartridges from the original developer and outside supplier, Toray Industries, Inc. ("Toray"), to a contract manufacturing facility with FDA certification run by Sanyoseiko Co. Ltd. ("Sanyoseiko"). On May 27, 2026, the Company entered into an agreement and statement of work with ALURIS Sciences (previously Argonaut Manufacturing ("Argonaut")) to provide the Company with US based manufacturing to de-risk the Company's overseas manufacturing. In July 2026, the Company announced that it has successfully completed patient enrollment of its SYMON-II clinical validation study for IL-6. The Company is now progressing toward analytical and clinical analysis to support a regulatory submission. To achieve its commercial plan, the Company expects to need to raise between $10.0 million and $14.0 million of further capital by the end of the 2027 fiscal year for commercialization, which the Company hopes to do in various tranches.

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

The Company's first product candidate, the Symphony IL-6 test, is an immunoassay for the measurement of interleukin-6 (IL-6) to be used for the monitoring of disease progression and prognostication in critical care settings. The Company is currently focused on pursuing the Symphony IL-6 test in the context of sepsis. IL-6 is a clinically established inflammatory biomarker, and is considered a 'first-responder,' for assessment of severity of infection and inflammation across many disease indications, including sepsis. A current challenge of healthcare professionals is the excessive time and cost associated with determining a patient's level of severity at triage and the Company believes that its Symphony IL-6 test, if ultimately successful and approved, could have the ability to consistently monitor this critical care biomarker with rapid results.

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

The Company was incorporated under the laws of Delaware on March 20, 2015. Its headquarters are located in Acton, Massachusetts.

On June 4, 2021, the Company formed Bluejay Spinco, LLC, a wholly-owned subsidiary of the Company, for purposes of further development of the Company's ALLEREYE diagnostic test. ALLEREYE is a point-of-care device offering healthcare providers a solution for diagnosing Allergic Conjunctivitis. The Company currently is not actively pursuing development of the ALLEREYE diagnostic test. On March 3, 2026, the Company completed the dissolution of its wholly owned subsidiary Bluejay Spinco, LLC.

FDA Regulatory Strategy

The sale of the Company's products in the U.S. are subject to regulation by the FDA. Generally, the products we develop must be cleared by the FDA before they are marketed in the United States. Before and after approval, authorization, or clearance in the United States, our products are subject to extensive regulation by the FDA, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, recordkeeping, market clearance, authorization or approval, labeling and promotion, import and export, marketing and sales, and distribution of medical devices.

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

In the second quarter of 2024, the Company completed a multicenter SYmphony IL-6 MONitoring Sepsis ("SYMON") pilot clinical study investigating the role of interleukin-6 (IL-6) in patients diagnosed with sepsis and septic shock. This prospective study assessed the performance of IL-6 upon initial presentation to the intensive care unit (ICU). A primary endpoint of the SYMON-I pilot clinical study (registered clinical trial number NCT06181604) suggested that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU may predict patient mortality out to 28 days. Furthermore, a secondary endpoint of the SYMON-I study suggested that IL-6 levels within 24 hours of sepsis or septic shock diagnosis and admission to the ICU is a predictor of patient mortality during their hospitalization. Other secondary endpoints suggested that lactate and Sequential Organ Failure Assessment (SOFA), standard clinical tests used for sepsis and septic shock patients, were not predictors of patient mortality out to 28 days. We believe that the findings underscore the potential importance of IL-6 as a predictor and provide new insights into the potential pathways for improving sepsis outcomes.

Using the data analysis from the SYMON-I pilot clinical study, the Company initiated the SYMON-II pivotal clinical study in the third quarter of 2024. The SYMON II clinical study has three components: (1) collection, freezing, and biobanking of patient samples, (2) measuring IL-6 concentrations in the biobanked samples near the end of patient enrollment or after the patient enrollment has completed, and (3) analysis of the IL-6 data with the patient outcomes to see if the established IL-6 cutoff value has been validated for 28-day all-cause mortality. Patient enrollment started during the fourth quarter of 2024. The Company has now successfully completed enrollment of the targeted 750 hospital patients, and it has collected, frozen and biobanked blood samples from the enrolled patients, while also obtaining all related patient data regarding their disease progression and outcomes. The Company has initiated preliminary testing of the samples, and preliminary patient data analysis. The final analytical testing will be performed upon verification and validation of the cartridges in accordance with FDA 820 QSR guidelines. The Company's goal is to produce and verify these cartridges during 2026.

In October 2026, the Company completed a preliminary baseline clinical characteristics analysis from the SYMON-II clinical validation study. This preliminary SYMON-II analysis includes 777 evaluable patients, consisting of 637 28-day survivors and 140 28-day non-survivors, representing an overall 28-day mortality rate of approximately 18%. The study population included patients across a broad spectrum of illness severity, ethnicity and geographical distribution with 39.5% meeting Sepsis-3 criteria for septic shock. The clinical characteristics demonstrate substantial disease burden and severity. 84.0% of patients had bacterial infection reported, 32.4% had a positive blood culture, and infection was considered highly likely or likely in 86.5% of the study population. Patients who did not survive through 28 days demonstrated greater baseline illness severity. Septic shock was present in 56.4% of non-survivors compared with 35.8% of survivors. The Company believes that the preliminary analysis shows a substantial number of 28-day mortality events across patients with differing levels of sepsis severity, creating an important clinical foundation for evaluating the prognostic performance of IL-6, which the Company intends to do in the next phase of the analysis[, which is currently in process].

If the SYMON-II results are positive, the Company intends to use the data generated from SYMON-II to support a 510(k) application to the FDA. This application is currently expected to be based on the following intended use: "Symphony IL-6 is intended for use to determine the IL-6 concentration as an aid in assessing the cumulative 28-day risk of all cause mortality in conjunction with other laboratory findings and clinical assessments for patients diagnosed with sepsis or septic shock in the ICU." The Company's goal is to submit a 510(k) regulatory application to the FDA during the first half of 2027, and an objective of achieving FDA clearance thereafter.

The Company's ability to complete the activities needed for an FDA submission will be contingent upon meeting analytical validation and clinical validation.

Product Manufacturing

The Company plans to manufacture its analyzers through Sanyoseiko and cartridges through both Sanyoseiko and ALURIS Sciences (previously Argonaut), as a contract manufacturing organization ("CMO"), and the Company has entered into commercial agreements with Sanyoseiko and ALURIS governing these matters. Pursuant to statements of work that the Company has begun providing to Sanyoseiko under these agreements, Sanyoseiko will provide end-to-end support for the Symphony platform, including supporting the manufacturing process for analyzers and cartridges (with hardware, software, and design updates), managing raw material sourcing and vendor compliance, and serving as the Company's contract manufacturing organization for analyzers, cartridges, and related components. Argonaut will provide fill-and-seal of the reagent reservoir, final assembly, labelling, packaging, storage, release criteria and distribution of the cartridges in the US and globally.

