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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2023

Or

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

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	BJDX	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) 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 the 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

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

The aggregate market value of the registrant's voting stock held by non-affiliates as of June 30, 2023, was approximately $3,030,130 based on the closing price of the common stock of the registrant as reported on the Nasdaq Capital Market on such date. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant have been excluded from this computation. The determination

of affiliate status for this purpose is not necessarily a conclusive determination for other purposes. As of March 28, 2024, there were 2,688,448 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement relating to its Annual Meeting of Stockholders within 120 days of the fiscal year ended December 31, 2023. Portions of such definitive proxy statement are incorporated by reference in Part III of the Form 10-K to the extent described therein.

TABLE OF CONTENTS

		Page
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS		ii
SUMMARY OF RISK FACTORS		iii
PART I		1
ITEM 1.	BUSINESS	1
ITEM 1A.	RISK FACTORS	8
ITEM 1B.	UNRESOLVED STAFF COMMENTS	27
ITEM 1C.	CYBERSECURITY	27
ITEM 2.	PROPERTIES	28
ITEM 3.	LEGAL PROCEEDINGS	28
ITEM 4.	MINE SAFETY DISCLOSURES	28
PART II		29
ITEM 5.	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	29
ITEM 6.	RESERVED	29
ITEM 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	29
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	34
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	34
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	34
ITEM 9A.	CONTROLS AND PROCEDURES	35
ITEM 9B.	OTHER INFORMATION	35
ITEM 9C.	DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS	35
PART III		36
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	36
ITEM 11.	EXECUTIVE COMPENSATION	36
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	36
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	36
ITEM 14.	PRINCIPAL ACCOUNTANT FEES AND SERVICES	36
PART IV		37
ITEM 15.	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	37
ITEM 16.	FORM 10-K SUMMARY	39

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 Annual Report on Form 10-K ("Form 10-K"). 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-K 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-K 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-K in the case of forward-looking statements contained in this Form 10-K.

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

SPECIAL NOTE REGARDING COMPANY REFERENCES

In this Form 10-K, 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.

SUMMARY OF RISK FACTORS

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, liquidity, results of operations and prospects. These risks are discussed more fully in Item 1A. Risk Factors. These risks include, but are not limited to, the following:

- We have incurred significant losses since inception and we will continue to incur net losses for the foreseeable future.
- We currently have no product revenue and we may not be able to commercialize our Symphony technology platform or achieve significant revenues or profitability.
- We will require additional capital to finance our operations to continue as a going concern, which may not be available to us on acceptable terms, or at all. Absent further funding, we currently expect to run out of available cash resources during the third quarter of 2024, and we have slowed the timeline of our clinical trial work to preserve cash resources in the near-term. As a result, we not be able to complete the development and commercialization of our Symphony technology platform and have substantial doubt about our ability to continue as a going concern.
- We have received a notification letter from the Nasdaq Listing Qualifications Staff that our common stock does not satisfy Nasdaq's $1.00 minimum price per share rule and we could face delisting by Nasdaq if we are unable to regain compliance with this requirement, which could adversely affect our ability to sell stock in the public markets, the liquidity of our common stock and our general ability to raise additional capital.
- Our new license agreement with Toray, which covers the license of the core technology used in our Symphony Cartridges, and our new supply agreement with Toray, which covers the supply of cartridge intermediates from Toray to SanyoSeiko for SanyoSeiko to manufacture cartridges for Bluejay, contain significant risks that may threaten our viability or otherwise have a material adverse effect on us and our business, assets and its prospects.
- We depend on, and are liable for, SanyoSeiko as our primary contract manufacturing organization (CMO), so its inability or failure to perform appropriately in that capacity may threaten our viability or have a material adverse effect on us and our business, assets and its prospects.
- We cannot accurately predict the volume or timing of any sales, making the timing of any revenues difficult to predict.
- If third-party payors do not provide coverage and reimbursement for the use of our platform, our business and prospects may be negatively impacted.
- If we are not able to attract and retain highly skilled managerial, scientific and technical personnel, we may not be able to implement our business model successfully, and our limited cash resources could require us to make personnel-related cost reductions in the near-term.
- Significant raw material shortages, supplier capacity constraints, supplier disruptions, and sourcing issues may adversely impact or limit our products sales and or impact our product margins.
- The regulatory approval process which we may be required to navigate may be expensive, time-consuming, and uncertain and may prevent us from obtaining clearance for our planned products.
- Product clearances and approvals can often be denied or significantly delayed.
- Clinical data obtained in the future may not meet the required objectives, which could delay, limit or prevent any regulatory approval.
- We may be unable to complete required clinical evaluations, or we may experience significant delays in completing such clinical evaluations, which could prevent or significantly delay our targeted product launch timeframe and impair our viability and business plan.
- We may be liable if the FDA or another regulatory agency concludes that we have engaged in the off-label promotion of our products.
- We depend on intellectual property licensed from Toray, and any dispute over the license would significantly harm our business.
- We face intense competition in the diagnostic testing market, particularly in the IL-6 space, and as a result we may be unable to effectively compete in our industry.
- If we or Toray fail to respond quickly to technological developments, our products may become uncompetitive and obsolete.

PART I

ITEM 1. BUSINESS

Overview

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

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

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

Our operations to date have been funded primarily through the proceeds of (i) our initial public offering (the "IPO") on November 2021 (the "IPO Date"), (ii) the registered direct offering of common stock and concurrent private placement of warrants that we completed on August 28, 2023, and (iii) the public offering of common stock and warrants that we completed on January 2, 2024. We were incorporated under the laws of Delaware on March 20, 2015. Our headquarters is located in Acton, Massachusetts.

Our Market

The Symphony platform and our initial biomarker test, Symphony IL-6 test, is well suited to address a subset of the global *in vitro* diagnostics devices ("IVDs") market, including sepsis, cardio-metabolic diseases, cancer and other diseases that require rapid tests. Symphony targets critical care markets where physicians must quickly determine patient acuity to identify optimal treatment regimens.

Our Business Model

Our goal is to become the first provider of rapid tests for infectious, inflammatory and metabolic diseases by leveraging the strengths of our Symphony platform. We intend to target our sales and marketing of Symphony to the largest critical care facilities in the United States. Our business model includes the following:

- *Attractive Financing Model*. We intend to offer various financing options for the device itself. As such, our business model should not require customers to incur a significant capital outlay.

- *Recurring Revenue*. We intend to sell single-use diagnostic test cartridges. Our cartridges will create a growing and recurring revenue stream, as adoption and utilization increase, and as we develop tests for additional indications. We expect the sale of test cartridges to generate the majority of our revenue and gross profit.

- *Expand our Menu of Diagnostic Products*. As adoption increases, the average customer use of the Symphony platform should also increase. As we expand our test menu, we will be able to increase our annual revenue per customer through the resulting increase in utilization.

The Symphony Platform

The Symphony platform is an innovative and proprietary technology platform that provides rapid and accurate measurements of key diagnostic biomarkers found in whole blood. Symphony is compact and can be deployed mobile as compared to current laboratory diagnostic platforms. Symphony incorporates a user-friendly interface where all sample preparation and reagents are integrated into disposable Symphony cartridges. Symphony only requires a few drops of blood to provide a measurement in less than 20 minutes.

The Symphony analyzer orchestrates whole blood processing, biomarker isolation, and immunoassay preparation using non-contact centrifugal force. All necessary reagents and components are integrated into the Symphony cartridges. Utilizing precision microchannel technology and high specificity antibodies, whole blood is processed, and the biomarker is isolated within the Symphony cartridge. Intermitted centrifugation cycles enable complex fluid movements, allowing sequential reagent additions and independent reaction steps inside the hermitically sealed Symphony cartridge. At the conclusion of the test, the Symphony analyzer measures the fluorescence signature correlating to a highly sensitive quantitation of the biomarker.

To perform a Symphony test, the test operator adds three drops of blood to the Symphony cartridge. After scanning in the patient ID, the Symphony cartridge is inserted into the Symphony analyzer and the test runs automatically. Each analyzer can run up to six cartridges simultaneously, either with six different patient samples or six different tests, in less than 20 minutes, providing quantitative measurements used for improved patient management and clinical decision-making.

Manufacturing

We plan to manufacture both our analyzers and cartridges through Contract Manufacturing Organizations ("CMOs"). We have contracts with Toray Industries, Inc ("Toray"), to license the intellectual property rights needed to manufacture our cartridges and Sanyoseiko Co. Ltd. ("Sanyoseiko"), to manufacture both our analyzers and cartridges. Each of our partners are well-established global manufacturing companies with capabilities to scale up, re-design and supply our analyzers and cartridges.

Sanyoseiko had been selected as our CMO, though in the near-term Toray will continue to manufacture certain product intermediate components for use in cartridges being manufactured for the Company by Sanyoseiko. These cartridges made using Toray intermediates are for the purpose of obtaining FDA approval and not for commercial sale. We expect to meet the demands of our global market. Both Toray's and Sanyoseiko's facilities are located in Japan. We license the technology for the Symphony cartridges from Toray. Our license grants us exclusive global use, with the exception of Japan.

FDA Regulatory Strategy

Our current regulatory strategy is designed to support commercialization of Symphony in the United States pending marketing authorization from the FDA. Previously, our regulatory strategy involved clinical studies involving COVID-19 patients. However, we have shifted our focus away from COVID-19 patients due to a significant decline in the number of COVID-19 related hospitalizations. Pursuant to this revised strategy, we are beginning to conduct a clinical study to support an FDA regulatory submission with an initial indication for risk stratification of hospitalized sepsis patients. We submitted a pre-submission application to the FDA presenting the new study design in May 2023 and participated in a pre-submission meeting on August 11, 2023. At the meeting, the FDA provided feedback on the new study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Based on this feedback, we determined to proceed on this basis, which considers the FDA's feedback.

In the first quarter of 2024, we initiated the study at multiple sites, which the study is intended to use the Symphony IL-6 test to monitor IL-6 concentrations in patients who are diagnosed with sepsis or septic shock and are admitted or intended to be admitted to the ICU. The objective of this study is to establish IL-6 concentrations in these sepsis patients that best predict 28-day all-cause mortality. We expect that we will need to bring several additional sites into the study in the future, which we believe will help support initial commercialization and market penetration. We believe that this clinical trial expansion could also support additional indications, but that any such expansion also could delay obtaining marketing authorization for the product. As a result of our lack of cash resources, we have recently slowed the timeline of this study to preserve cash resources in the near-term, and we expect that this will delay our Symphony platform regulatory submission timeline until 2025.

Sales and Marketing

Until Symphony products are authorized by the FDA, we will focus our sales and marketing efforts on brand awareness and market education to potential customers, emphasizing the value of monitoring a critical care patient's IL-6 levels to improve decision making and patient outcomes. If cleared or approved by the FDA, we will target sales to ERs and ICUs at United States hospitals, as well as to long-term acute care facilities. We plan to establish a market presence by selling Symphony devices and tests both directly and through various distribution channels to maximize sales volume and market penetration.

License Agreement

On October 6, 2020, we entered into a License and Supply Agreement, as amended (the "License Agreement"), with Toray, providing us with an exclusive global license with Toray, excluding Japan, to use their patents and know-how related to the Symphony detection cartridges for the manufacturing, marketing and sale of the products (as defined in the License Agreement).

On October 23, 2023, we entered into an Amended and Restated License Agreement (the "New Toray License Agreement") and a Master Supply Agreement (the "New Toray Supply Agreement" and, together, the "Toray Agreements") with Toray. Under the New Toray License Agreement, we continue to license from Toray intellectual property rights needed to manufacture single-use test cartridges, and we have received the right to sublicense certain Toray intellectual property to Sanyoseiko in connection with our ongoing agreement with Sanyoseiko to manufacture our Symphony analyzers and cartridges. In addition, the New Toray License Agreement provides for the transfer of certain technology related to the cartridges to Sanyoseiko. The royalty payments we are required to pay Toray have been reduced under the New Toray License Agreement from 15% to 7.5% (or less in certain circumstances) of net sales of certain cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. The New Toray License Agreement contemplates that applicable royalty payment obligations from us to Toray for other products will be determined separately in the future.

Under the New Toray Supply Agreement, Toray will manufacture in the near-term (through its wholly owned subsidiary Kamakura Techno-Science, Inc.) certain product intermediate components for use in cartridges being manufactured for the Company by Sanyoseiko. These cartridges made using Toray intermediates are for the purpose of obtaining FDA approval and not for commercial sale. The New Toray Supply Agreement has a term ending on the earlier of October 23, 2025 or the date that we obtain FDA approval for our product, and may be extended for up to six months by mutual agreement. Once FDA approval has been obtained, the intermediates and cartridges will be manufactured by Sanyoseiko under a separate supply agreement between us and Sanyoseiko. The FDA may not clear or approve these product submissions or applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

Intellectual Property, Proprietary Technology

We do not currently hold any patents directly. We rely on a combination either directly or through the License Agreement with Toray of patent, copyright, trade secret, trademark, confidentiality agreements, and contractual protection to establish and protect our proprietary rights.

Competition

Our primary competition in the IL-6 market is laboratory size equipment including the Roche Cobas®, Siemens ADVIA Centaur® and Beckman Coulter Access 2®, which require pre-processing of whole blood prior to performing their test. We believe that our technology, which uses whole blood, provides us with a substantial competitive advantage over our existing competition that will sustain through commercialization, despite the major life science companies and consistent entry of innovative start-ups that define our competitive landscape.

Government Regulation

The design, development, manufacture, testing and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA, and corresponding state and foreign regulatory agencies.

FDA Regulation

Medical Devices

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, advertising and promotion, import and export, marketing and sales, and distribution of medical devices, including IVDs. IVDs are a type of medical device and include reagents and instruments used in the diagnosis or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals or other biomarkers. Predictive, prognostic and screening tests can also be IVDs.

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and effectiveness:

- Class I: general controls, such as labeling and adherence to quality system regulations;
- Class II: special controls, premarket notification (often referred to as a 510(k)), specific controls such as performance standards, patient registries, post-market surveillance, additional controls such as labeling and adherence to quality system regulations; and
- Class III: special controls and requires a premarket approval ("PMA").

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a de novo application, or approval of a premarket approval (PMA).

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our initial product is a Class II device subject to 510(k) clearance.