Our Market

The Symphony platform is designed to address a subset of the global in vitro diagnostics devices ("IVDs") market, with a focus on targeting critical care markets where physicians must quickly determine patient acuity to identify optimal treatment regimens. We are currently focused on our initial biomarker test, Symphony IL-6 test, in the context of the evaluation of the risk of mortality due to sepsis. We hope in the future to also explore the potential for adding new biomarker tests to the Symphony platform to also be used in the context of cardio-metabolic diseases, cancer and other diseases that require rapid tests.

Sales and Marketing

Prior to potential FDA authorization of our Symphony products, our sales and marketing efforts will focus on brand awareness and market education. Specifically, we will emphasize the clinical value of monitoring IL-6 levels to improve decision-making and patient outcomes in critical care settings.

To ensure immediate scalability upon regulatory approval, we have partnered with several strategic third-party organizations. Central to this strategy is our agreement with Lovell Government Services, Inc., which has been contracted to act as a non-exclusive distributor of our medical diagnostic products to certain federal, state, and local government agencies within the United States, including the Department of Veterans Affairs, Department of Defense, Defense Health Agency, and Indian Health Service. Additionally, we have engaged third-party experts to establish our medical billing, reimbursement positioning, and commercial infrastructure.

Exploratory Artificial Intelligence Integration Initiative

The Company is pursuing a strategic initiative to evaluate the integration of artificial intelligence ("AI") capabilities into its Symphony™ platform. This initiative assesses whether advanced analytics can enhance the clinical interpretation of biomarker data, including IL-6 measurements, and support the development of models for sepsis risk stratification and patient outcome optimization. Conducted in a phased manner, the initiative has focused on data collection, data integrity, clinical validation, and regulatory strategy. The AI platform is currently undergoing internal testing.

Risks and Uncertainties

As noted above, the Company will be reliant upon its CMOs, Sanyoseiko and ALURIS Sciences, to provide analyzers and cartridges in sufficient quantity and quality to complete the validations for its FDA application. The Company's FDA application submission could be delayed if the Company encounters any material supply interruptions. In addition, there can be no assurance that the Company will be able to obtain necessary regulatory authorization for the marketing of the Symphony in the United States or elsewhere. There also can be no assurance that the Company will successfully complete any clinical evaluations necessary to receive regulatory clearances, or that the clinical study will demonstrate sufficient effectiveness of the Symphony IL-6 test. The failure to adequately demonstrate the clinical performance of the Symphony IL-6 test could delay or prevent regulatory clearance, which could prevent or result in delays to market launch and could materially harm the Company's 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. Additional risk and uncertainties regarding the Company are described in "Part I – Item 1A. Risk Factors" of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025 and in "Part II – Item 1A Risk Factors" of this Quarterly Report on Form 10-Q.

Reverse Stock Splits and Increase to Authorized Capital

On January 29, 2026, the Company effected a reverse stock split of its shares of common stock at a ratio of 1-for-4 (the "January 2026 Reverse Stock Split"). On November 3, 2026, the Company effected an additional reverse stock split of its shares of common stock at a ratio of 1-for-4 (the "November 2026 Reverse Stock Split"). 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 were adjusted, on a retroactive basis, to reflect the January 2026 Reverse Stock Split, the November 2026 Reverse Stock Split, and other reverse stock splits consummated by the Company in prior years.

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, 2025 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, 2026, its results of operations and cash flows for the three and nine months ended September 30, 2026 and 2025, 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, 2026 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2026, or any other interim period within this fiscal year.

Going Concern

The accompanying unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2026 and 2025 were prepared under the assumption that the Company will continue as a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business.

The Company had cash and cash equivalents of $7,379,983 and current liabilities of $1,927,320 as of September 30, 2026. The Company has incurred net losses and negative cash flows from operations since its inception and has an accumulated deficit of $47,772,364 as of September 30, 2026. The Company expects that its net cash used in operating activities will continue to be negative over at least the next several years as it attempts to produce product capable of meeting analytical validation and clinical validation and conducts clinical trial work and, if such production and trials are successful, prepares an FDA submission. These financial results and financial position, and the Company's expected forward-looking outlook of significant negative cash flow in the future, raise substantial doubt with respect to its ability to continue as a going concern. The Company expects that it will be in position to submit a 510(k) regulatory application to the FDA for Symphony during the first half of 2027, assuming that it is able to generate sufficient clinical trial results to support such a submission. If the Company fails to obtain sufficient future financing, its clinical trials and targeted FDA submission timeline could be delayed, and it could be forced to abandon such activities entirely and cease operations, with the possible loss of such properties or assets. If the Company is unable to obtain additional financing as it continues to generate negative cash flow, its board of directors could determine to cause the Company to undertake a process of liquidation under Chapter 7 of applicable U.S. bankruptcy laws, or otherwise seek other protection under such laws. In such event, holders of shares of the Company's common stock could recoup little, if any, value in such process. The Company currently estimates cash resources will be sufficient to fund its operations through the second quarter of 2027.

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

2. SIGNIFICANT ACCOUNTING POLICIES

During the nine months ended September 30, 2026, there were no changes to the significant accounting policies as described in the 2025 Audited Financial Statements.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in these consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. 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 consolidated financial statements.

Warrants

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

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

Segment Reporting

The Company follows the guidance in ASC 280, Segment Reporting. Management has determined that the Company operates as one operating and reportable segment, as the Chief Executive Officer, who serves as the Chief Operating Decision Maker, evaluates performance of the operating segment and allocates resources based on amounts as reported on the consolidated statements of operations and cash flows. Segment expenses are presented on the Company's consolidated statements of operations. The operating segment assets are reported on the consolidated balance sheets as total assets. The Company's operations consist solely of the development of its Symphony diagnostic platform, a near-patient diagnostic platform designed to provide rapid results for critical care settings, and no discrete financial information is produced for separate business components. Accordingly, the consolidated financial statements represent the Company's single reportable segment.

Net Loss per Share

Basic net loss per share to common stockholders is computed by dividing the net loss applicable to common stockholders 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,	
Potentially Dilutive Securities Listing:	**2026**	**2025**
Restricted Stock Units (RSUs)	22,500	-
Options to purchase common stock	100,001	5
Warrants for common stock	36	41
Class A warrants for common stock	19	19
Class B warrants for common stock	1	1
January 2024 warrants for common stock	421	421
January 2024 placement agent warrants for common stock	29	29
Class C warrants for common stock	17,975	17,975
Class E warrants for common stock	67,825	67,825
Series F warrants for common stock	281,250	-
Series F placement agent warrants for common stock	11,251	-
Series G warrants	913,986	-
June 2026 Placement Agent Warrants	63,981	-
Series H warrants	913,986	-

Recently Issued Accounting Standards

Expense Disaggregation Disclosures

In November 2024, the FASB issued ASU 2024-03, Reporting Comprehensive Income-Expense Disaggregation Disclosures. This change requires disaggregated disclosures of certain categories of expenses that are included in expense line items on the face of the income statement. The disclosures are required on an annual and interim basis. The guidance also requires the total amount of selling expenses to be disclosed and, on an annual basis, the definition of selling expenses. The guidance will be effective for annual reporting periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027. Early adoption is permitted. This new guidance will result in increased disclosures in the notes to the financial statements.

3. LICENSE AND SUPPLY AGREEMENT WITH TORAY INDUSTRIES

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

On October 23, 2023, the Company and Toray entered into an Amended and Restated License Agreement (the "New Toray License Agreement") and a Master Supply Agreement (the "New Toray Supply Agreement"). Under the New Toray License Agreement, the Company continues to license from Toray intellectual property rights needed to manufacture single-use test cartridges, and the Company has received the right to sublicense certain Toray intellectual property to Sanyoseiko and ALURIS Sciences in connection with the ongoing agreement with the Company to manufacture the Company's Symphony analyzers and cartridges (including in connection with the Company's clinical trials). In addition, the New Toray License Agreement provided for the transfer of certain technology related to the cartridges to Sanyoseiko and ALURIS Sciences. The royalty payment percentage payable by the Company to Toray was reduced under the New Toray License Agreement from 15% to 7.5% (or less in certain circumstances) of net sales of certain cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. The New Toray License Agreement contemplates that applicable royalty payment obligations from the Company to Toray for other products will be determined separately by the parties in the future.

On July 23, 2025, the Company entered into an amendment (the "Amendment") to the New Toray License Agreement and the New Toray Supply Agreement with Toray. The Amendment provided that the deadline under the New Toray License Agreement for the Company to establish an alternative manufacturing site for the Company's Symphony cartridges would be extended from October 23, 2025 to October 23, 2026, and the Company agreed to use its best efforts to establish the site by such date. On October 4, 2026, the Company notified Toray that it has completed the establishment of the manufacturing site.

The Amendment also confirmed that Toray has provided to the Company all applicable know-how required under the New Toray License Agreement and is not under any further obligation to provide know-how or technical assistance to the Company. Pursuant to the Amendment, the Company paid $71,212 to Toray for a final supply of certain chip components prior to the expiration of the New Toray Supply Agreement, which occurred on October 23, 2025. There were no sales of or revenues from the cartridges during the three and nine-month periods ended September 30, 2026 and 2025.

The Company has completed cartridge manufacturing process redevelopment through Sanyoseiko, a third-party contractor who is managing such manufacturing process. The Company is proceeding with verification and validation testing and commercial manufacturing. At September 30, 2026 and 2025, there were no amounts accrued related to the New Toray License Agreement or the License Agreement.

4. FINANCINGS

June 2026 Private Placement

On June 2, 2026, the Company entered into a securities purchase agreement and registration rights agreement with certain institutional, accredited investors pursuant to which the Company sold in a private placement (i) pre-funded warrants to purchase up to 913,976 shares of common stock (the "June 2026 Pre-Funded Warrants"), (ii) Series G warrants (the "Series G Warrants") to purchase up to 913,986 shares of common stock and (iii) Series H warrants (the "Series H Warrants") to purchase up to 913,986 shares of common stock. The combined price of the securities sold in the private placement was $9.2996 per Pre-Funded Warrant and accompanying Series G Warrant and Series H Warrant. The June 2026 Pre-Funded Warrants are immediately exercisable for shares of common stock at an exercise price of $0.0004 per share, and expire once exercised in full. As of November 9, 2026, 858,330 of the June 2026 Pre-Funded Warrants have been exercised and 55,646 remain unexercised and outstanding. The Series G Warrants and Series H Warrants are immediately exercisable for shares of common stock at an exercise price of $8.30 per share. The Series G Warrants expire on June 26, 2031 and the Series H Warrants expire on June 26, 2028.

The transaction closed on June 5, 2026. The gross proceeds to the Company from the sale of the securities sold in the private placement were approximately $8.5 million. The Company incurred total offering costs of $960,822, including a 7% financial advisory fee to H.C. Wainwright & Co. ("Wainwright"), the placement agent, of approximately $595,000. Under the terms of the Company's engagement letter with Wainwright, the Company issued Wainwright (or its designees) warrants to purchase up to 63,981 shares of common stock on the same terms as the Series G Warrants, except that the exercise price is $11.6252 per share (the "June 2026 Placement Agent Warrants").

In connection with this private placement, the Company filed a registration statement on Form S-3, which became effective on June 26, 2026 to register 2,805,933 shares of common stock (including any shares of common stock issued in the future pursuant to the Series G Warrants, the Series H Warrants or June 2026 Placement Agent Warrants) for resale in public markets.

Holders of the warrants will not have the right to exercise any portion of such warrants if such holder, together with its affiliates, would beneficially own in excess of 4.99% or 9.99% (at the initial election of the holder) of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise, provided that a holder may increase or decrease such beneficial ownership limitation up to, and no higher than, 9.99%, by giving 61 calendar days' notice to the Company.

March 2026 Private Placement

On March 14, 2026, the Company entered into a securities purchase agreement pursuant to which the Company issued and sold to the purchasers named therein an aggregate of 15,625 shares of the Company's common stock at a price of $8.00 per share. The transaction closed on March 17, 2026 for aggregate gross proceeds to the Company of $125,000.

The purchasers were Neil Dey, President and Chief Executive Officer of the Company and a director, Donald Chase, Chairman of the Board, and Svetlana Dey, Douglas Wurth and Fred Zeidman, each of whom are Company directors. Each of the purchasers acquired 3,125 shares of common stock for their own individual account. See Note 7 Related Party Transactions.

The sale was not registered under the Securities Act of 1933, as amended (the "Securities Act"), and the shares were issued and sold in a private placement pursuant to Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D as promulgated by the Securities and Exchange Commission under the Securities Act. Each of the purchasers represented that it is an "accredited investor" within the meaning of Rule 501 of Regulation D, was acquiring the shares for his or her own account, and had no direct or indirect arrangement or understanding with any other persons to distribute or regarding the distribution of such shares. The shares were offered and sold without any general solicitation by the Company or its representatives. The Company has not agreed to provide registration rights with respect to any of the shares.

October 2025 Private Placement

On October 9, 2025, the Company entered into a securities purchase agreement with two institutional investors pursuant to which the Company sold in a private placement (i) an aggregate of 10,938 shares of common stock and prefunded warrants to purchase up to 129,680 shares of common stock (the "October 2025 Prefunded Warrants"), and (ii) Series F warrants (the "Series F Warrants") to purchase up to 281,250 shares of common stock. The combined price of the securities sold in the private placement was $32.00 per share of common stock (or prefunded warrant in lieu thereof, in which case such price was reduced by $0.0016) and accompanying Series F Warrants to acquire two shares of common stock. The October 2025 Prefunded Warrants were exercisable for shares of common stock at an exercise price of $0.0016 per share, were immediately exercisable and expire once exercised in full. As of March 31, 2026, all of the October 2025 Prefunded Warrants were exercised in full. The Series F Warrants are exercisable for shares of common stock at an exercise price of $28.00 per share, are immediately exercisable and expire five and one-half years from the date of issuance.