510(k) Clearance Marketing Pathway

To obtain 510(k) clearance, a company must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

De Novo Classification

Devices of a new type that FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FDCA, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDCA. This provision allows FDA to classify a low- to moderate-risk device not previously classified into Class I or II. After de novo authorization, an authorized device may be used as a predicate for future devices going through the 510(k) process.

The FDA has classified Symphony as de novo, a device of a new type that the FDA has not previously classified. Once obtained, a de novo authorization may lead to Symphony's use as a predicate for future devices going through the 510(k) process.

Clinical Trials

Clinical trials are often required for a de novo authorization. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE study and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Sponsors of applicable clinical trials of devices also are required to register with www.clinicaltrials.gov, a public database of clinical trial information. Information related to the device, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration. Although the FDA's Quality System Regulation (QSR) does not fully apply to investigational devices, the requirement for controls on design and development does apply.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of ‘‘off-label’’ uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Once we have a commercialized product, our manufacturing processes will be required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;
- withdrawing a PMA that has already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Employees

As of March 28, 2024, we have 10 full-time employees. We also contract with several consultants and contractors performing finance, accounting, regulatory advisory, investor relations and manufacturing scale-up support. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Reverse Stock Split

On July 24, 2023, we effected a reverse stock split of our shares of common stock at a ratio of 1-for-20 (the "Reverse Stock Split"), with a corresponding reduction in the number of authorized outstanding number of shares of common stock from 100,000,000 to 7,500,000. The Reverse Stock Split became effective on July 24, 2023, when the Company's common stock opened for trading on Nasdaq on a post-split basis under the Company's existing trading symbol, "BJDX." All historical share and per share amounts reflected throughout this prospectus have been adjusted to reflect the Reverse Stock Split. However, our periodic and current reports, and all other documents incorporated by reference into this prospectus that were filed prior to July 24, 2023, do not give effect to the Reverse Stock Split.

Available Information

Our principal executive offices are located at 360 Massachusetts Avenue, Suite 203, Acton, MA 01720 and our telephone number is (844) 327-7078. Our website address is www.bluejaydx.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, proxy statements and other information about us are made available, free of charge, through the Securities and Exchange Commission ("SEC") Filings section of our website at www.ir.bluejaydx.com/financial-information/sec-filings and at the SEC's website at www.sec.gov as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. We include our website address in this report only as an inactive textual reference and do not intend it to be an active link to our website. The contents of our website are not incorporated into this report.

In addition, our Board of Directors has adopted a written Code of Business Conduct and Ethics applicable to all officers, directors and employees, which is available through the "Governance Overview" section of our website at www.ir.bluejaydx.com/corporate-governance/governance-overview. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of the Code of Business Conduct and Ethics and by posting such information on the website address and location specified above.

ITEM 1A. RISK FACTORS

Investing in our securities carries a significant degree of risk. You should carefully consider the risks described below, together with all of the other information in this Form 10-K, including our consolidated financial statements and related notes included elsewhere in this Form 10-K, before deciding whether to invest in our securities. If any or a combination of the following risks were to materialize, our results of operations, financial condition and prospects could be materially adversely affected. If that were to be the case, the market price of our securities could decline, and investors could lose all or part of their investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since inception and we will continue to incur net losses for the foreseeable future.

Since our inception, we have engaged primarily in development activities, including planning and implementing clinical trials to support commercialization and FDA approval of our Symphony platform. We have funded our operations primarily through debt and equity financings, and have incurred losses since inception, including a net loss of approximately $9.8 million and approximately $9.3 million for the years ended December 31, 2023 and 2022, respectively.

We currently have no product revenue and we may not be able to commercialize our Symphony technology platform or achieve significant revenues or profitability. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development process of our product candidates, including regulatory approvals, and thereafter achieve substantial acceptance in the marketplace for our products. We may be unable to achieve any or all of these goals.

We will require additional funding to finance our operations to continue as a going concern, which may not be available to us on acceptable terms, or at all, and our lack of cash resources has slowed the timeline of our clinical trial work and could cause us to run out of cash resources in the near-term.

To date, we have relied primarily on private debt and equity financing to carry on our business. We have limited financial resources, negative cash flow from operations and no assurance that sufficient funding will be available to us to fund our operating expenses and to further our product development efforts and pursue clinical trials for FDA approval. Based on these and other factors, in our audited consolidated financial statements for the years ended December 31, 2023 and 2022, we concluded that this circumstance raised substantial doubt about our ability to continue as a going concern within one year from the original issuance date of such financial statements. Similarly, in its report on the consolidated financial statements for the years ended December 31, 2023 and 2022, our independent registered public accounting firm included an emphasis of matter paragraph stating that our recurring losses from operations and continued cash outflows from operating activities raised substantial doubt about our ability to continue as a going concern. Our consolidated financial statements for the years ended December 31, 2023 and 2022 do not include any adjustments that may result from the outcome of this uncertainty.

Absent further funding, we currently expect to run out of available cash resources during the third quarter of 2024. As such, we anticipate that we will need to raise additional capital to fund our operations while we implement and execute our business plan. 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. We currently do not have any contracts or commitments for additional financing. In addition, any additional equity financing may involve substantial dilution to our existing stockholders.

As a result of our lack of cash resources, we have recently slowed the timeline of our clinical trial work to preserve cash resources in the near-term, and we expect that this will delay our Symphony platform regulatory submission timeline until 2025. If we fail to obtain additional financing, this timeline could be delayed further, and we could be forced to abandon such activities entirely, with the possible loss of such properties or assets. We may also be forced to pursue strategic alternatives, such as a potential sale of the Company or its assets or other restructuring efforts. As a result, any inability to obtain additional financing in the near-term could have a material adverse effect on our business, results of operations, cash flow, financial condition and prospects.

The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock and this could adversely impact the consideration our other stockholders would receive.

As part of our public offerings of common stock in August 2023 and January 2024, we issued common stock warrants to purchase an aggregate of 2,908,308 shares of our common stock, and pre-funded warrants to purchase up to an aggregate of 2,154,540 shares of our common stock. As of the date hereof, the two holders of pre-funded warrants, Armistice Capital Master Fund Ltd. and Sabby Volatility Warrant Master Fund, have collectively exercised pre-funded warrants to purchase 911,540 shares of common stock, and pre-funded warrants remain exercisable to purchase 1,243,000 shares of common stock. Each pre-funded warrant has an exercise price per share of common stock equal to $0.0001 per share, which has previously been funded by the Company, and is exercisable from the date of issuance until exercised in full, and the exercise price has previously been funded to the Company. Common stock warrants to purchase 216,000 shares of common stock are exercisable at a price of $7.24 per share, and common stock warrants to purchase 2,692,308 shares of common stock are exercisable at a price of $1.30 per share. Each common stock warrant is exercisable for five years from the date of issuance (until August 24, 2028 or January 2, 2029, respectively).

The common stock warrants are generally only exercisable solely by means of a cash exercise. The common stock warrants include certain rights upon "fundamental transactions" as described in the common stock warrants, including the right of the holders thereof to receive from us or a successor entity 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 described in such common stock warrants) of the unexercised portion of the applicable common stock warrants on the date of the consummation of such fundamental transaction. A holder of common stock warrants (together with its affiliates) may not exercise any portion of a common stock warrant to the extent that the holder would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding common stock immediately after exercise.

Although these warrants are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and the holders of these warrants, concerning the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline significantly.

We have registered the issuance of shares upon exercise of these warrants under registration statements. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public market upon issuance. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur.

Given the amount and terms of these warrants, we may find it more difficult to raise additional equity capital on favorable terms or at all while these warrants are outstanding.

As a result of our January 2024 public offering, we have reserved for issuance substantially all of our available authorized shares of common stock, and will not be able to issue additional shares for future capital raising transactions or strategic transactions unless and until we obtain stockholder approval to amend our restated certificate of incorporation to increase the number of authorized shares of common stock.

Under our amended and restated certificate of incorporation, as amended, we have 7,500,000 shares of common stock and 5,000,000 shares of preferred stock authorized for issuance. As of March 28, 2024, we had (i) 2,688,448 shares of common stock outstanding, (ii) zero shares of preferred stock outstanding, (iii) 37,645 shares of common stock issuable upon the exercise of outstanding stock options or settlement of outstanding restricted stock units, 4,523,454 shares of common stock issuable upon the exercise of outstanding warrants, and 53,490 shares reserved for future issuance under our 2018 Stock Incentive Plan or 2021 Stock Incentive Plan. As a result, as of such date, we had only 196,963 additional authorized shares of common stock available for issuance (in addition to the 5,000,000 shares of preferred stock that remain available). We intend to seek shareholder approval at our 2024 annual meeting of shareholders to amend our amended and restated certificate of incorporation to further increase the number of authorized shares of common stock available for issuance. Unless and until such amendment is approved by our shareholders, we will be limited in our ability to issue further shares of common stock, including in connection with potential future capital raising transactions.

Our ability to raise additional capital via a registered public offering on Form S-3 will be limited in the near-term as a result of the SEC's "baby shelf" rules.

In June 2023 we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on June 20, 2023 (the "Shelf Registration Statement"). The Shelf Registration Statement allows us to sell from time to time up to $25 million of common stock, preferred stock, debt securities, debentures, warrants, rights or units comprised of any combination of these securities, for our own account in one or more offerings. In August 2023, we completed a public offering under the Shelf Registration Statement pursuant to which we raised gross proceeds of approximately $1.6 million. Under applicable SEC rules, smaller companies like us are only permitted to raise up to 1/3rd of their public float under Form S-3 over a 12-month period. As a result, based on our current public float, we are unable to use Form S-3 for further offerings by us at the present time, and absent a significant increase in the trading price of our common stock, we will be unable to raise further capital under Form S-3 until late August of 2024 (at which time we will again be able to sell up to 1/3rd of our public float pursuant to Form S-3, assuming we continue the applicable eligibility requirements thereof. Our inability to use Form S-3 in the near-term may make it more difficult for us to raise equity capital in the public markets, as we expect to be required to conduct any such fundraising via private placements, or sales on Form S-1, which sales of Form S-1 may be more difficult for us to execute in a timely manner.

We have received a notification letter from the Nasdaq Listing Qualifications Staff that our common stock does not satisfy Nasdaq's $1.00 minimum price per share rule and we could face delisting by Nasdaq if we are unable to regain compliance with this requirement, which could adversely affect our ability to sell stock in the public markets, the liquidity of our common stock and our general ability to raise additional capital.

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

Under the Nasdaq Listing Rules, we have a period of 180 calendar days to regain compliance. To regain compliance, the closing bid price of our common stock must be at least $1.00 or higher for a minimum of ten consecutive business days, and in such case, Nasdaq will provide us with written confirmation of compliance. If we do not regain compliance by August 26, 2024, we may be eligible for an additional 180 calendar days, provided that we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, except the bid price requirement. If we are not eligible or it appears to Nasdaq that we will not be able to cure the deficiency during the second compliance period, Nasdaq will provide written notice to us that our common stock will be subject to delisting. In the event of such notification, we may appeal Nasdaq's determination to delist its securities, but there can be no assurance that Nasdaq would grant our request for continued listing.

We intend to take all reasonable measures available to us to achieve compliance to allow for continued listing on the Nasdaq Capital Market. However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria. If our common stock does not regain compliance with the minimum price requirement during the applicable compliance period, we may need to effect a reverse stock split, whereby shares of our common stock are consolidated so that the per-share trading price becomes greater than $1.00 per share. We intend to seek shareholder approval for such a reverse stock split at our 2024 annual meeting of shareholders.

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.

Risks Related to Our Business

We are subject to the risks associated with new businesses.

We are effectively a new business with a plan to commercialize our licensed technology. Our limited operating history may not be adequate to enable you to fully assess our ability to develop and market our Symphony platform and test cartridges, assuming we receive regulatory clearances, for which there is no assurance, and respond to competition. Our efforts to date have related to the organization and formation of our Company, research and development and performing clinical trials. We have no approved products, have not yet generated sustainable revenue, and we cannot guarantee we will ever be able to generate future revenues. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties, inherent in a new business focused on the development and sale of new medical devices. As a result, we may be unable to further develop, obtain regulatory approval for, manufacture, market, sell and derive revenues from our Symphony platform and test cartridges and the other product candidates in our pipeline, and our inability to do so would materially and adversely impact our viability. In addition, we still must optimize many functions necessary to operate a business, including expanding our managerial, personnel and administrative structure, continuing product research and development, and assessing and commencing our marketing activities.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies that have not yet commercialized their products, particularly those in the medical device field. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, or that our business plan is sound;
- maintain our management team and Board of Directors;
- determine that the technologies that have been developed are commercially viable;
- attract, enter into or maintain contracts with, and retain customers; and
- raise any necessary additional funds in the capital markets or otherwise to effectuate our business plan.

In the event that we do not successfully address these risks, our business, prospects, financial condition, and results of operations could be materially and adversely affected.

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

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

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

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

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

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

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

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

- Toray has the right to terminate the New Toray License Agreement or make it non-exclusive if we do not generate commercial sales by October 2028, or by October 2030 if the lack of commercial sales is due to events within our control and not due to Toray's failure to perform its obligations in a timely manner. The exclusive license shall be extended for an additional six months, repeatedly if necessary, provided that such additional extension period shall not exceed twenty four months.

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

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

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

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

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

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

We have not yet launched any products and the ability to do so will depend on the acceptance of our Symphony platform in the healthcare market.

We have not yet launched or received regulatory approvals in any country or territory for our Symphony platform or test cartridges. Even if we receive regulatory approvals, we are faced with the risk that our Symphony platform will not be accepted over competing products and that we will be unable to enter the marketplace or compete effectively. We cannot assure you that our Symphony platform or test cartridges will gain market acceptance. If the market for our future products fails to develop or develops more slowly than expected, or if any of the technology and standards supported by us do not achieve or sustain market acceptance, our business and operating results would be materially and adversely affected.

We cannot accurately predict the volume or timing of any sales, making the timing of any revenues difficult to predict.

We may be faced with lengthy and unpredictable customer evaluation and approval processes associated with our Symphony platform. Consequently, we may incur substantial expenses and devote significant management effort and expense in developing customer adoption of our Symphony platform, which may not result in revenue generation. We must also obtain regulatory approvals of our Symphony platform and test cartridges in jurisdictions in which we pursue approvals, which is subject to risk and potential delays. The same risks apply to other tests we may develop based on our Symphony platform. As such, we cannot accurately predict the volume, if any, or timing of any future sales.