The transaction closed on October 10, 2025. The gross proceeds to the Company from the sale of the securities sold in the private placement were approximately $4.5 million. The Company incurred total offering costs of $787,755, including an 8% financial advisory fee to Rodman and Renshaw LLC ("Rodman"), the placement agent, of approximately $360,000. Under the terms of the Company's engagement letter with Rodman, the Company issued Rodman's designees warrants to purchase up to 11,251 of common stock at an exercise price of $40.00 per share, which expire 5.5 years from the date of issuance (the "October 2025 Placement Agent Warrants").

In connection with this private placement, the Company filed a registration statement on Form S-3, which became effective on November 26, 2025 to register 433,119 shares of common stock (including any shares of common stock issued in the future pursuant to the Series F Warrants or October 2025 Placement Agent Warrants) for resale in public markets.

Holders of the warrants will not have the right to exercise any portion of such warrants if such holder, together with its affiliates, would beneficially own in excess of 4.99% or 9.99% (at the initial election of the holder) of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise, provided that a holder may increase or decrease such beneficial ownership limitation up to, and no higher than, 9.99%, by giving 61 calendar days' notice to the Company.

April 2025 Private Placement

On April 7, 2025, the Company entered into inducement letter agreements with certain existing holders of the Company's Class C warrants (the "Class C Warrants"), pursuant to which such holders agreed to purchase an aggregate of 67,819 shares of the Company's common stock (or, to the extent the applicable holder would have exceeded a specified beneficial ownership limitation, prefunding the future exercise of such warrants, other than a remaining $0.0016 per share exercise price). The Class C Warrants were originally issued on June 28, 2024 for an exercise price of $1,568.00 per share and were subsequently reduced to $260.80 per share pursuant to stockholder approval on August 21, 2024. Pursuant to the inducement letter agreements, the applicable holders agreed to exercise their Series C Warrants at a reduced exercise price of $54.72 per share, and to purchase an equivalent number of new Class E warrants (the "Class E Warrants") for an additional $2.00 per share. The Class E Warrants have an exercise price of $54.72 per share and expire on April 8, 2030.

The transaction closed on April 8, 2025. The exercise of the Class C Warrants resulted in the Company issuing 42,638 shares of common stock at closing pursuant to the inducement letters, and the exercise price of 25,182 of the Class C Warrants being amended to $0.0016 per share. As of December 31, 2025, all such reduced exercise price Class C Warrants had been exercised.

The gross proceeds to the Company from the exercise of the Class C Warrants and the sale of the new Class E Warrants were $3,846,692. The Company incurred total cash offering costs of $464,670, including a 10% financial advisory fee to Aegis Capital Corp. of $384,670.

The modification of the terms or conditions of the Class C Warrants in this transaction is treated as an exchange of the original instrument for a new instrument. Using the Black Scholes option pricing model, the fair value of the Series C Warrants immediately prior to the inducement transaction was $479,299 and immediately after the inducement transaction was $1,590,930. In addition, Series E Warrants with a fair value of $1,730,652 were provided as part of the inducement transaction for a purchase price of $135,638. The Company recorded additional equity issuance costs of $2,706,645 related to the modification of the Series C Warrants and issuance of Series E Warrants related to the inducement transaction. As this equity issuance cost was a non-cash transaction, the Company recorded an increase to additional paid-in capital to offset the expense.

5. WARRANTS

The following table summarizes information with regard to warrants outstanding at September 30, 2026:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
June 2026 Pre-funded warrants	55,646	Common Stock	$ 0.0004	-
Series G warrants	913,986	Common Stock	$ 8.30	4.7
June 2026 Placement Agent warrants	63,981	Common Stock	$ 11.62	4.7
Series H warrants	913,986	Common Stock	$ 8.30	1.7
Series F warrants	281,250	Common Stock	$ 28.00	4.5
Series F Placement Agent warrants	11,251	Common Stock	$ 40.00	4.5
Class E warrants	67,825	Common Stock	$ 54.72	3.5
Class C warrants	17,975	Common Stock	$ 260.80	2.7
January 2024 warrants	421	Common Stock	$ 8,320.00	2.3
January 2024 Placement Agent warrants	29	Common Stock	$ 10,400.00	2.3
August 2023 Common Stock warrants	34	Common Stock	$ 46,336.00	1.9
August 2023 Placement Agent warrants	2	Common Stock	$ 58,944.00	1.9
Class A warrants	19	Common Stock	$ 896,000.00	0.1
Class B warrants	1	Common Stock	$ 1,280,000.00	0.1

June 2026 Private Placement

On June 2, 2026, the Company entered into a securities purchase agreement and registration rights agreement with certain institutional, accredited investors pursuant to which the Company sold in a private placement (i) the June 2026 Pre-Funded Warrants to purchase up to 913,976 shares of common stock, and (ii) Series G Warrants to purchase up to 913,986 shares of common stock and (iii) Series H Warrants to purchase up to 913,986 shares of common stock. The Pre-Funded Warrants are immediately exercisable for shares of common stock at an exercise price of $0.0004 per share, and expire once exercised in full.

June 2026 Series G Warrants, June 2026 Placement Agent Warrants and Series H Warrants

The Series G Warrants and Series H Warrants are immediately exercisable for shares of common stock at an exercise price of $8.30 per share. The Series G Warrants expire on June 26, 2031 and the Series H Warrants expire on June 26, 2028. Under the terms of the Company's engagement letter with Wainwright, the Company issued Wainwright (or its designees) warrants to purchase up to 63,981 shares of common stock on the same terms as the Series G Warrants, except that the exercise price is $11.6252 per share.

October 2025 Private Placement

On October 9, 2025, the Company entered into a securities purchase agreement with two institutional investors pursuant to which the Company sold in a private placement (i) an aggregate of 10,938 shares of common stock and prefunded warrants to purchase up to 129,680 shares of common stock. The October 2025 Prefunded Warrants were exercisable for shares of common stock at an exercise price of $0.0016 per share, were immediately exercisable and expired once exercised in full. As of March 31, 2026, all of the October 2025 Prefunded Warrants were exercised in full.

October 2025 Series F Warrants

Pursuant to the October 2025 private placement, the Company issued 281,250 Series F warrants for common stock with an exercise price of $28.00 per share and 11,251 Placement Agent Series F warrants for common stock with an exercise price of $40.00 per share. The Series F warrants and Placement Agent Series F warrants became exercisable immediately upon issuance and for a period of five and one half years following the date of issuance.

April 2025 Class E Warrants

Pursuant to the April 2025 private placement, certain existing holders of the Company's Class C Warrants agreed to purchase an aggregate of 67,819 shares of the Company's common stock. As a part of the April 2025 private placement, the Company sold 67,825 Class E Warrants to the Class C Warrant exercising holders for $2.00 per warrant. The Class E warrants have an exercise price of $54.72 per share, became exercisable immediately upon issuance and for a period of five years following the date of issuance.

Fundamental Transaction

The warrants described above include certain rights upon a "fundamental transaction" (as defined in such warrants), including the right of the holders thereof to receive from the Company or a successor entity cash or the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction in the amount of the Black Scholes value (as defined in such warrants) of the unexercised portion of the applicable warrants on the date of the consummation of such fundamental transaction.

Warrant Accounting

Each of the Company's warrants to acquire shares of common stock were accounted for as equity classified financial instruments as they meet the requirements for equity classification under ASC 815, *Derivatives and Hedging*.

6. STOCK COMPENSATION

Stock Incentive Plans

In 2018, the Company adopted the 2018 Stock Incentive Plan (the "2018 Plan") for employees, consultants, and directors. The 2018 Plan, which is administered by the Board of Directors, permits the Company to grant incentive and nonqualified stock options for the purchase of common stock, and restricted stock units. The maximum number of shares reserved for issuance under the 2018 Plan is 5. At September 30, 2026, there were 2 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 Stock Plan"). A total of 4 shares of common stock were approved to be initially reserved for issuance under the 2021 Stock Plan. On April 28, 2026, the Company's board of directors approved Amendment No. 1 to the 2021 Stock Plan, which was further approved by the shareholders on June 9, 2026, to increase the number of shares of common stock issuable by 37,500. At September 30, 2026, there were 37,504 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, 2026:

	Non-vested Restricted Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested Restricted Stock Units at December 31, 2025	-	$ -
Granted	22,500	4.08
Vested	-	-
Forfeited	-	-
Non-vested Restricted Stock Units at September 30, 2026	22,500	$ 4.08

On August 17, 2026, the Company approved the issuance of restricted stock units to certain eligible participants. These units have a three-month vesting period and are subject to continued employment during that period. The grant date fair value of these instruments was valued $4.08 for all units granted during the period. The total value of restricted stock units granted was $91,800. For the three and nine months ended September 30, 2026, the Company recognized $30,600 in stock-based compensation expense. As of September 30, 2026, there was $61,200 of unrecognized stock-based compensation expense related to the remaining value of these grants related to the restricted stock units. These stock units will be fully recognized upon their vesting on November 17, 2026.

The following is a summary of stock option activity for the nine months ended September 30, 2026:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2025	1	$ 81,504	3.0	$ -
Granted	100,000	8.32	-	-
Exercised	-	-	-	-
Cancelled and forfeited	-	-	-	-
Outstanding at September 30, 2026	100,001	$ 9.13	4.9	$ -
Exercisable at September 30, 2026	1	$ 81,504	2.3	$ -

On August 17, 2026, the Company granted 100,000 stock options. As of September 30, 2026, the weighted-average exercise price of these newly granted options was $8.32 per share, and their weighted-average grant-date fair value was $8.32 per share. For the three and nine months ended September 30, 2026 the Company recognized $25,372 in stock-based compensation expense related to the stock options. These options fully vest on the first anniversary of the date of grant of the shares are subject to exercise conditions related to FDA and regulatory approval. Prior to meeting the exercise conditions the stock options remain unvested. As of September 30, 2026, the unrecognized portion of the stock-based compensation expense associated with stock options is $279,090 and will be recognized over a period of 0.9 years.

Stock-Based Compensation Expense

For the three and nine months ended September 30, 2026, and 2025, the Company recorded stock-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 12,240	$ 183	$ 12,240	$ (267)
General and administrative	43,732	-	43,732	199
Total stock-based compensation	$ 55,972	$ 183	$ 55,972	$ (68)

7. RELATED PARTY TRANSACTIONS

March 2026 Private Placement

On March 14, 2026, the Company entered into a securities purchase agreement pursuant to which the Company issued and sold to the purchasers named therein an aggregate of 15,625 shares of the Company's common stock at a price of $8.00 per share. The transaction closed on March 17, 2026 for aggregate gross proceeds to the Company of $125,000.

The purchasers were Neil Dey, President and Chief Executive Officer of the Company and a director, Donald Chase, Chairman of the Board, and Svetlana Dey, Douglas Wurth and Fred Zeidman, each of whom are directors. Each of the purchasers acquired 3,125 shares of common stock for their own individual account.

NanoHybrids, LLC

In December 2021, the Company entered into an agreement with NanoHybrids, Inc. ("NanoHybrids"), an entity in which the Company's former Chief Technology Officer, Jason Cook, served as Chief Executive Officer of prior to becoming employed by the Company, to enable NanoHybrids to utilize the Company's research and development staff and laboratory facility (the "Sharing and Services Agreement"). Any hours worked by Company employees for NanoHybrids were billed to NanoHybrids at a bill rate of the respective employee's fully burdened personnel cost plus 10%. Dr. Cook was the majority shareholder of NanoHybrids during the time of this arrangement. The table below summarizes the amounts earned and due from NanoHybrids as of and for the three and nine-month periods ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Income from NanoHybrids included in other income	$ -	$ -	$ -	$ 6,873
Cash receipts from NanoHybrids	$ -	$ -	$ -	$ 21,437

There were no balances due as of September 30, 2026 and December 31, 2025.

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

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

8. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at September 30, 2026 and December 31, 2025:

	Depreciable lives	September 30, 2026	December 31, 2025
Construction-in-process		$ 1,011,665	$ 1,279,173
Manufacturing equipment	3-5 years	853,223	239,872
Furniture, Fixtures and equipment	3-5 years	132,669	116,782
Leasehold improvements	Shorter of useful life or life of lease	43,231	43,231
		2,040,788	1,679,058
Less: accumulated depreciation		(262,495)	(144,617)
Property and equipment, net		$ 1,778,293	$ 1,534,441

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. During the year ended December 31, 2025, the Company made the decision to close its internal lab and transferred the related fixed assets with a net book value of $62,376 to a third party to be marketed and sold. The Company wrote off $9,549 of lab equipment and recognized an impairment charge of $26,706, both of which are included in research and development expenses. During the nine months ended September 30, 2026, the Company returned assets held for sale of $3,150, which is recorded as Furniture, fixtures and equipment in the Company's balance sheets, and wrote-off an additional $2,880 of assets held for sale.

Construction in process consists of symphony cartridge manufacturing equipment. The Company expects to place the remaining construction-in-process into service in 2026 to support its SYMON II clinical study. The Company has $504,589 of construction in process and $727,385 of manufacturing equipment held and operated by Sanyoseiko Co. LTD, its contract manufacturing organization in Japan.