If third-party payors do not provide coverage and reimbursement for the use of our platform, our business and prospects may be negatively impacted.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in certain countries, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Our Symphony platform, including its software and systems, may contain undetected errors, which could limit our ability to provide our products and diminish the attractiveness of our offerings.

Our Symphony platform may contain undetected errors, defects, or bugs. As a result, our customers or end users may discover errors or defects in our products, software or systems, or our products, software or systems may not operate as expected. We may discover significant errors or defects in the future that we may not be able to fix. Our inability to fix any of those errors could limit our ability to provide our products and services, impair the reputation of our brand and diminish the attractiveness of our product and service offerings to our customers.

In addition, we may utilize third party technology or components in our products, and we rely on those third parties to provide support services to us. The existence of errors, defects, or bugs in third party technology or components, or the failure of those third parties to provide necessary support services to us, could materially adversely impact our business.

We will rely on the proper function, security and availability of our information technology systems and data to operate our business, and a breach, cyber-attack or other disruption to these systems or data could materially and adversely affect our business, results of operations, financial condition, cash flows, reputation, or competitive position.

We will depend on sophisticated software and other information technology systems to operate our business, including to process, transmit and store sensitive data, and our future products and services may include information technology systems that collect data regarding patients. We could experience attempted or actual interference with the integrity of, and interruptions in, our technology systems, as well as data breaches, such as cyber-attacks, malicious intrusions, breakdowns, interference with the integrity of our products and data or other significant disruptions. Furthermore, we may rely on third-party vendors to supply and/or support certain aspects of our information technology systems. These third-party systems could also become vulnerable to cyber-attack, malicious intrusions, breakdowns, interference, or other significant disruptions, and may contain defects in design or manufacture or other problems that could result in system disruption or compromise the information security of our own systems.

If in the future we pursue foreign jurisdictions, such international operations will mean that we are subject to laws and regulations, including data protection and cybersecurity laws and regulations, in many jurisdictions. Furthermore, there has been a developing trend of civil lawsuits and class actions relating to breaches of consumer data held by large companies or incidents arising from other cyber-attacks. Any data security breaches, cyber-attacks, malicious intrusions or significant disruptions could result in actions by regulatory bodies and/or civil litigation, any of which could materially and adversely affect our business, results of operations, financial condition, cash flows, reputation, or competitive position.

In addition, our information technology systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving legal and regulatory standards, the increasing need to protect patient and customer information, changes in the techniques used to obtain unauthorized access to data and information systems, and the information technology needs associated any new products and services. There can be no assurance that our process of consolidating, protecting, upgrading and expanding our systems and capabilities, continuing to build security into the design of our products, and developing new systems to keep pace with continuing changes in information processing technology will be successful or that additional systems issues will not arise in the future.

If our information technology systems, products or services or sensitive data are compromised, patients or employees could be exposed to financial or medical identity theft or suffer a loss of product functionality, and we could lose existing customers, have difficulty attracting new customers, have difficulty preventing, detecting, and controlling fraud, be exposed to the loss or misuse of confidential information, have disputes with customers, physicians, and other health care professionals, suffer regulatory sanctions or penalties, experience increases in operating expenses or an impairment in our ability to conduct our operations, incur expenses or lose revenues as a result of a data privacy breach, product failure, information technology outages or disruptions, or suffer other adverse consequences including lawsuits or other legal action and damage to our reputation.

If we are not able to attract and retain highly skilled managerial, scientific and technical personnel, we may not be able to implement our business model successfully, and our limited cash resources could require us to make further cost reductions.

We believe that our management team must be able to act decisively to apply and adapt our business model in the markets in which we will compete. Our future performance depends to a large extent on the continued services of members of our current management, including our President and Chief Executive Officer, Neil Day, and our Chief Technology Officer, Jason Cook. At present, our Interim Chief Financial Officer, Frances Scally, is not an employee of ours, but instead provides services to us pursuant to a scope of work agreement and master services agreement with DLA LLC, where Ms. Scally is an employee. In addition, we rely upon technical and scientific employees or third-party contractors to effectively establish, manage and grow our business. Consequently, we believe that our future viability will depend largely on our ability to attract and retain highly skilled managerial, sales, scientific and technical personnel. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we currently expect, and such higher compensation payments would have a negative effect on our operating results. Competition for experienced, high-quality personnel is intense and we cannot assure that we will be able to recruit and retain such personnel, or that we will possess the cash resources to do so. For example, our limited cash resources could require us to implement personnel-related cost reductions in the near-term. As such, we may not be able to hire or retain the necessary personnel to implement our business strategy. Our failure to hire and retain such personnel could impair our ability to develop new products and manage our business effectively. In the event that we lose the continued services of such key personnel for any reason, this could have a material adverse effect on our business, operations and prospects.

If we or our manufacturers fail to comply with the regulatory quality system regulations or any applicable equivalent regulations, our proposed operations could be interrupted, and our operating results would suffer.

We and any third-party manufacturers and suppliers of ours will be required, to the extent of applicable regulation, to follow the quality system regulations of each jurisdiction we will seek to penetrate and also will be subject to the regulations of these jurisdictions regarding the manufacturing processes. If we or any third-party manufacturers or suppliers of ours are found to be in significant non-compliance or fail to take satisfactory corrective action in response to adverse regulatory findings in this regard, regulatory agencies could take enforcement actions against us and such manufacturers or suppliers, which could impair or prevent our ability to produce our products in a cost-effective and timely manner in order to meet customers' demands. Accordingly, our operating results would suffer.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of our Symphony platform or test cartridges. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If our Symphony platform or test cartridges, or any future tests based on our Symphony platform, are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our devices or failing to adhere to the operating guidelines or our devices producing inaccurate readings could cause significant harm to patients. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we expect to maintain product liability insurance, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenue. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of laws around the world protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. Privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. We may face difficulties in holding such information in compliance with applicable law. If we are found to be in violation of the privacy rules, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Significant raw material shortages, supplier capacity constraints, supplier disruptions, and sourcing issues may adversely impact or limit our products sales and or impact our product margins.

Our key suppliers are limited- or sole-source suppliers. Disruptions in deliveries, capacity constraints, production disruptions up- or down-stream, price increases, or decreased availability of raw materials or commodities, including as a result of war, natural disasters (including the effects of climate change such as sea level rise, drought, flooding, wildfires and more intense weather events), actual or threatened public health emergencies or other business continuity events, adversely affect our operations and, depending on the length and severity of the disruption, can limit our ability to meet our commitments to customers or significantly impact our operating profit or cash flows.

Risks Related to Product Development and Regulatory Approval

We adapted our clinical trial design in 2023 to obtain more patient data to reflect recent FDA feedback, and our regulatory pathway remains subject to further FDA review and feedback and the results of ongoing and future clinical studies.

Our current regulatory strategy is designed to support commercialization of Symphony in the United States pending marketing authorization from the FDA. Previously, our regulatory strategy involved clinical studies involving COVID-19 patients. However, we have shifted our focus away from COVID-19 patients due to a significant decline in the number of COVID-19 related hospitalizations. Pursuant to this revised strategy, we are beginning to conduct a clinical study to support an FDA regulatory submission with an initial indication for risk stratification of hospitalized sepsis patients. We submitted a pre-submission application to the FDA presenting the new study design in May 2023 and participated in a pre-submission meeting on August 11, 2023. At the meeting, the FDA provided feedback on the new study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Based on this feedback, we determined to proceed on this basis, which considers the FDA's feedback.

In the first quarter of 2024, we initiated the study at multiple sites, which study is intended to use the Symphony IL-6 test to monitor IL-6 concentrations in patients who are diagnosed with sepsis or septic shock and are admitted or intended to be admitted to the ICU. The objective of this study is to establish IL-6 concentrations in these sepsis patients that best predict 28-day all-cause mortality. We expect that we will need to bring several additional sites into the study in the future, which we believe will help support initial commercialization and market penetration. We believe that this clinical trial expansion could also support additional indications, but that any such expansion also could delay obtaining marketing authorization for the product. As a result of our lack of cash resources, we have recently slowed the timeline of this study to preserve cash resources in the near-term, and we expect that this will delay our Symphony platform regulatory submission timeline until 2025.

Although we believe that we have a sound strategy for obtaining FDA regulatory approval and clearance, there can be no assurance that it will ultimately be obtained. Reasons that approval and clearance might not be obtained, on our expected timeline or at all, include that we are unable to complete our planned studies (due to lack of funding, delays or interruptions in the manufacturing of quality-sufficient cartridges needed to be used in the study, or otherwise), that clinical results are not sufficient to demonstrate required efficacy, or that the FDA does not agree with our study design or aspects of our submission. In addition, the FDA could also change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which could prevent or delay approval or clearance. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

The regulatory approval process which we may be required to navigate may be expensive, time-consuming, and uncertain and may prevent us from obtaining clearance for our planned products.

We intend to market our Symphony platform and test cartridges following regulatory approval. To date, we have not received regulatory approval in any jurisdiction. The research, design, testing, manufacturing, labeling, selling, marketing, and distribution of medical devices are subject to extensive regulation by country-specific regulatory authorities, which regulations differ from country to country. There can be no assurance that, even after such time and expenditures, we will be able to obtain necessary regulatory approvals for clinical testing or for the manufacturing or marketing of any products. In addition, during the regulatory process, other companies may develop other technologies with the same intended use as our products.

We also will be subject to numerous post-marketing regulatory requirements, which may include labeling regulations and medical device reporting regulations, which may require us to report to different regulatory agencies if our device causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by regulatory agencies, which may include, among others, any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notification, or orders for repair, replacement, or refunds;

- voluntary or mandatory recall or seizure of our products;
- imposing operating restrictions, suspension, or shutdown of production;
- refusing our requests for clearance or pre-market approval of new products, new intended uses or modifications to any products;
- rescinding clearance or suspending or withdrawing pre-market approvals that have already been granted; and
- criminal prosecution.

The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Product clearances and approvals can often be denied or significantly delayed.

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the de novo classification process, or is the subject of a PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data.

The PMA process typically is more costly, lengthy, and stringent than either the 510(k) process or the de novo classification process. Unlike a 510(k) review, which determines "substantial equivalence," a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the United States and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements, de novo classification, or additional 510(k) pre-market clearances to market modifications to our products once they are approved and commercialized. The FDA requires device manufacturers to make and document a determination of whether a device modification requires approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing of the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not clear or approve our product submissions or applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

The FDA may also change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

International regulatory approval processes may take more or less time than the FDA's clearance or approval process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA's clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. Any failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations.

Our Symphony platform may be sold as a research use only product. The FDA could disagree with this strategy and subject the product to regulation as a regulated medical device, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

In the United States, we may decide to label and sell our Symphony platform for research use only, and not for the diagnosis or treatment of disease. Our future product candidates also may follow this same pathway to market. Because such products are not intended for use in clinical practice in diagnostics, and the products cannot include clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, while FDA regulations require that RUO products be labeled, "For Research Use Only. Not for use in diagnostic procedures," the regulations do not otherwise subject such products to the FDA's pre- and post-market controls for medical devices.

A significant change in the laws governing RUO products or how they are enforced may require us to change our ability to consider generating revenue via this path in order to maintain compliance. For instance, in November 2013 the FDA issued a guidance document entitled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only" (the "RUO Guidance") which highlights the FDA's interpretation that distribution of RUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as a laboratory developed test is in conflict with RUO status. The RUO Guidance further articulates the FDA's position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, conflicts with RUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO status held by the products that we sell, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO products in a manner that is inconsistent with its regulations or guidance, we may be forced to stop distribution of our RUO tests until we are in compliance, which would reduce our revenue, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In addition, the FDA's proposed implementation for a new framework for the regulation of laboratory developed tests (LDTs) may negatively impact the LDT market and thereby reduce demand for RUO products.

Clinical data obtained in the future may not meet the required objectives, which could delay, limit or prevent any regulatory approval.

There can be no assurance that we will successfully complete any clinical evaluations necessary to receive regulatory approvals. While preliminary results have been encouraging and indicative of the potential performance of our Symphony platform and test cartridges, data already obtained, or in the future obtained, from clinical studies do not necessarily predict the results that will be obtained from later clinical evaluations. The failure to adequately demonstrate the performance characteristics of the device under development could delay or prevent regulatory approval of the device, which could prevent or result in delays to market launch and could materially harm our business. There can be no assurance that we will be able to receive approval for any potential applications of our principal technology, or that we will receive regulatory clearances from targeted regions or countries.

We may be unable to complete required clinical evaluations, or we may experience significant delays in completing such clinical evaluations, which could prevent or significantly delay our targeted product launch timeframe and impair our viability and business plan.

The completion of any future clinical evaluations of our Symphony platform or test cartridges, or other studies that we may be required to undertake in the future, could be delayed, suspended, or terminated for several reasons, including:

- we may fail to or be unable to conduct the clinical evaluation in accordance with regulatory requirements;
- sites participating in the trial may drop out of the trial, which may require us to engage new sites for an expansion of the number of sites that are permitted to be involved in the trial;
- patients may not enroll in, remain in or complete, the clinical evaluation at the rates we expect; and
- clinical investigators may not perform our clinical evaluation on our anticipated schedule or consistent with the clinical evaluation protocol and good clinical practices.

If our clinical evaluations are delayed it will take us longer to ultimately launch our Symphony platform and test cartridges in the market and generate revenues. Moreover, our development costs will increase if we have material delays in our clinical evaluation or if we need to perform more or larger clinical evaluations than planned.

We and our suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.

As a medical device manufacturer, we will need to register with the FDA and various non-U.S. regulatory agencies and will be subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain Good Manufacturing Practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our product and component suppliers may also be required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our products or component suppliers will comply with all regulatory requirements. The failure by us or one of our suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, until a new supplier has been identified and evaluated. Our or any product or component supplier's failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we can locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition and results of operations.

We may be liable if the FDA or another regulatory agency concludes that we have engaged in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of our products. Once our products are cleared or approved for clinical use, healthcare providers may use our products for off-label uses, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional, or training materials for sales representatives or physicians constitute promotion of an off-label use, the FDA could request that we modify our training, promotional materials and/or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, significant penalties, including civil fines and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion, reimbursement or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In those possible events, our reputation could be damaged, and adoption of the products would be impaired.