9. LEASES

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

	Nine Months Ended	
	September 30, 2026	September 30, 2025
Weighted average remaining lease term – operating leases (in years)	0.5	1.5
Weighted average remaining lease term – finance leases (in years)	1.3	2.3
Weighted average discount rate – operating leases	7.0%	7.0%
Weighted average discount rate – finance leases	7.0%	7.0%
Operating cash flows from operating leases	$ 25,000	$ 88,259
Operating cash flows from finance leases	$ 282	$ 612

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

	September 30, 2026	December 31, 2025
Operating lease right-of-use asset	$ 46,672	$ 113,289
Finance lease asset – property & equipment, net	2,141	5,689
Total lease assets	$ 48,813	$ 118,978
Current portion of operating lease liability	$ 49,441	$ 100,000
Current portion of finance lease liability included in accrued expenses	4,807	4,807
Non-current portion of operating lease liabilities	-	20,211
Non-current portion of finance lease liabilities included in other non-current liabilities	1,331	4,540
Total lease liabilities	$ 55,579	$ 129,558

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

Year	
2026 (1)	$ 25,000
2027	25,000
Thereafter	-
Total future lease payments	50,000
Less: Imputed interest	559
Present value of lease liability	$ 49,441

(1) Excludes the nine months ended September 30, 2026

10. COMMITMENTS AND CONTINGENCIES

Minimum Royalties

As required under the License Agreement (see Note 3), following the first sale of cartridges, the Company will also make royalty payments to Toray equal to 7.5% of the net sales of the cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. There were no sales of or revenues from the cartridges through September 30, 2026.

Indemnification

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

11. SUPPLEMENTAL BALANCE SHEET INFORMATION

Prepaid expenses and other current assets consist of the following:

	September 30, 2026	December 31, 2025
Prepaid insurance	$ 28,252	$ 183,211
Prepaid and other	117,849	92,746
Total prepaid expenses and other current assets	$ 146,101	$ 275,957

Accrued expenses and other current liabilities consist of the following:

	September 30, 2026	December 31, 2025
Accrued personnel costs	$ 125,938	$ 47,117
Accrued legal fees	35,173	43,077
Accrued clinical trial expenses	982,834	274,532
Accrued board of director fees	147,500	147,500
Accrued other	140,591	156,567
Accrued Delaware franchise tax	-	136,149
Total accrued expenses and other current liabilities	$ 1,432,036	$ 804,942

12. SUBSEQUENT EVENTS

On November 3, 2026, the Company executed a reverse stock split of its shares of common stock at a ratio of 1-for-4 (the “November 2026 Reverse Stock Split”). This resulted in the Company’s outstanding stock being reduced from 4,468,051, at the time of the reverse split to approximately 1,117,009 shares outstanding after the split.

All of the Company’s historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect the November 2026 Reverse Stock Split, as well as all year-to-date 2026 numbers.

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

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

Overview

Bluejay Diagnostics, Inc. ("Bluejay," the "Company," "we" and/or "us") is a medical diagnostics company focused on improving patient outcomes in critical care settings. The Company is working on developing rapid, near-patient tests using whole blood on its Symphony technology platform ("Symphony"), which consists of an analyzer and single-use protein detection cartridges. The Company does not yet have regulatory clearance for Symphony, and it will need to receive regulatory authorization from the U.S. Food and Drug Administration (the "FDA") before Symphony can be marketed as a diagnostic product in the United States. The Company has completed development of the Symphony analyzer and the cartridges. To achieve its clinical and commercial plan, the Company expects to need to raise between $10.0 million and $14 million of capital between the date of this filing and the end of the 2027 fiscal year, which the Company hopes to do in various tranches during this time period. The Company's current plan is to complete analytical and clinical testing of the SYMON-II clinical trial samples by the end of 2026, with a goal of being in position to submit a 510(k) regulatory application to the FDA in first half of 2027, with an objective of achieving FDA clearance thereafter.

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

The Company's first product candidate, the Symphony IL-6 test, is an immunoassay for the measurement of interleukin-6 (IL-6) to be used for the monitoring of disease progression in critical care settings. The Company is currently focused on pursuing the Symphony IL-6 test in the context of sepsis. IL-6 is a clinically established inflammatory biomarker, and is considered a 'first-responder,' for assessment of severity of infection and inflammation across many disease indications, including sepsis. A current challenge of healthcare professionals is the excessive time and cost associated with determining a patient's level of severity at triage and the Company believes that its Symphony IL-6 test, if ultimately successful and approved, could have the ability to consistently monitor this critical care biomarker with rapid results.

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

Since inception, we have incurred net losses from operations each year and we expect to continue to incur losses for the foreseeable future. We incurred net losses of approximately $6.3 million and $5.4 million for the nine months ended September 30, 2026 and 2025, respectively. We had negative cash flow from operating activities of approximately $5.1 million and $4.6 million for the nine months ended September 30, 2026 and 2025, respectively, and had an accumulated deficit of approximately $47.8 million as of September 30, 2026.

As further described below under "Liquidity and Going Concern Uncertainty" as of September 30, 2026, the Company possessed cash and cash equivalents of approximately $7.4 million, while having current liabilities of approximately $1.9 million. The Company will need to raise a material amount of additional capital in the future to continue as a going concern. If we are unable to obtain financing in the near-term, or otherwise consummate strategic alternatives, we could determine to undertake a process of liquidation under U.S. bankruptcy laws.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

The following table sets forth our results of operations for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30		Nine Months Ended September 30	
	2026	**2025**	**2026**	**2025**
Operating expenses				
Research and development	$ 1,116,568	$ 785,608	$ 3,366,212	$ 2,460,304
General and administrative	944,845	831,339	2,983,157	3,030,921
Total operating expenses	2,061,413	1,616,947	6,349,369	5,491,225
Operating loss	(2,061,413)	(1,616,947)	(6,349,369)	(5,491,225)
Other income:				
Interest income	49,510	18,961	93,198	66,016
Other income (expense), net	60	354	1,074	6,538
Total other income, net	49,570	19,315	94,272	72,554
Net loss	$ (2,011,843)	$ (1,597,632)	$ (6,255,097)	$ (5,418,671)

Research and Development

Research and development expenses for the three and nine months ended September 30, 2026 were approximately $1.1 million and $3.4 million as compared to approximately $0.8 million and $2.5 million for the same periods in 2025. The increase in research and development expenses was primarily due to increased Product and Clinical Development costs, which were partially offset by decreases in personnel costs. We expect future research and development expenses to be focused on costs specifically associated with our clinical trial program supporting our regulatory strategy, technology transfer efforts and any necessary manufacturing improvements.

General and Administrative

General and administrative expenses for the three and nine months ended September 30, 2026, were approximately $0.9 million and $3.0 million as compared to approximately $0.8 million and $3.0 million for the comparable period in 2025. General and Administrative expenses during the period in 2026 reflected increases in both employee and insurance costs compared to 2025, which were somewhat offset by decreases in consulting, insurance and other expense. The Company continues its efforts to preserve capital by limiting our investment in infrastructure and reducing professional services commensurate with our commercialization timeline. We expect to monitor and continue to pare our general and administrative spend, as necessary, to optimize operational alignment.