Our products may be subject to recalls after receiving FDA or foreign approval or clearance or cause or contribute to a death or a serious injury or malfunction in certain ways prompting voluntary corrective actions or agency enforcement actions, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.

The FDA and similar foreign governmental authorities have the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture, or if there is a reasonable likelihood our products might cause or contribute to a death or a serious injury or malfunction. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality-related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation, and adversely affect our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

In addition, we will be subject to medical device reporting regulations that will require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals, and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation, and have a material adverse effect on our business, financial condition and results of operations. Any adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of any future products and to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new products would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing clearance that we may have obtained and we may not achieve or sustain profitability.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Industry

We face intense competition in the diagnostic testing market, particularly in the IL-6 space, and as a result we may be unable to effectively compete in our industry.

We expect to compete directly and primarily with large medical device companies. These large companies have most of the diagnostic testing business and strong research and development capacity. Their dominant market position and significant control over markets could significantly limit our ability to introduce our Symphony platform or effectively market and generate sales of our products.

We have not yet entered the revenue stage and most of our competitors have long histories and strong reputations within the industry. They have significantly greater brand recognition, financial and human resources than we do. They also have more experience and capabilities in researching and developing testing devices, obtaining and maintaining regulatory clearances and other requirements, manufacturing and marketing those products than we do. There is a significant risk that we may be unable to overcome the advantages held by our competition, and our inability to do so could lead to the failure of our business.

Competition in the diagnostic testing markets is intense, which can lead to, among other things, price reductions, longer selling cycles, lower product margins, loss of market share and additional working capital requirements. To succeed, we must, among other critical matters, gain consumer acceptance for our products, technical solutions, prices and response time, or a combination of these factors. If our competitors offer significant discounts on certain products, we may need to lower our prices or offer other favorable terms in order to compete successfully. Moreover, any broad-based changes to our prices and pricing policies could make it difficult to generate revenues or cause our revenues, if established, to decline. Moreover, if our competitors develop and commercialize products that are more desirable than the products that we may develop, we may not convince customers to use our products. Any such changes would likely reduce our commercial opportunity and revenue potential and could materially adversely impact our operating results.

If we or Toray fail to respond quickly to technological developments, our products may become uncompetitive and obsolete.

The diagnostic testing market may experience rapid technology developments, changes in industry standards, changes in customer requirements and frequent new product introductions and improvements. If we or Toray are unable to respond to these developments, we may lose competitive position, and our products or technology may become uncompetitive or obsolete, causing our business and prospects to suffer. In order to compete, we and Toray may have to develop, license or acquire new technology on a schedule that keeps pace with technological developments and the requirements for products addressing a broad spectrum and designers and designer expertise in our industries.

Risks Related to Ownership of Our Common Stock

We could issue "blank check" preferred stock without stockholder approval with the effect of diluting interests of then-current stockholders and impairing their voting rights, and provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable.

Our Certificate of Incorporation provides for the authorization to issue up to 5,000,000 shares of "blank check" preferred stock with designations, rights and preferences as may be determined from time to time by our Board of Directors. Our Board of Directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying or preventing a change in control. For example, it would be possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our Company. In addition, advanced notice is required prior to stockholder proposals, which might further delay a change of control.

Shares eligible for future sale may adversely affect the market for our common stock.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers, employees, and significant stockholders, or when there is a large number of shares of our common stock available for sale.

Our existing stockholders (including the holders of our preferred stock and warrants) may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market, subject to the limitations of Rule 144, promulgated under the Securities Act. In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person is entitled to sell those shares without complying with any of the requirements of Rule 144. Our affiliates and other persons selling shares on behalf of our affiliates also are entitled to sell as long as they comply with Rule 144's manner of sale, volume limitation and notice provisions, in addition to the provisions applicable to non-affiliates described above.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our common stock could be negatively affected.

Any trading market for our common stock will be influenced in part by any research reports that securities industry analysts publish about us. We do not currently have and may never obtain research coverage by securities industry analysts. If no securities industry analysts commence coverage of us, the market price and market trading volume of our common stock could be negatively affected. In the event we are covered by analysts, and one or more of such analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage or us, the market price and market trading volume of our common stock could be negatively affected.

As an "emerging growth company" under applicable law, we are subject to lessened disclosure requirements, which could leave our stockholders without information or rights available to stockholders of other public companies that are not "emerging growth companies."

For as long as we remain an "emerging growth company" as defined in the JOBS Act, we have elected to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We expect to take advantage of these reporting exemptions until we are no longer an "emerging growth company." We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of: (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the date on which we are deemed to be a large accelerated filer, which is the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the end of our most recent second fiscal quarter, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Because of these lessened regulatory requirements, our stockholders would be left without information or rights available to stockholders of other public companies that are not "emerging growth companies." In addition, we cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

Because we have elected to use the extended transition period for complying with new or revised accounting standards for an "emerging growth company" our financial statements may not be comparable to companies that comply with public company effective dates.

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. While we are not currently delaying the implementation of any relevant accounting standards, in the future we may avail ourselves of these rights, and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. Because our financial statements may not be comparable to companies that comply with public company effective dates, investors may have difficulty evaluating or comparing our business, performance or prospects in comparison to other public companies, which may have a negative impact on the value and liquidity of our common stock.

Anti-takeover provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our Company and may affect the trading price of our common stock.

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and by-laws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and bylaws will:

- provide for the issuance of "blank check" preferred stock that could be issued by our Board of Directors to thwart a takeover attempt;
- provide that stockholders will not be able to take action by written consent, and special meetings of stockholders may only be called by our Chief Executive Officer, our President, our Board of Directors or a majority of our stockholders;
- provide that our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our Board of Directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our Company; and
- do not provide stockholders with the ability to cumulate their votes, which limits the ability of minority stockholders to elect director candidates.

These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

We will continue incurring increased costs as a result of operating as a public company, and our management is now required to devote substantial time to new compliance initiatives and corporate governance practices.

Our common stock began trading on the NASDAQ Global Select Market in November 2021. As a public company, and particularly after we are no longer an EGC, we are incurring and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. These requirements result in significant legal and financial compliance costs and make some activities more time-consuming and costly. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This results in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have material adverse effect on our business and stock price, and our limited internal staffing may enhance the likelihood of such a controls failure.

Pursuant to SOX Section 404 we are required to furnish a report by our management on our internal control over financial reporting in our Annual Reports on Form 10-K with the SEC since becoming a public company, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we are not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To comply with SOX Section 404, we document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have and will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, we may identify one or more material weaknesses, which could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. At present, our Interim Chief Financial Officer, Frances Scally, is not an employee of ours, but instead provides services to us on a limited basis pursuant to a scope of work agreement and master services agreement with DLA LLC, where Ms. Scally is an employee. We also do not presently employ an internal legal officer. Our lack of a directly employed principal financial and accounting officer or principal legal officer may increase the likelihood that we will fail to successfully maintain effective internal controls over financial reporting, or effective disclosure controls and procedures.

Our amended and restated certificate of incorporation will provide, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our amended and restated certificate of incorporation will require, to the fullest extent permitted by law, subject to limited exceptions, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel in any action brought to enforce the exclusive forum provision. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our amended and restated certificate of incorporation.

Notwithstanding the foregoing, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will provide that the Court of Chancery and the federal district court for the District of Delaware will have concurrent jurisdiction over any action arising under the Securities Act or the rules and regulations thereunder, and the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction. To the extent the exclusive forum provision restricts the courts in which our stockholders may bring claims arising under the Securities Act and the rules and regulations thereunder, there is uncertainty as to whether a court would enforce such provision. Investors cannot waive compliance with the federal securities laws and the rules and regulations promulgated thereunder.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. By requiring a stockholder to bring such a claim in the Court of Chancery (or the federal district court for the District of Delaware, in the case of an action under the Securities Act or the rules and regulations thereunder), the exclusive forum provision also may increase the costs to a stockholder of bringing such a claim. Alternatively, if a court were to find the exclusive forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, strategic or competitive in nature, and proprietary or confidential information, including clinical trial data, personal and financial information ("Information Systems and Data").

Our President and Chief Executive Officer works directly with third party service providers, as applicable, to identify, assess and manage the Company's cybersecurity threats and risks. In doing so, he seeks to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods including, for example, automated and manual tools, accessing reports and services that identify cybersecurity threats, analyzing reports of threats and threat actors, evaluating the Company's and the industry's risk profile, evaluating reported threats, coordinating with law enforcement relating to threats, conducting threat assessments for internal and external threats and conducting vulnerability assessments to identify vulnerabilities.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures and processes designed to manage and mitigate material risks from cybersecurity threats to our information systems and data.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our IT department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

Governance

Our Board of Directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Board is responsible for overseeing Company's cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats. Our cybersecurity risk assessment and management processes are implemented and maintained by our President and Chief Executive Officer.

Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents to members of management and/or the Board of Directors depending on the circumstances. The Board receives periodic reports and updates from our senior management concerning significant cybersecurity threats and risks, and the processes that the Company has implemented to address them, when deemed appropriate.

ITEM 2. PROPERTIES

We have leased two facilities in Acton, Massachusetts which will expire in November 2024 and March 2027.

ITEM 3. 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. However, we are currently not a party to any pending legal actions. We have insurance policies covering any potential losses where such coverage is cost effective.

We are not at this time involved in any additional legal proceedings that we believe could have a material effect on our business, financial condition, results of operations or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is currently listed on the Nasdaq Capital Market under the symbol "BJDX".

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in any financing instruments, provisions of applicable law and other factors our Board of Directors deems relevant.

Holders of Common Stock

As of March 28, 2024, we had 2,688,448 shares of common stock outstanding held by approximately fifteen qualified stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Equity Compensation Plan Information

See Part III, Item 12 to this Form 10-K for information relating to securities authorized for issuance under our equity compensation plans.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with our Consolidated Financial Statements and the notes thereto included elsewhere in this Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. For additional discussion, see "CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS" above.

Overview

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

Since inception, we have incurred net losses from operations each year and we expect to continue to incur losses for the foreseeable future. We incurred net losses of approximately $10.0 million and $9.3 million for the years ended December 31, 2023 and 2022, respectively. We had negative cash flow from operating activities of approximately $8.3 million and $7.7 million for the years ended December 31, 2023 and 2022, respectively, and had an accumulated deficit of approximately $26.9 million and $17.0 million as of December 31, 2023 and 2022, respectively.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022:

	For Years Ended December 31,	
	2023	**2022**
Revenue	$ -	$ 249,040
Cost of sales	-	200,129
Gross profit	-	48,911
Operating expenses:		
Research and development	5,714,574	4,152,152
General and administrative	4,313,200	4,763,114
Sales and marketing	283,443	451,421
Total operating expenses	10,311,217	9,366,687
Operating loss	(10,311,217)	(9,317,776)
Other income (expense):		
Impairment of property and equipment	-	(237,309)
Interest income	164,900	89,673
Other income, net	192,429	168,464
Total other income	357,329	20,828
Net loss	$ (9,953,888)	$ (9,296,948)

Revenue and Gross Profit

Revenue and gross profit decreased approximately $0.2 million and $0.1 million respectively, for the year ended December 31, 2023, as compared to 2022. The decrease was due to a minor sale of five Symphony analyzers to our business partner, Toray, during 2022. Future sales to Toray after 2022 are not anticipated.

Research and Development

Research and development expenses increased approximately $1.6 million, or 38%, for the year ended December 31, 2023, as compared to 2022. The increase in research and development expenses was primarily due to an approximately $0.2 million increase in personnel related costs, approximately $0.6 million of additional product development costs related to bringing the Symphony analyzer and cartridges in compliance with the FDA manufacturing standards, and approximately $0.6 million of additional depreciation expense associated with the acceleration of depreciation of certain assets used for research and development activities.

We expect increases in our future research and development expenses which will be focused on our clinical trial program and any necessary manufacturing improvements.

General and Administrative

General and administrative expenses decreased approximately $0.5 million, or 9%, for the year ended December 31, 2023, as compared to 2022. The decrease in general and administrative expenses is primarily due to the cost reduction efforts focused on reducing personnel and insurance costs.

We expect to monitor and continue to reduce our general and administrative spend, as necessary, to optimize operational alignment.

Sales and Marketing

Sales and marketing expenses decreased approximately $0.2 million, or 37%, for year ended December 31, 2023, as compared to 2022. The decrease was primarily attributable to the Company's cost savings efforts as the Company seeks to limit marketing costs.

Other Income

Total other income increased approximately $0.3 million, or 1,616%, for the year ended December 31, 2023 as compared to 2022. The increase primarily related to increases in interest income from the Company's sweep account due to increased interest rates as compared to the prior period, as well as no material impairment charge being recognized during 2023 as compared to 2022, which had an impairment charge of approximately $0.2 million.

Summary Statement of Cash Flows

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

	Years Ended December 31,	
	2023	**2022**
Cash proceeds provided by (used in):		
Operating activities	$ (8,313,870)	$ (7,741,593)
Investing activities	(704,166)	(1,199,270)
Financing activities	1,111,562	8,075
Net (decrease) increase in cash and cash equivalents	$ (7,906,474)	$ (8,932,788)

Net cash used in operating activities

During 2023, we used approximately $8.3 million in cash for operating activities, an increase of approximately $0.6 million from 2022. The increase in net cash used in operating activities was primarily due to increases in personnel and product development costs, which ultimately led to the reduction of personnel in the second and third quarters of 2023.

Net cash used in investing activities

During 2023, we used approximately $0.7 million in cash for investing activities, an approximately $0.5 million decrease from 2022. The Company acquired laboratory equipment and manufacturing equipment for the development of the Symphony devices in both 2022 and 2023.

Net cash provided by financing activities

During 2023, we generated approximately $1.1 million in cash from financing activities, as compared to less than $0.1 million in 2022. The increase in net cash provided by financing activities was primarily due to the proceeds from the August 2023 Financing.

Contractual Obligations

See Note 8 to consolidated financial statements for our lease obligations and Note 9 to the consolidated financial statements for our other non-cancellable contractual obligations.

Liquidity and Going Concern

The Company had cash and cash equivalents of $2,208,516, as of December 31, 2023. The Company has incurred net losses since its inception, and has negative cash flows from operations and had the accumulated deficit of $26,950,990 as of December 31, 2023. The Company continues to develop the Symphony device and its first test for the measurement of IL-6. The Company remains committed to obtaining FDA clearance and will conduct clinical trials to obtain sufficient data to support its FDA submission, while also continuing to build its manufacturing operations with its contract manufacturing organizations. Current cash resources and expected operating expenses are considered in determining its liquidity requirement; as well as $1,771,375 of current liabilities on its balance sheet as of December 31, 2023. The Company estimates cash resources will be sufficient to fund its operations through the second quarter of 2024. The Company will need additional capital to fund its planned operations for the next 12 months. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements for the years ended December 31, 2023 and 2022 were prepared under the assumption that the Company will continue as a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business.

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

Recent Offerings

August 2023 Offering

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

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

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

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

January 2024 Offering

On January 2, 2024, the Company sold in a public offering (such transaction, the "January 2024 Offering") (i) 537,768 shares of the Company's common stock, par value $0.0001 per share and (ii) prefunded warrants to purchase up to an aggregate 2,154,540 shares of Common Stock (the "Prefunded Warrants"). The Shares and Prefunded Warrants were sold together with warrants to purchase up to an aggregate of 2,692,308 shares of Common Stock at an exercise price of $1.30 per share (the "January 2024 Warrants"). The combined public offering price was $1.30 per share of Common Stock and related January 2024 Warrant and $1.2999 per Prefunded Warrant and related January 2024 Warrant. The Company intends to use the net proceeds from the January Offering to fund matters related to obtaining FDA approval (including clinical studies related thereto), as well as for other research and development activities, and for general working capital needs.

The Prefunded Warrants are immediately exercisable and may be exercised at any time until all of the Prefunded Warrants are exercised in full. The January 2024 Warrants are exercisable immediately upon issuance for a period of five years following the date of issuance.

Pursuant to an engagement letter, dated as of August 7, 2023, as amended October 11, 2023 (the "Amended Engagement Letter"), by and between the Company and the Placement Agent, the Company paid the Placement Agent a total cash fee of $245,000 equal to 7.0% of the gross proceeds received in the January 2024 Offering. The Company also paid the Placement Agent in connection with the January Offering a management fee of $35,000 equal to 1.0% of the gross proceeds raised in the January 2024 Offering and certain expenses incurred in connection with the January Offering. In addition, the Company issued to the Placement Agent, warrants to purchase up to an aggregate 188,462 shares of Common Stock (the "January 2024 Placement Agent Warrants"), which represents 7.0% of the aggregate number of shares of Common Stock and Prefunded Warrants sold in the January 2024 Offering. The January 2024 Placement Agent Warrants have substantially the same terms as the January 2024 Warrants, except that the January 2024 Placement Agent Warrants have an exercise price equal to $1.6250, or 125% of the offering price per share of Common Stock and related January 2024 Warrant sold in the January Offering and expire on the fifth anniversary from the date of the commencement of sales in the January 2024 Offering.

Concurrently with the closing of the January 2024 Offering, certain purchasers have elected to exercise Prefunded Warrants to purchase 174,770 shares of Common Stock.

Critical Accounting Policies and Estimates

Some of our critical accounting policies require us to make difficult, subjective or complex judgments or estimates. An accounting estimate is considered to be critical if it meets both of the following criteria: (i) the estimate requires assumptions about matters that are highly uncertain at the time the accounting estimate is made, and (ii) different estimates reasonably could have been used, or changes in the estimate that are reasonably likely to occur from period to period may have a material impact on the presentation of our financial condition, changes in financial condition or results of operations.

As an emerging growth company, we have elected to opt-in to the extended transition period for new or revised accounting standards. As a result, our consolidated financial statements may not be comparable to those of companies that comply with public company effective dates.

Stock-Based Compensation

Our stock-based compensation expense for stock awards is estimated at the grant date based on the award's fair value as determined by the consideration received or as calculated by the Black-Scholes option pricing model, whichever is more readily measurable. The Black-Scholes pricing model requires various highly judgmental assumptions including expected volatility and expected term. The expected volatility is based on the historical stock volatilities of several similar public companies over a period equal to the expected terms of the awards as we do not have a sufficient trading history to use the volatility of our own common stock. To estimate the expected term, we have opted to use the simplified method, which uses of the midpoint of the vesting term and the contractual term. We recognize the compensation cost of share-based awards on a straight-line basis over the requisite service period, however, for stock awards for which vesting is subject to performance – based milestones, the expense is recorded over the implied service period after the point when the achievement of the milestone is probable, or the performance condition has been achieved. If any of the assumptions used in the Black-Scholes pricing model changes significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period.

Recently Adopted Accounting Standards

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

Recently Issued Accounting Standards

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information requested by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements and The Report of Independent Registered Public Accounting Firm are included in this Form 10-K on pages F-1 through F-20.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our President and Chief Executive Officer, who is our principal executive officer, and our Interim Chief Financial Officer, who is our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer and our Interim Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on this evaluation, our President and Chief Executive Officer and our Interim Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2023.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Our President and Chief Executive Officer and our Interim Chief Financial Officer assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, our President and Chief Executive Officer and our Interim Chief Financial Officer used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework. Based on that assessment and using the COSO criteria, our President and Chief Executive Officer and our Interim Chief Financial Officer have concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financial reporting for as long as we are an "emerging growth company" pursuant to the provisions of the Jumpstart Our Business Startups Act.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the most recent fiscal quarter, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. Controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

Not applicable.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2023.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans at December 31, 2023:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities (by class) remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	37,645	$ 31.16	53,490
Equity compensation plans not approved by security holders (2)	43,100	$ 17.95	-

(1) Represents shares of common stock issuable upon exercise of outstanding stock options and rights under our 2018 Stock Incentive Plan (the "2018 Plan") and 2021 Stock Plan (the "2021 Plan"). Both plans permit the Company to grant incentive and nonqualified stock options for the purchase of common stock, and restricted stock awards. The maximum number of shares of common stock reserved for issuance under the 2018 Plan and 2021 Plan are 31,472 and 98,000, respectively. At December 31, 2023 there were 13,113 and 40,377 shares of common stock available for grant under the 2018 Plan and 2021 Plan, respectively.

(2) Consists of warrants issued to placement agents, underwriters and consultants.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements—See Index to Consolidated Financial Statements at Part II, Item 8 on page F-1 of this Form 10-K.

(2) All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the financial statements or the Notes thereto.

(3) See the accompanying Index to Exhibits filed as a part of this Form 10-K, which list is incorporated by reference in this Item.

(b) See the accompanying Index to Exhibits filed as a part of this Form 10-K.

(c) Other schedules are not applicable.

INDEX TO EXHIBITS

Exhibit No.	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Bluejay Diagnostics, Inc., filed with the Delaware Secretary of State on July 21, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 21, 2023).
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.2	Form of Prefunded Common Stock Warrant (January 2024 Offering) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 2, 2024).
4.3	Form of Common Stock Warrant (January 2024 Offering (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on January 2, 2024).
4.4	Form of Placement Agent Common Stock Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on January 2, 2024).
4.5	Form of Common Stock (August 2023 Offering) (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed on August 28, 2023).
4.6	Form of Class A Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 16, 2021).
4.7	Form of Class B Warrant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.8	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.9	Form of IPO Underwriters' Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
4.10*	Description of Securities of Bluejay Diagnostics, Inc.
10.1**	2021 Stock Plan (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.2**	Employment Agreement, dated July 1, 2021, between Neil Dey and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.3**	First Amendment to Employment Agreement, dated January 27, 2023, between Neil Dey and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 27, 2023).
10.4**	Employment Agreement, dated July 1, 2021, between Jason Cook and Bluejay Diagnostics, Inc. * (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.5	Form of Securities Purchase Agreement, dated December 27, 2023, between certain purchasers and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 2, 2024).
10.6	Form of Securities Purchase Agreement, dated August 24, 2023, by and between the Company and each of the Purchasers signatory thereto (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on August 28, 2023).
10.7	Securities Purchase Agreement, dated June 7, 2021, between certain purchasers and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.8	Registration Rights Agreement, dated June 7, 2021, between certain purchasers and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).

10.9	Amended and Restated License Agreement, entered into on October 23, 2023, by and between Bluejay Diagnostics, Inc. and Toray Industries, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 26, 2023).
10.10	Master Supply Agreement, entered into on October 23, 2023, by and between Bluejay Diagnostics, Inc. and Toray Industries, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 26, 2023).
14.1	Code of Ethics (incorporated by reference to Exhibit 14.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
32.1*	Certification of Principal Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1*	Incentive Compensation Recovery Policy
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 included in Exhibit 101)

* Filed herewith.

** Management contract or compensatory plan, contract or arrangement.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 28, 2024.

Bluejay Diagnostics, Inc.

By: /s/ Neil Dey
Neil Dey
President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Neil Dey Neil Dey	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2024
/s/ Frances Scally Frances Scally	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2024
/s/ Douglas C. Wurth Douglas C. Wurth	Chairman of the Board of Directors	March 28, 2024
/s/ Donald R. Chase Donald R. Chase	Director	March 28, 2024
/s/ Svetlana Dey Svetlana Dey	Director	March 28, 2024
/s/ Fred S. Zeidman Fred S. Zeidman	Director	March 28, 2024
/s/ Gary Gemignani Gary Gemignani	Director	March 28, 2024

Index to Consolidated Financial Statements

Contents

Report of Independent Registered Public Accounting Firm (PCAOB ID #392)	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Changes in Stockholders' Equity	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Bluejay Diagnostics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Bluejay Diagnostics, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred net losses since its inception, and has negative cash flows from operations and will need additional funding to complete planned development efforts. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Wolf & Company, P.C.

We have served as the Company's auditor since 2017.

Boston, Massachusetts
March 28, 2024

Bluejay Diagnostics, Inc.
Consolidated Balance Sheets

ASSETS	December 31, 2023	December 31, 2022
Current assets:		
Cash and cash equivalents	$ 2,208,516	$ 10,114,990
Prepaid expenses and other current assets	747,263	1,673,480
Deferred offering costs	265,081	-
Total current assets	3,220,860	11,788,470
Property and equipment, net	1,285,741	1,232,070
Operating lease right-of-use assets	333,267	465,514
Other non-current assets	28,663	35,211
Total assets	$ 4,868,531	$ 13,521,265
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 491,474	$ 635,818
Operating lease liability, current	162,990	168,706
Accrued expenses	1,116,911	835,730
Total current liabilities	1,771,375	1,640,254
Operating lease liability, non-current	189,987	323,915
Other non-current liabilities	12,321	15,823
Total liabilities	1,973,683	1,979,992
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.0001 par value; 7,500,000 shares authorized; 1,239,140 and 1,010,560 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	124	101
Additional paid-in capital	29,845,714	28,538,274
Accumulated deficit	(26,950,990)	(16,997,102)
Total stockholders' equity	2,894,848	11,541,273
Total liabilities and stockholders' equity	$ 4,868,531	$ 13,521,265

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

Bluejay Diagnostics, Inc.
Consolidated Statements of Operations

	For Years Ended December 31,	
	2023	**2022**
Revenue	$ -	$ 249,040
Cost of sales	-	200,129
Gross profit	-	48,911
Operating expenses:		
Research and development	5,714,574	4,152,152
General and administrative	4,313,200	4,763,114
Sales and marketing	283,443	451,421
Total operating expenses	10,311,217	9,366,687
Operating loss	(10,311,217)	(9,317,776)
Other income (expense):		
Impairment of property and equipment	-	(237,309)
Interest income	164,900	89,673
Other income, net	192,429	168,464
Total other income	357,329	20,828
Net loss	$ (9,953,888)	$ (9,296,948)
Net loss per share - Basic and diluted	$ (9.08)	$ (9.22)
Weighted average common shares outstanding:		
Basic and diluted	1,096,500	1,008,196

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

Bluejay Diagnostics, Inc.
Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2021	1,005,612	$ 101	$ 28,076,394	$ (7,694,786)	$ 20,381,709
Impact of adoption of ASC 842	-	-	-	(5,368)	(5,368)
Stock-based compensation expense	-	-	433,004	-	433,004
Exercise of stock options	3,147	-	28,876	-	28,876
Exercise of common stock Series B Warrants	1,801	-	-	-	-
Net loss	-	-	-	(9,296,948)	(9,296,948)
Balance as of December 31, 2022	1,010,560	101	28,538,274	(16,997,102)	11,541,273
Stock-based compensation expense	-	-	24,385	-	24,385
Issuance of common stock from exercised RSU's	750	-	-	-	-
RSU tax withholding	(358)	-	(1,453)	-	(1,453)
Issuance of common stock to settle accrued bonus, net of shares withheld	12,188	1	107,234	-	107,235
Issuance of common stock, net of issuance costs of $413,544	216,000	22	1,177,274	-	1,177,296
Net loss	-	-	-	(9,953,888)	(9,953,888)
Balance as of December 31, 2023	1,239,140	$ 124	$ 29,845,714	$ (26,950,990)	$ 2,894,848

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

Bluejay Diagnostics, Inc.
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,953,888)	$ (9,296,948)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	648,708	156,598
Stock-based compensation expense	189,245	433,004
Amortization of right-of-use asset	132,247	149,770
Non-cash interest expense for finance lease	1,305	-
Impairment of property and equipment	1,787	237,309
Loss on disposal of property and equipment	-	137
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	926,217	(40,772)
Other non-current assets	6,548	(14,192)
Accounts payable	(235,760)	298,881
Due to related party	-	(2,000)
Accrued expenses and other current liabilities	(30,279)	336,620
Net cash used in operating activities	(8,313,870)	(7,741,593)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(704,166)	(1,199,270)
Net cash used in investing activities	(704,166)	(1,199,270)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, gross	1,590,840	-
Payment for issuance costs of common stock	(413,544)	-
Payment of tax withholding on obligations on restricted stock units	(59,078)	-
Payment of deferred offering costs	(1,849)	(20,000)
Proceeds from exercise of stock options	-	28,876
Payment of finance lease	(4,807)	(801)
Net cash provided by financing activities	1,111,562	8,075
Net decrease in cash and cash equivalents	(7,906,474)	(8,932,788)
Cash and cash equivalents, beginning of period	10,114,990	19,047,778
Cash and cash equivalents, end of period	$ 2,208,516	$ 10,114,990
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH INVESTING ACTIVITIES		
Cash paid for interest on finance lease	$ 1,305	$ 364
Offering costs included in accounts payable and accrued expenses	$ 263,232	$ -
Purchases of property and equipment included in accrued expenses	$ -	$ 41,159

See notes to 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 developing rapid tests using whole blood on its Symphony technology platform ("Symphony") to improve patient outcomes in critical care settings. The Company's Symphony platform is a combination of Bluejay's intellectual property ("IP") and exclusively licensed and patented IP that consists of a mobile device and single-use test cartridges that if cleared, authorized, or approved by the U.S. Food and Drug Administration (the "FDA"), can provide a solution to a significant market need in the United States.