Other Income (expense), net

Other income, net for the three and nine months ended September 30, 2026 was $49,570 and $94,272 compared to $19,315 and $72,554 for the same periods in 2025. The increase in other income, net was primarily due to an increase in interest income.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,	
	2026	**2025**
Cash proceeds (used in) provided by:		
Operating activities	$ (5,091,516)	$ (4,598,705)
Investing activities	(354,530)	-
Financing activities	7,661,154	3,379,028
Net increase in cash and cash equivalents	$ 2,215,108	$ (1,219,677)

Net cash used in operating activities

During the nine months ended September 30, 2026, we used approximately $5.1 million in cash for operating activities, an increase of approximately $0.5 million as compared to the same period in 2025. The increase in net cash used in operating activities was primarily due to an increase in working capital of approximately $259,141 and largely offset by an increase in net loss of $836,426.

Net cash used in investing activities

During the nine months ended September 30, 2026, we used $354,530 in cash for investing activities, an increase of $354,530 as compared to the same period in 2025. The increase in net cash used in investing activities was due to the acquisition of equipment necessary for the manufacture of cartridges in 2026, partially offset by proceeds from the sale of assets.

Net cash provided by financing activities

During the nine months ended September 30, 2026, we generated $7.7 million of cash from financing activities, an increase from the cash provided of approximately $4.3 million in the same period in 2025. The increase in 2026 is due to the June 2026 Private Placement net proceeds of $7.6 million and March 2026 Private Placement net proceeds of $125,000 when compared to the April 2025 private placement net proceeds of $3.4 million.

Liquidity and Going Concern Uncertainty

The Company had cash and cash equivalents of $7,379,983 and current liabilities of $1,927,320 on its balance sheet as of September 30, 2026. The Company has incurred net losses since its inception, and has negative cash flows from operations and had an accumulated deficit of $47,772,364 as of September 30, 2026. The Company continues to develop its Symphony device and its first test for the measurement of IL-6. The Company remains committed to obtaining FDA clearance and hopes 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 requirements. The Company estimates cash resources will be sufficient to fund its operations through the second quarter of 2027. The Company will need additional capital to fund its planned operations for the next 12 months for commercialization and manufacturing scale-up. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these financial statements are issued.

The condensed consolidated financial statements for the three and nine months ended September 30, 2026 and 2025 were prepared under the assumption that the Company will continue as a going concern, and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company expects that it will seek to raise such additional capital through public or private equity offerings. 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 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.

Recent Offerings

April 2025 Private Placement

On April 7, 2025, the Company entered into inducement letter agreements with certain existing holders of the Company's Class C Warrants, pursuant to which such holders agreed to purchase an aggregate of 67,819 shares of the Company's common stock (or, to the extent the applicable holder would have exceeded a specified beneficial ownership limitation, prefunding the future exercise of such warrants, other than a remaining $0.0016 per share exercise price). The Class C Warrants were originally issued on June 28, 2024 for an exercise price of $1,568.00 per share and were subsequently reduced to $260.80 per share pursuant to stockholder approval on August 21, 2024. Pursuant to the inducement letter agreements, the applicable holders agreed to exercise their Series C Warrants at a reduced exercise price of $54.72 per share, and to purchase an equivalent number of new Class E Warrants for an additional $2.00 per share. The Class E Warrants have an exercise price of $54.72 per share and expire on April 8, 2030.

The transaction closed on April 8, 2025. The exercise of the Class C Warrants resulted in the Company issuing 42,638 shares of common stock at closing pursuant to the inducement letters, and the exercise price of 25,182 of the Class C Warrants being amended to $0.0016 per share. As of December 31, all such reduced exercise price Class C Warrants had been exercised.

The gross proceeds to the Company from the exercise of the Class C Warrants and the sale of the new Class E Warrants were $3,846,692. The Company incurred total offering costs of $464,670, including a 10% financial advisory fee to Aegis Capital Corp. of $384,670.

The modification of the terms or conditions of the Class C Warrants in this transaction is treated as an exchange of the original instrument for a new instrument. Using the Black Scholes option pricing model, the fair value of the Series C Warrants immediately prior to the inducement transaction was $479,299 and immediately after the inducement transaction was $1,590,930. In addition, Series E Warrants with a fair value of $1,730,652 were provided as part of the inducement transaction for a purchase price of $135,638. The Company recorded additional equity issuance costs of $2,706,645 related to the modification of the Series C Warrants and issuance of Series E Warrants related to the inducement transaction. As this equity issuance cost was a non-cash transaction, the Company recorded an increase to additional paid-in capital to offset the expense.

October 2025 Private Placement

On October 9, 2025, the Company entered into a securities purchase agreement with two institutional investors pursuant to which the Company sold in a private placement (i) an aggregate of 10,938 shares of common stock and prefunded warrants to purchase up to 129,680 shares of common stock, and (ii) Series F warrants to purchase up to 281,250 shares of common stock. The combined price of the securities sold in the private placement was $32.00 per share of common stock (or prefunded warrant in lieu thereof, in which case such price was reduced by $0.0016) and accompanying Series F Warrants to acquire two shares of common stock. The October 2025 Prefunded Warrants, were exercisable for shares of common stock at an exercise price of $0.0016 per share and have all been fully exercised as of the date hereof. The Series F Warrants are exercisable for shares of common stock at an exercise price of $28.00 per share, are immediately exercisable and expire five and one-half years from the date of issuance.

The transaction closed on October 10, 2025. The gross proceeds to the Company from the sale of the securities sold in the private placement were approximately $4.5 million. The Company incurred total offering costs of $787,755, including an 8% financial advisory fee to Rodman and Renshaw LLC ("Rodman"), the placement agent, of approximately $360,000. Under the terms of the Company's engagement letter with Rodman, the Company issue Rodman's designees warrants to purchase up to 11,251 of common stock at an exercise price of $40.00 per share, which expire 5.5 years from the date of issuance.

In connection with this private placement, the Company filed a registration statement on Form S-3, which became effective on November 26, 2025, to register 433,119 shares of common stock (including any shares of common stock issued in the future pursuant to the Series F Warrants or October 2025 Placement Agent Warrants) for resale in public markets.

March 2026 Private Placement

On March 14, 2026, the Company entered into a securities purchase agreement pursuant to which the Company issued and sold to the purchasers named therein an aggregate of 15,625 shares of the Company's common stock at a price of $8.00 per share. The transaction closed on March 17, 2026 for aggregate gross proceeds to the Company of $125,000.

The purchasers are Neil Dey, President and Chief Executive Officer of the Company and a director, Donald Chase, Chairman of the Board, and Svetlana Dey, Douglas Wurth and Fred Zeidman, each a Company director. Each of the purchasers acquired 3,125 shares of common stock for his or her own individual account.

The sale of the shares was not registered under the Securities Act of 1933, and the shares were issued and sold in a private placement pursuant to Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D as promulgated by the Securities and Exchange Commission under the Securities Act. Each of the purchasers represented that he or she is an "accredited investor" within the meaning of Rule 501 of Regulation D, was acquiring the Securities for his or her own account, and had no direct or indirect arrangement or understanding with any other persons to distribute or regarding the distribution of such shares. The shares were offered and sold without any general solicitation by the Company or its representatives. The Company has not agreed to provide registration rights with respect to any of the shares.