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.

August 2023 Offering

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

In a concurrent private placement, the Company also issued to such institutional and accredited investors unregistered warrants to purchase up to 216,000 shares of Common Stock (the "Warrants"). Pursuant to the terms of the Purchase Agreement, for each share of Common Stock issued in this offering an accompanying Warrant was issued to the purchaser thereof. Each Warrant is exercisable for one share of Common Stock (the "August 2023 Warrant Shares") at an exercise price of $7.24 per share, is immediately exercisable upon issuance and will expire five years from the date of issuance. The Warrants were offered and sold at a purchase price of $0.125 per underlying warrant share, which purchase price is included in the offering price per share of Common Stock issued in the Offering (the "Private Placement").

Pursuant to an engagement letter, dated as of August 7, 2023 (the "Engagement Letter"), between the Company and H.C. Wainwright & Co., LLC (the "Placement Agent") the Company paid the placement agent a total cash fee of $111,359 equal to 7.0% of the gross proceeds received in the Offering and the Private Placement. The Company also paid the placement agent the management fee equal to $15,908 or 1.0% of the gross proceeds raised in the Offering and Private Placement, $45,000 for non-accountable expenses, and $15,950 for clearing fees. In addition, the Company issued to the placement agent, warrants to purchase up to 15,120 shares of Common Stock (the "Placement Agent Warrants"), which represents 7.0% of the aggregate number of shares of Common Stock sold in the Offering. The Placement Agent Warrants have substantially the same terms as the Warrants, except that the Placement Agent Warrants have an exercise price equal to $ 9.2063, or 125% of the offering price per share of Common Stock sold in the Offering, and a term of five years from the commencement of the sales pursuant to the Offering.

The gross proceeds to the Company from the August 2023 Offering and the August 2023 Private Placement are $1,590,840. The Company incurred offering costs of $413,544.

FDA Regulatory Strategy

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

In the first quarter of 2024, the Company initiated the study at multiple sites, which study is intended to use the Symphony IL-6 test to monitor IL-6 concentrations in patients who are diagnosed with sepsis or septic shock and are admitted or intended to be admitted to the ICU. The objective of this study is to establish IL-6 concentrations in these sepsis patients that best predict 28-day all-cause mortality. The Company expects that it will need to bring several additional sites into the study in the future, which it believes will help support initial commercialization and market penetration. The Company believes that this clinical trial expansion could also support additional indications, but that any such expansion also could delay obtaining marketing authorization for the product. As a result of its lack of cash resources, the Company has recently slowed the timeline of this study to preserve cash resources in the near-term, and the Company expects that this will delay its Symphony platform regulatory submission timeline until 2025.

Product Manufacturing

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

Risks and Uncertainties

As noted above, Bluejay is reliant upon Toray and Sanyoseiko to provide cartridges in sufficient quantity and quality to complete our clinical trials, and our clinical trials could be delayed if the Company encountered any material supply interruptions while the clinical trials are being conducted. In addition, there can be no assurance that we will be able to obtain necessary regulatory authorization for the manufacturing or marketing of the Symphony in the United States or elsewhere. There also can be no assurance that we will successfully complete any clinical evaluations necessary to receive regulatory approvals, or that the clinical trial will demonstrate sufficient safety and efficacy of the Symphony. The failure to adequately demonstrate the clinical performance of the Symphony device could delay or prevent regulatory approval of the device, which could prevent or result in delays to market launch and could materially harm our business.

In addition to the FDA regulatory strategy risks and uncertainties, the Company is subject to a number of risks similar to other companies in its industry, including rapid technological change, competition from larger biotechnology companies and dependence on key personnel. The Company is also impacted by inflationary pressures and global supply chain disruptions currently impacting many companies.

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

On July 24, 2023, the Company effected a reverse stock split of its shares of common stock at a ratio of 1-for-20 (the "Reverse Stock Split"), with a corresponding reduction in the number of authorized outstanding number of shares of common stock from 100,000,000 to 7,500,000.

All of the Company's historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect this 1-for-20 reverse stock split.

On August 8, 2023, the Company received a letter from the Listing Qualifications Department of Nasdaq notifying the Company that, based on the closing bid price of the Company's common stock having been at least $1.00 per share for the required period, the Company has regained compliance with Nasdaq Listing Rule 5550(a)(2) and the minimum bid price deficiency matter previously disclosed by the Company on October 25, 2022 was closed. However, as further described below under note 12, on February 28, 2024, the Company received a new deficiency letter from the Listing Qualifications Department as a result of the closing bid price for its common stock having again been below $1.00 for the previous 30 consecutive business days.

Going Concern

The Company had cash and cash equivalents of $2,208,516, as of December 31, 2023. The Company has incurred net losses since its inception, and has negative cash flows from operations and had the accumulated deficit of $26,950,990 as of December 31, 2023. The Company continues to develop the Symphony device and its first test for the measurement of IL-6. The Company remains committed to obtaining FDA clearance and will conduct clinical trials to obtain sufficient data to support its FDA submission, while also continuing to build its manufacturing operations with its contract manufacturing organizations. Current cash resources and expected operating expenses are considered in determining its liquidity requirement; as well as $1,771,375 of current liabilities on its balance sheet as of December 31, 2023. The Company estimates cash resources will be sufficient to fund its operations through the second quarter of 2024. The Company will need additional capital to fund its planned operations for the next 12 months. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements for the years ended December 31, 2023 and 2022 were prepared under the assumption that the Company will continue as a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles in the United States ("GAAP") and include all adjustments necessary for the presentation of the Company's consolidated financial position, results of operations and cash flows for the periods presented. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with 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 believes judgment is involved in accounting for the fair value-based measurement of stock-based compensation, accruals, and warrant issuances. The Company evaluates its estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the condensed consolidated financial statements.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents, consisting of highly liquid money market funds are carried at fair market value which approximates cost. The Company recognized interest income associated with cash equivalents of $164,900 and $89,673 for the years ended December 31, 2023 and 2022, respectively.

Revenue Recognition

The Company recognizes revenue under the core principles of depicting the transfer of control to the Company's customers in an amount reflecting the consideration to which the Company expected to be entitled. In order to achieve that core principle, the Company applies the following five step approach: (1) identify the contract with a customer, (2) identify the performance obligations in that contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied.

The Company recognizes revenue when performance obligations under the terms of the contract with the customer are satisfied and are recognized at a point in time, which is also when control is transferred. When the Company performs shipping and handling activities after the transfer of control to the customer (e.g. when control transfers prior to delivery), they are considered fulfillment activities and, accordingly, the costs are accrued for when the related revenue is recognized. Sales tax and valued added taxes collected from the customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Leases

The Company accounts for its leases under the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") ASC 842, *Leases* ("ASC 842").

The Company has arrangements involving the lease of facilities and the lease of copiers. Under ASC 842, at inception of the arrangement, the Company determines whether the contract is or contains a lease and whether the lease should be classified as an operating or a financing lease. This determination, among other considerations, involves an assessment of whether the Company can control the underlying asset and have the right to obtain substantially all of the economic benefits or outputs from the asset. The Company accounts for the leases of less than 12 months as short-term leases.

The Company recognizes right-of-use ("ROU") assets and lease liabilities as of the lease commencement date based on the net present value of the future minimum lease payments over the lease term. The Company amortizes the right-of-use assets over the remaining terms of the lease. ASC 842 requires the leases to use the rate implicit in the lease unless it is not readily determinable and then it may use its incremental borrowing rate ("IBR") to discount the future minimum lease payments. Most of the Company's leases do not provide an implicit rate; therefore, the Company uses its IBR to discount the future minimum lease payments. The Company determines its IBR with its credit rating and other economic information available as of the commencement date, as well as the identified lease term. During the assessment of the lease term, the Company considers its renewal options and extensions within the arrangements and the Company includes these options when it's reasonably certain to extend the term of the lease.

The Company has lease arrangements that contain incentives for tenant improvements as well as fixed rent escalation clauses. For contracts with tenant improvement incentives that are determined to be leasehold improvements and the Company is reasonably certain to exercise, it records a reduction to the lease liability and amortizes the incentive over the identified term of the lease as a reduction to rent expense. The Company records rental expense on a straight-line basis over the identified lease term on contracts with rent escalation clauses.

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and requires disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company determines fair value for cash equivalents with Level 1 inputs through the reference to the quoted market prices.

There were no liabilities measured at fair value on a recurring basis, and no assets or liabilities measured at fair value on a non-recurring basis as of December 31, 2023 and 2022.

The carrying values of financial instruments such as prepaid expenses, accounts payable, and accrued expenses approximated fair value as of December 31, 2023 and 2022 due to their short-term maturities.

Impairment of Property and Equipment

The Company evaluates its long-lived assets with definite lives, such as fixed assets and right-of-use assets for impairment. The carrying value of fixed assets and right-of use assets is reviewed on a regular basis for the existence of facts or circumstances, both internally and externally, that may suggest impairment. Some factors which the Company considers to be triggering events for impairment review include a significant decrease in the market value of an asset, a significant change in the extent or manner in which an asset is used, a significant adverse change in the business climate that could affect the value of an asset, an accumulation of costs for an asset in excess of the amount originally expected, a current period operating loss or cash flow decline combined with a history of operating loss or cash flow uses or a projection that demonstrates continuing losses and a current expectation that, it is more likely than not, a long-lived asset will be disposed of at a loss before the end of its estimated useful life. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If the assets are not recoverable, the impairment charge is measured as the amount by which the carrying value of the asset group exceeds the fair value.

Concentration of Credit Risk

Cash, and cash equivalents consist of financial instruments that potentially subject the Company to a concentration of credit risk in the event of a default by the related financial institution holding the securities, to the extent of the value recorded in the balance sheet. The Company invests cash that is not required for immediate operating needs primarily in highly liquid instruments with lower credit risk.

Research and Development Expenses

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

The Company estimates preclinical study and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Stock-Based Compensation

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

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

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The Company does not have a history of market prices of its common stock, and as such, volatility is estimated using historical volatilities of similar public entities. The expected life of the awards is estimated based on the simplified method for grants to employees and is based on the contractual term for non-employee awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the awards. The dividend yield assumption is based on history and expectation of paying no dividends.

The Company recognizes forfeitures related to employee share-based payments when they occur.

Segment Reporting

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

Income Taxes

The Company follows accounting guidance regarding the recognition, measurement, presentation and disclosure of uncertain tax positions in the consolidated financial statements. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the consolidated financial statements. There are no uncertain tax positions that require accrual or disclosure as of December 31, 2023. Any interest or penalties are charged to expense. During the years ended December 31, 2023 and 2022, the Company had no significant interest and penalties. Tax years subsequent to December 31, 2019 are subject to examination by federal and state authorities.

The Company recognizes deferred tax assets and liabilities based on the impact of temporary differences between assets and liabilities recognized for tax and financial reporting purposes measured by applying enacted tax rates and laws that will be in effect when the differences are expected to reverse, net operating loss carryforwards and tax credits. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized. The deferred tax benefit or expense for the period represents the change in the deferred tax asset or liability from the beginning to the end of the period.

Deferred Offering Costs

Deferred offering costs consist of underwriting, legal, accounting and other expenses incurred through December 31, 2023 that are directly related to the January 2024 Offering and that will be charged to stockholders' equity upon the completion of the January 2024 Offering.

Net Loss per Share

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

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

	December 31,	
	2023	**2022**
Options to purchase common stock	29,770	35,992
Restricted stock units	7,875	-
Warrants for common stock	271,714	40,594
Class A Warrants for common stock	124,200	124,200
Class B Warrants for common stock	3,770	3,770

Recently Adopted Accounting Standards

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

Recently Issued Accounting Standards

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

3. LICENSE AND SUPPLY AGREEMENT WITH TORAY INDUSTRIES

On October 6, 2020, the Company entered into a License and Supply Agreement ("License Agreement") with Toray Industries, Inc. ("Toray"). Under the License Agreement, the Company received the exclusive license (outside of Japan) to make and distribute protein detection cartridges that have a function of automatic stepwise feeding of reagent (the "Cartridges"). In exchange for the license, the Company committed to make two payments of $120,000 each, both of which were made in 2021. In addition, following the first sale of the Cartridges after regulatory approval, the Company will make royalty payments to Toray equal to 15% of the net sales of the Cartridges for the period that any underlying patents exist or five years after the first sale. Following the first sale after obtaining regulatory approval, the Company will make minimum annual royalty payments of $60,000 for the first year and $100,000 for each year thereafter, which shall be creditable against any royalties owed to Toray in such calendar year.

On October 23, 2023, the Company and Toray entered into an Amended and Restated License Agreement (the "New Toray License Agreement") and a Master Supply Agreement (the "New Toray Supply Agreement"). Under the New Toray License Agreement, the Company continues to license from Toray intellectual property rights needed to manufacture single-use test cartridges, and the Company has received the right to sublicense certain Toray intellectual property to Sanyoseiko in connection with Sanyoseiko's ongoing agreement with the Company to manufacture its Symphony device and cartridges (including in connection with the Company's clinical trials). In addition, the New Toray License Agreement provides for the transfer of certain technology related to the cartridges to Sanyoseiko. The royalty payments payable by the Company to Toray have been reduced under the New Toray License Agreement from 15% to 7.5% (or less in certain circumstances) of net sales of certain cartridges for a term of 10 years. A 50% reduction in the royalty rate applies upon expiry of applicable Toray patents on a product-by-product and country-by-country basis. The New Toray License Agreement contemplates that applicable royalty payment obligations from the Company to Toray for other products will be determined separately by the parties in the future. There were no sales of or revenues from the cartridges during the 12-month periods ended December 31, 2023 and 2022.

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

At December 31, 2023 and 2022, there were no amounts accrued related to the New Toray License Agreement or the License Agreement.

4. WARRANTS

The following table summarizes information with regard to warrants outstanding at December 31, 2023:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
Common Stock Warrants	271,714	Common Stock	$ 15.94	4.3
Class A Warrants	124,200	Common Stock	$ 140.00	2.8
Class B Warrants	3,770	Common Stock	$ 200.00	2.8

As part of the August 2023 Offering that occurred during the year ended December 31, 2023, the Company issued 216,000 Warrants and 15,120 Placement Agent Warrants, which were accounted for as equity classified financial instruments under ASC 815, *Derivatives and Hedging*. There were no exercises of Common Stock Warrants during the years ended December 31, 2023 and 2022.

Holders of Class B Warrants may also exercise such warrants on a "cashless" basis after the earlier of (i) 10 trading days from closing date of the offering or (ii) the time when $10.0 million of volume is traded in the Company's common stock, if the volume weighted average price of the Company's common stock on any trading day on or after the closing date of the offering fails to exceed the exercise price of the Class B Warrant (subject to adjustment as described in the warrant agreement). During the year ended December 31, 2023, no Class A or Class B Warrants were exercised. During the year ended December 31, 2022, 2,005 Class B Warrants were exercised, all on a cashless basis, while there were no exercises of Class A Warrants.

5. STOCK COMPENSATION

Stock Incentive Plans

In 2018, the Company adopted the 2018 Stock Incentive Plan (the "2018 Plan") for employees, consultants, and directors. The 2018 Plan, which is administered by the Company's Board of Directors, permits the Company to grant incentive and nonqualified stock options for the purchase of common stock, and restricted stock awards. The maximum number of shares of common stock reserved for issuance under the 2018 Plan is 31,472. At December 31, 2023 there were 13,113 shares of common stock available for grant under the 2018 Plan.

On July 6, 2021, the Company's Board of Directors and stockholders approved and adopted the Bluejay Diagnostics, Inc. 2021 Stock Plan (the "2021 Plan"). A total of 98,000 shares of common stock were approved to be initially reserved for issuance under the 2021 Stock Plan. At December 31, 2023 there were 40,377 shares of common stock available for grant under the 2021 Plan.

Stock Award Activity

The following table summarizes the status of the Company's non-vested restricted stock awards for years ended December 31, 2023:

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

The following is a summary of stock option activity for the year ended December 31, 2023:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2022	35,992	$ 39.25	6.5	$ 20,578
Granted	1,000	10.60		
Exercised	-	-		
Cancelled / forfeited	(7,222)	46.57		
Outstanding at December 31, 2023	29,770	$ 36.51	6.7	$ -
Exercisable at December 31, 2023	25,548	$ 35.59	6.5	$ -

The weighted average grant date fair value of options granted during the years ended December 31, 2023 and 2022 was $10.60 per share and $28.40 per share, respectively. The Company determined the grant-date fair value of stock option awards granted during the years ended December 31, 2023 and 2022 using the Black-Scholes model with the following assumptions:

	2023	2022
Risk-free interest rate	3.63%	1.58% – 4.35%
Expected dividend yield	0.00%	0.00%
Volatility factor	108.78%	102.03% – 107.36%
Expected life of option (in years)	6.00	5.40 – 6.00

Stock-Based Compensation Expense

For the years ended December 31, 2023 and 2022, the Company recorded stock-based compensation expense as follows:

	Year ended December 31,	
	2023	2022
Research and development	$ 62,955	$ 64,352
General and administrative	133,840	367,702
Marketing and business development	(7,550)	950
Total stock-based compensation	$ 189,245	$ 433,004

At December 31, 2023, there was approximately $38,002 of unrecognized compensation expense related to non-vested stock option awards that are expected to be recognized over a weighted-average period of 1.16 years. At December 31, 2023, there was approximately $14,060 of unrecognized compensation expense related to non-vested restricted stock awards that are expected to be recognized over a weighted-average period of 0.75 years.

6. RELATED PARTY TRANSACTIONS

NanoHybrids, LLC

In December 2021, the Company entered into an agreement with NanoHybrids, LLC ("NanoHybrids") to utilize the Company's research and development staff and laboratory facility when available to perform work for NanoHybrids. Any hours worked by Company employees for NanoHybrids is billed to NanoHybrids at a bill rate of the respective employee's fully burdened personnel cost plus 10%. Additionally, the Company may purchase certain lab supplies for NanoHybrids and rebill these costs to NanoHybrids. The Company's Chief Technology Officer is the majority shareholder of NanoHybrids. The table below summarizes the amounts earned for the years ended December 31, 2023 and 2022 and balances due from NanoHybrids as of December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	**2022**
Income from NanoHybrids included in Other Income	$ 178,042	$ 163,256
Cash receipts from NanoHybrids	$ 156,504	$ 143,525

	As of December 31,	
	2023	**2022**
Amounts receivable from NanoHybrids included in Prepaids and Other Current Assets	$ 41,269	$ 19,731

Toray Industries, Inc.

In June 2022, the Company sold five Symphony analyzers to the Company's business partner, Toray, for $249,040, all of which was paid in June 2022. Future sales to Toray are not currently anticipated.

7. PROPERTY AND EQUIPMENT

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

		December 31,	
	Depreciable lives	**2023**	**2022**
Construction in process		$ 1,052,822	$ 375,466
Furniture, fixtures, and equipment	3-5 years	141,164	136,942
Software	3 years	4,457	4,457
Lab equipment	3-5 years	1,287,783	1,268,380
Leasehold improvements	Life of lease	43,231	43,231
		2,529,457	1,828,476
Less: accumulated depreciation		(1,243,716)	(596,406)
Property and equipment, net		$ 1,285,741	$ 1,232,070

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

8. LEASES

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

	December 31,	
	2023	2022
Weighted average remaining lease term - operating leases (in years)	2.9	3.7
Weighted average remaining lease term - finance leases (in years)	4.1	5.1
Weighted average discount rate	7.0%	7.0%
Operating cash flows from operating leases	$ 174,640	$ 149,700
Operating cash flows from finance leases	$ 4,807	$ -

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

	December 31,	
	2023	2022
Operating lease right-of-use asset	$ 333,267	$ 465,514
Finance leases in Property and Equipment	15,152	21,067
Total lease assets	348,419	486,581
Current portion of operating lease liability	162,990	168,706
Current portion of finance lease liability included in accrued expenses	4,807	4,807
Noncurrent operating lease liabilities	189,987	323,915
Noncurrent finance lease liabilities	12,321	15,823
Total lease liabilities	$ 370,105	$ 513,251

The following table reconciles the undiscounted lease liabilities to the total lease liabilities recognized on the consolidated balance sheet as of December 31, 2023:

Year	Operating Lease	Finance Lease
2024	$ 162,990	$ 4,807
2025	100,000	4,807
2026	100,000	4,807
2027	25,000	5,207
Thereafter	-	-
Total future lease payments	387,990	19,628
Less: Imputed interest	35,013	2,500
Present value of lease liability	$ 352,977	$ 17,128

9. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

In October 2022, the Company entered into a non-cancelable purchase commitment with an international materials vendor for items needed for both development of the Symphony product line and also to resell to its customers. This agreement commits the Company to purchase approximately $800,000 in goods, of which 50% was prepaid in 2022, with the remainder being paid in 2023. All goods have been received under this arrangement as of December 31, 2023.

The Company had multiple open purchase commitments with its primary contract manufacturing organization in Japan related to the buildout of a manufacturing line for the IL-6 cartridges for the Symphony device as of December 31, 2022 for approximately $375,000. During the year ended December 31, 2023, the Company purchased all items related to these purchase commitments.

Separation Agreement

Under the terms of a separation agreement with Mr. Kenneth Fisher, the Company's former Chief Financial Officer, the Company has agreed to compensate Mr. Fisher $240,000 (representing six months of base salary and the pro rata amount of Mr. Fisher's 2023 target bonus). The payments of such amounts are subject to the compliance by Mr. Fisher of certain ongoing covenants with respect to confidentiality, cooperation and other matters. Mr. Fisher departed from the Company on September 26, 2023, and the Company has recorded a severance liability of $240,000, which was included in accrued severance in the amount of $150,000 and in accrued bonuses of $90,000.

The Company has paid Mr. Fisher $80,000 as of December 31, 2023, resulting in an remaining accrual of $160,000 which has been included accrued expenses and other current liabilities on the Company's Consolidated Balance Sheets as of December 31, 2023.

Minimum Royalties

As required under the License Agreement (see Note 3), following the first sale of Cartridges, the Company will also make royalty payments to Toray equal to 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 December 31, 2023.

Indemnification

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

10. SUPPLEMENTAL BALANCE SHEET INFORMATION

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2023	**2022**
Prepaid insurance	$ 136,342	$ 751,979
Vendor prepayments	558,959	681,218
Prepaid other	51,962	240,283
Total prepaid expenses and other current assets	$ 747,263	$ 1,673,480

Accrued expenses and other current liabilities consist of the following:

	December 31,	
	2023	**2022**
Accrued personnel costs	$ 566,087	$ 533,577
Goods received but unpaid	78,579	10,077
Accrued expenses for CFO separation agreement	160,000	-
Accrued legal fees	157,670	61,737
Accrued other	154,575	230,339
Total accrued expenses and other current liabilities	$ 1,116,911	$ 835,730

11. INCOME TAX

No provision for federal income taxes has been recorded for the years ended December 31, 2023 and 2022 due to net losses and the valuation allowance established.

Significant components of the Company's deferred tax assets are as follows:

	As of December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses	$ 4,553,431	$ 3,043,585
Tax credits	546,325	190,489
Intangible assets	58,063	66,716
Capitalized R&D expenses	2,106,995	1,018,165
Fixed assets	114,657	37,580
Other	314,958	272,106
Total deferred tax assets	7,694,429	4,628,641
Valuation allowance	(7,694,429)	(4,628,641)
Deferred tax asset, net of allowance	$ -	$ -

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 2023 and 2022 is as follows:

	Year Ended December 31,	
	2023	2022
Federal statutory rate	21.00%	21.00%
State income taxes, net of federal benefit and tax credits	7.43%	6.86%
Change in valuation allowance	(30.80)%	(29.06)%
Permanent differences	2.37%	1.20%
Effective tax rate	0.00%	0.00%

The Company regularly assesses the need for a valuation allowance against its deferred tax assets. In making that assessment, the Company considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets to determine, based on the weight of available evidence, whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. In assessing the realizability of deferred tax assets, the Company considers taxable income in prior carryback years, as permitted under the tax law, forecasted taxable earnings, tax planning strategies, and the expected timing of the reversal of temporary differences. This determination requires significant judgment, including assumptions about future taxable income that are based on historical and projected information and is performed on a jurisdiction-by-jurisdiction basis.

The Company continues to maintain a full valuation allowance against its deferred tax assets. During the years ended December 31, 2023 and 2022, management assessed the positive and negative evidence in its operations, and concluded that it is more likely than not that its deferred tax assets as of December 31, 2023 and 2022 will not be realized given the Company's history of operating losses. The valuation allowance against deferred tax assets increased by approximately $3.1 million and $2.7 million during 2023 and 2022, respectively, related to a full valuation allowance recorded against capitalized research expenditures, additional net operating losses and tax credits generated in the year.

As of December 31, 2023, the Company had federal net operating losses of approximately $16.8 million. The Company's federal net operating losses incurred prior to 2018 totaling $713,000 expire through 2037, while its federal net operating losses incurred in 2018 to 2023 totaling approximately $16.1 million can be carried forward indefinitely but are limited to 80% utilization against future taxable income each year.

As of December 31, 2023, the Company had post-apportioned state net operating losses of approximately $16.3 million that can generally be carried forward 20 years and will expire at various dates through 2043. As of December 31, 2022, the Company had post-apportioned Massachusetts net operating losses of approximately $10.8 million that can generally be carried forward 20 years and will expire at various dates through 2042.

12. SUBSEQUENT EVENTS

January 2024 Offering

On January 2, 2024, the Company sold in a public offering (such transaction, the "January 2024 Offering") (i) 537,768 shares of the Company's Common stock, par value $0.0001 per share and (ii) prefunded warrants to purchase up to an aggregate 2,154,540 shares of Common Stock (the "Prefunded Warrants"). The Shares and Prefunded Warrants were sold together with warrants to purchase up to an aggregate of 2,692,308 shares of Common Stock at an exercise price of $1.30 per share (the "January 2024 Warrants"). The combined public offering price was $1.30 per share of Common Stock and related January 2024 Warrant and $1.2999 per Prefunded Warrant and related January 2024 Warrant. The Company intends to use the net proceeds from the January Offering to fund matters related to obtaining FDA approval (including clinical studies related thereto), as well as for other research and development activities, and for general working capital needs.

The Prefunded Warrants are immediately exercisable and may be exercised at any time until all of the Prefunded Warrants are exercised in full The January 2024 Warrants are exercisable immediately upon issuance for a period of five years following the date of issuance.

Pursuant to an engagement letter, dated as of August 7, 2023, as amended October 11, 2023 (the "Amended Engagement Letter"), by and between the Company and the Placement Agent, the Company paid the Placement Agent a total cash fee of $245,000 equal to 7.0% of the gross proceeds received in the January 2024 Offering. The Company also paid the Placement Agent in connection with the January Offering a management fee of $35,000 equal to 1.0% of the gross proceeds raised in the January 2024 Offering and certain expenses incurred in connection with the January Offering. In addition, the Company issued to the Placement Agent, warrants to purchase up to an aggregate 188,462 shares of Common Stock (the "January 2024 Placement Agent Warrants"), which represents 7.0% of the aggregate number of shares of Common Stock and Prefunded Warrants sold in the January 2024 Offering. The January 2024 Placement Agent Warrants have substantially the same terms as the January 2024 Warrants, except that the January 2024 Placement Agent Warrants have an exercise price equal to $1.6250, or 125% of the offering price per share of Common Stock and related January 2024 Warrant sold in the January Offering and expire on the fifth anniversary from the date of the commencement of sales in the January 2024 Offering.