June 2026 Private Placement

On June 2, 2026, the Company entered into a securities purchase agreement and registration rights agreement with certain institutional, accredited investors pursuant to which the Company sold in a private placement (i) pre-funded warrants to purchase up to 913,976 shares of common stock, and (ii) Series G warrants to purchase up to 913,986 shares of common stock and (iii) Series H warrants to purchase up to 913,986 shares of common stock. The combined price of the securities sold in the private placement was $9.30 per pre-funded warrant and accompanying Series G Warrant and Series H Warrant. The pre-funded warrants are immediately exercisable for shares of common stock at an exercise price of $0.0004 per share, and expire once exercised in full. As of September 30, 2026, 858,330 of the June 2026 Pre-Funded Warrants have been exercised and 55,646 remain unexercised and outstanding. The Series G Warrants and Series H Warrants are immediately exercisable for shares of common stock at an exercise price of $8.30 per share. The Series G Warrants expire on June 26, 2031 and the Series H Warrants expire on June 26, 2028.

The transaction closed on June 5, 2026. The gross proceeds to the Company from the sale of the securities sold in the private placement were approximately $8.5 million. The Company incurred total offering costs of $960,822, including a 7% financial advisory fee to H.C. Wainwright & Co. ("Wainwright"), the placement agent, of approximately $595,000. Under the terms of the Company's engagement letter with Wainwright, the Company issued Wainwright (or its designees) warrants to purchase up to 63,981 shares of common stock on the same terms as the Series G Warrants, except that the exercise price is $11.63 per share (the "June 2026 Placement Agent Warrants").

In connection with this private placement, the Company filed a registration statement on Form S-3, which became effective on June 26, 2026 to register 2,805,933 shares of common stock (including any shares of common stock issued in the future pursuant to the Series G Warrants, the Series H Warrants or June 2026 Placement Agent Warrants) for resale in public markets.

Recently Issued Accounting Standards

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

Emerging Growth Company and Smaller Reporting Company Status

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

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of IPO (November 2021), (b) in which we have total annual gross revenues of at least $1.235 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 Accounting Election

The JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We conducted an evaluation under the supervision and with the participation of our President and Chief Executive Officer (who serves as our principal executive officer and principal financial and accounting officer), regarding the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on this evaluation, our President and Chief Executive Officer concluded that our disclosure controls and procedures were effective as of September 30, 2026. 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, 2026 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 annual report on Form 10-K for the fiscal year ended December 31, 2025. The following disclosures supplement such Risk Factors, and should be read in conjunction therewith:

Additional Risks Related to Our Financial Condition and Capital Requirements

To remain a going concern, we expect to need to raise additional capital and if we are unable to do so, we could become unable to finance our business plan, ultimately leading to us undertaking a process of liquidation under U.S. bankruptcy laws.

As of September 30, 2026, we possessed cash and cash equivalents of approximately $7.4 million, while having current liabilities of approximately $1.9 million. We incurred losses of approximately $6.8 million and $7.7 million for fiscal years 2025 and 2024, respectively, and $6.3 million for the nine months ended September 30, 2026. From our inception through September 30, 2026, we have an accumulated deficit of approximately $47.7 million, and we do not currently generate any operating income. To achieve our current strategic plan, which strives to be in position to submit a 510(k) regulatory application to the FDA in the first half of 2027 and achieve FDA approval thereafter, we expect to raise additional capital. There can be no assurance that such additional capital will be available on a timely basis or on terms that will be acceptable to us. If we are ultimately unable to obtain the needed financing to implement our business plans, our board of directors could determine to cause the Company to undertake a process of liquidation under Chapter 7 of applicable U.S. bankruptcy laws. In such event, holders of shares of our common stock may not recoup any significant value.

Our common stock currently is listed for quotation on the Nasdaq Capital Market. We are required to meet specified financial requirements in order to maintain such listing, including a requirement that the bid price for our common stock remains above $1.00. In addition, a Nasdaq proposal establishing a new continued listing requirement that all Nasdaq-listed companies maintain a minimum value of listed securities of $5 million is currently under review and consideration by the SEC. Currently, the market value of our common stock is substantially below this proposed threshold, and we therefore would be at risk of failing to meet this requirement and being delisted if this proposal is ultimately approved and our market capitalization does not increase above the proposed $5 million threshold.

Nasdaq Listing Rule 5550(a)(2) requires listed companies to maintain a minimum bid price of $1.00 for continued inclusion on the Nasdaq Capital Market. As of the close of business on November 11, 2026, the most recent closing price of our common stock on the Nasdaq Capital Market was $2.80 per share. If the trading price of our common stock closes below $1.00 for more than 30 consecutive trading days, we will not be compliant with this requirement. In such event, we would be subject to delisting, and because we consummated a reverse stock split in January 2026, we would be ineligible for any compliance period under recently implemented Nasdaq listing rules if this event occurred prior to the one-year anniversary of such reverse stock split.

In addition, on July 22, 2026, the staff of the SEC's Division of Trading and Markets, acting pursuant to delegated authority, approved a Nasdaq proposal establishing a new continued listing requirement that all Nasdaq-listed companies maintain a minimum value of listed securities of $5 million, and providing that companies not meeting this standard will be delisted if they fail to meet this requirement for 30 consecutive trading days. On July 29, 2026, the full SEC stayed approval of the rule so that the full SEC may further consider whether the rule should be approved, and the proposed rule is therefore currently not effective. At the present time, the market value of our outstanding common stock is substantially below the threshold that would be implemented if the rule were approved, and we therefore would be at risk of failing to meet this requirement and being delisted on that basis if the rule is ultimately approved and our market capitalization does not increase above the proposed $5 million threshold.

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

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

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

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

March 2026 Private Placement

See "Recent Offerings - March 2026 Private Placement" under Part I, Item 2 of this report, which is incorporated herein by reference.

June 2026 Private Placement

See "Recent Offerings - June 2026 Private Placement" under Part I, Item 2 of this report, which is incorporated herein by reference.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Insider Trading Arrangements and Policies

During the fiscal quarter ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified or terminated any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Securities Exchange Act of 1934 or any "non-Rule 10b5-1 trading arrangement."

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit Number	Description
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*(1)	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*(1)	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

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

SIGNATURES

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

Bluejay Diagnostics, Inc.

SIGNATURE	TITLE	DATE
/s/ Neil Dey Neil Dey	President, Chief Executive Officer and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	November 12, 2026

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, Neil Dey, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2026

By: /s/ Neil Dey

Neil Dey
President and Chief Executive Officer
(Principal executive officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Neil Dey, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2026

By: /s/ Neil Dey

Neil Dey
President and Chief Executive Officer
(Principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

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

The quarterly report on Form 10-Q for the quarter ended September 30, 2026 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2026

By: /s/ Neil Dey

Neil Dey
President and Chief Executive Officer
(Principal executive officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

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

The quarterly report on Form 10-Q for the quarter ended September 30, 2026 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2026

By: /s/ Neil Dey

Neil Dey
President and Chief Executive Officer
(Principal financial and accounting officer)