Concurrently with the closing of the January 2024 Offering, certain purchasers have elected to exercise Prefunded Warrants to purchase 174,770 shares of Common Stock.

Nasdaq Notification

On February 28, 2024, the Company received a notification letter from the Nasdaq Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that the closing bid price for its common stock had been below $1.00 for the previous 30 consecutive business days and that the Company therefore is not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). The notification has no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market. The Company intends to take all reasonable measures available to achieve compliance and allow for continued listing on the Nasdaq Capital Market. However, there can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria.

Exhibit 4.10

DESCRIPTION OF CAPITAL STOCK

The summary of general terms and provisions of our capital stock set forth below does not purport to be complete and is subject to and qualified by reference to the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and Amended and Restated Bylaws (the "Bylaws," and together with the Certificate of Incorporation, the "Charter Documents"), each of which is included as an exhibit to the Company's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission and incorporated by reference herein. For additional information, please read the Charter Documents and the applicable provisions of the Delaware General Corporation Law (the "DGCL").

Authorized Capital Stock

We are authorized to issue up to 12,500,000 shares, of which (i) 7,500,000 have been designated common stock, par value $0.0001 per share, and (ii) 5,000,000 have been designated preferred stock, par value $0.0001 per share. As of March 28, 2024, there were (x) 2,688,448 shares of our common stock outstanding, held by approximately 15 stockholders of record, and (y) zero shares of our preferred stock outstanding. This figure does not reflect the number of beneficial owners of shares of our common stock as a single stockholder of record often holds shares in nominee name (also referred to as, in "street name") on behalf of multiple beneficial owners.

Common Stock

Voting

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Any action at a meeting at which a quorum is present will be decided by a majority of the voting power present in person or represented by proxy, except in the case of any election of directors, which will be decided by a plurality of votes cast. There is no cumulative voting.

Dividends

Holders of our common stock are entitled to receive dividends when, as and if declared by our Board of Directors out of funds legally available for payment, subject to the rights of holders, if any, of any class of stock having preference over the common stock. Any decision to pay dividends on our common stock will be at the discretion of our Board of Directors. Our Board of Directors may or may not determine to declare dividends in the future. See "Dividend Policy." The board's determination to issue dividends will depend upon our profitability and financial condition, any contractual restrictions, restrictions imposed by applicable law and the SEC, and other factors that our Board of Directors deems relevant.

Liquidation Rights

In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of our common stock will be entitled to share ratably on the basis of the number of shares held in any of the assets available for distribution after we have paid in full, or provided for payment of, all of our debts and after the holders of all outstanding series of any class of stock have preference over the common stock, if any, have received their liquidation preferences in full.

Other

Our issued and outstanding shares of common stock are fully paid and nonassessable. Holders of shares of our common stock are not entitled to preemptive rights. Shares of our common stock are not convertible into shares of any other class of capital stock, nor are they subject to any redemption or sinking fund provisions.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock. Our amended and restated certificate of incorporation authorizes the board to issue these shares in one or more series, to determine the designations and the powers, preferences and relative, participating, optional or other special rights and the qualifications, limitations and restrictions thereof, including the dividend rights, conversion or exchange rights, voting rights (including the number of votes per share), redemption rights and terms, liquidation preferences, sinking fund provisions and the number of shares constituting the series. Our Board of Directors could, without stockholder approval, issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of common stock and which could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, a majority of our outstanding voting stock. We have no shares of preferred stock outstanding.

Outstanding Warrants to Acquire Common Stock

As of March 28, 2024, we had outstanding:

- 1,243,000 shares of common stock issuable upon the exercise of prefunded warrants issued in January 2024 at an exercise price of $0.0001 per share
- 2,692,308 shares of common stock issuable upon the exercise of warrants issued in January 2024 at an exercise price of $1.30 per share;
- 188,462 shares of common stock issuable upon the exercise of warrants issued in January 2024 at an exercise price of $1.625 per share;
- 216,000 shares of common stock issuable upon the exercise of warrants issued in August 2023 at an exercise price of $7.24 per share;
- 15,120 shares of common stock issuable upon the exercise of warrants issued in August 2023 at an exercise price of $9.2063 per share;
- 40,594 shares of common stock issuable upon the exercise of additional Common Stock warrants at a weighted average exercise price of $64.73 per share;
- 124,200 shares of common stock issuable upon the exercise of Class A warrants at an exercise price of $140.00; and
- 3,770 shares of common stock issuable upon the exercise of Class B warrants at an exercise price of $200.00.

Outstanding Stock Options to Purchase our Common Stock

As of December 31, 2023, options to purchase an aggregate of 29,770 shares of our common stock.

Unvested Restricted Stock Units

As of December 31, 2023, 7,875 unvested restricted stock units were outstanding.

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Our Bylaws and Delaware Law

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make hostile takeovers, including the following transactions, more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. As a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the Board of Directors. A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Undesignated Preferred Stock

The ability of our Board of Directors, without action by the stockholders, to issue undesignated shares of preferred stock with voting or other rights or preferences as designated by our Board of Directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Authorized Common Stock

Our authorized but unissued shares of common stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our amended and restated bylaws will provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at any meeting of stockholders. Our amended and restated bylaws also will specify certain requirements regarding the form and content of a stockholder's notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our meetings of stockholders.

No Cumulative Voting; No Action Without a Meeting; Special Meeting of Stockholders

Stockholders will not be permitted to cumulate their votes for the election of directors. In addition, stockholders will not be able to take action by written consent and will only be able to take action at annual or special meetings of our stockholders. Furthermore, special meetings of our stockholders may be called only by our Chief Executive Officer, our President or our Board of Directors.

Exclusive Forum Selection

Our amended and restated certificate of incorporation will require, to the fullest extent permitted by law, subject to limited exceptions, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel in any action brought to enforce the exclusive forum provision. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our amended and restated certificate of incorporation.

Notwithstanding the foregoing, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will provide that the Court of Chancery and the federal district court for the District of Delaware will have concurrent jurisdiction over any action arising under the Securities Act or the rules and regulations thereunder, and the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction. To the extent the exclusive forum provision restricts the courts in which our stockholders may bring claims arising under the Securities Act and the rules and regulations thereunder, there is uncertainty as to whether a court would enforce such provision. Investors cannot waive compliance with the federal securities laws and the rules and regulations promulgated thereunder.

Although we believe this provision benefits our company by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, a court may determine that this provision is unenforceable, and to the extent it is enforceable, the provision may have the effect of discouraging lawsuits against our directors and officers and increasing the cost to stockholders of bringing such lawsuits.

Listing

The common stock is listed on Nasdaq under the symbol "BJDX."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company, 1 State Street, 30th Floor, New York, New York 10004.

Exhibit 31.1

CERTIFICATION
PURSUANT TO RULE 13a-14 AND 15d-14
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Neil Dey, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 officers 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 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 officers 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 controls over financial reporting.

Date: March 28, 2024

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

Exhibit 31.2

CERTIFICATION
PURSUANT TO RULE 13a-14 AND 15d-14
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Frances Scally, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 officers 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 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 officers 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 controls over financial reporting.

Date: March 28, 2024

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. 1350
(SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)

In connection with the Annual Report of Bluejay Diagnostics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neil Dey, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2024

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. 1350
(SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002)

In connection with the Annual Report of Bluejay Diagnostics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Frances Scally, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2024

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

Exhibit 97.1

BLUEJAY DIAGNOSTICS, INC.

INCENTIVE COMPENSATION RECOVERY POLICY

Introduction

Bluejay Diagnostics, Inc. (the "*Company*") has adopted this Incentive Compensation Recovery Policy (this "*Policy*") to foster a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy with respect to executive compensation. This Policy is intended to comply with Section 10D of the Securities Exchange Act of 1934, as amended, the rules promulgated thereunder by the U.S. Securities and Exchange Commission and the listing rules of the Nasdaq Stock Market LLC ("*Nasdaq*"). This Policy shall apply to any Incentive Compensation (as defined below) received on or after October 2, 2023.

Statement of Policy

In the event that the Company is required to prepare an Accounting Restatement, except as otherwise set forth in this Policy, the Company shall recover, reasonably promptly, the Excess Incentive Compensation received by any Covered Executive during the Recoupment Period.

This Policy applies to all Incentive Compensation received during the Recoupment Period by a person (a) after beginning service as a Covered Executive, (b) who served as a Covered Executive at any time during the performance period for that Incentive Compensation and (c) while the Company has a class of securities listed on Nasdaq or another national securities exchange or association. This Policy may therefore apply to a Covered Executive even after that person that is no longer a Company employee or a Covered Executive at the time of recovery.

Incentive Compensation is deemed "received" for purposes of this Policy in the fiscal period during which the financial reporting measure specified in the Incentive Compensation award is attained, even if the payment or issuance of such Incentive Compensation occurs after the end of that period. For example, if the performance target for an award is based on total stockholder return for the year ended December 31, 2023, the award will be deemed to have been received in 2023 even if paid in 2024.

Exceptions

The Company is not required to recover Excess Incentive Compensation pursuant to this Policy to the extent the Committee makes a determination that recovery would be impracticable for one of the following reasons (and the applicable procedural requirements are met):

(a) after making a reasonable and documented attempt to recover the Excess Incentive Compensation, which documentation will be provided to Nasdaq to the extent required, the Committee determines that the direct expenses that would be paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered;

(b) based on a legal opinion of counsel acceptable to the Nasdaq, the Committee determines that recovery would violate a United States law adopted prior to November 28, 2022; or

(c) the Committee determines that recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

Definitions

"*Accounting Restatement*" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. For the avoidance of doubt, a restatement resulting solely from the retrospective application of a change in generally accepted accounting principles is not an Accounting Restatement.

"*Board*" shall mean the Board of Directors of the Company.

"*Committee*" shall mean the Compensation Committee of the Board.

"*Covered Executive*" shall mean the Company's Chief Executive Officer, President, Chief Financial Officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function, any other officer who performs a policy-making function for the Company, any other person who performs similar policy-making functions for the Company, and any other employee who may from time to time be deemed subject to this Policy by the Committee.

"*Excess Incentive Compensation*" means the amount of Incentive Compensation received during the Recoupment Period by any Covered Executive that exceeds the amount of Incentive Compensation that otherwise would have been received by such Covered Executive if the determination of the Incentive Compensation to be received had been determined based on restated amounts in the Accounting Restatement and without regard to any taxes paid.

"*Incentive Compensation*" means any compensation (including cash and equity compensation) that is granted, earned, or vested based wholly or in part upon the attainment of a financial reporting measure. For purposes of this definition, a "*financial reporting measure*" is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such measures, or (ii) the Company's stock price and/or total shareholder return. A financial reporting measure need not be presented within the financial statements or included in a filing with the commission. Incentive Compensation subject to this Policy may be provided by the Company or subsidiaries or affiliates of the Company ("Company Affiliates"). For the avoidance of doubt, the following do not constitute Incentive Compensation: (v) salaries, (w) bonuses paid solely at the discretion of the Committee or Board that are not paid from a "bonus pool" that is determined by satisfying a financial reporting measure performance goal, (x) bonuses paid solely upon satisfying one or more subjective standards (e.g., demonstrated leadership) and/or completion of a specified employment period, (y) non-equity incentive plan awards earned solely upon satisfying one or more strategic measures (e.g., consummating a merger or divestiture), or operational measures (e.g., completion of a project, increase in market share), and (z) equity awards for which the grant is not contingent upon achieving any financial reporting measure performance goal and vesting is contingent solely upon completion of a specified employment period and/or attaining one or more nonfinancial reporting measures.

"*Recoupment Period*" means the three completed fiscal years preceding the Trigger Date, and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years, provided that any transition period of nine months or more shall count as a full fiscal year.

"*Trigger Date*" means the earlier to occur of: (a) the date the Board of Directors, the Audit Committee (or such other Committee of the Board as may be authorized to make such a conclusion), or the officer or officers of the Company authorized to take such action if action by the Board of Directors is not required concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; or (b) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement; in the case of both (a) and (b) regardless of if or when restated financial statements are filed.

Administration

This Policy is intended to comply with Nasdaq Listing Rule 5608, Section 10D of the Securities Exchange Act of 1934, as amended (the "Act"), and Rule 10D-1(b)(1) as promulgated under the Act, and shall be interpreted in a manner consistent with those requirements. The Committee has full authority to interpret and administer this Policy. The Committee's determinations under this Policy shall be final and binding on all persons, need not be uniform with respect to each individual covered by the Policy, and shall be given the maximum deference permitted by law.

The Committee has the authority to determine the appropriate means of recovering Excess Incentive Compensation based on the particular facts and circumstances, which could include, but is not limited to, seeking direct reimbursement, forfeiture of awards, offsets against other payments, and forfeiture of deferred compensation (subject to compliance with Section 409A of the Internal Revenue Code).

Subject to any limitations under applicable law, the Committee may authorize any officer or employee of the Company to take actions necessary or appropriate to carry out the purpose and intent of this Policy, provided that no such authorization shall relate to any recovery under this Policy that involves such officer or employee.

If the Committee cannot determine the amount of excess Incentive Compensation received by a Covered Executive directly from the information in the Accounting Restatement, such as in the case of Incentive Compensation tied to stock price or total stockholder return, then it shall make its determination based on its reasonable estimate of the effect of the Accounting Restatement and shall maintain documentation of such determination, including for purposes of providing such documentation to Nasdaq.

Except where an action is required by Nasdaq Listing Rule 5608, Section 10D of the Act or Rule 10D-1(b)(1) promulgated under the Act to be determined in a different matter, the Board may act to have the independent directors of the Board administer this policy in place of the Committee.

No Indemnification or Advancement of Legal Fees

Notwithstanding the terms of any indemnification agreement, insurance policy, contractual arrangement, the governing documents of the Company or other document or arrangement, the Company shall not indemnify any Covered Executive against, provide advancement of expenses for or pay the premiums for any insurance policy to cover, any amounts recovered under this Policy or any expenses that a Covered Executive incurs in opposing Company efforts to recoup amounts pursuant to the Policy.

Non-Exclusive Remedy; Successors

Recovery of Incentive Compensation pursuant to this Policy shall not in any way limit or affect the rights of the Company to pursue disciplinary, legal, or other action or pursue any other remedies available to it. This Policy shall be in addition to, and is not intended to limit, any rights of the Company to recover Incentive Compensation from Covered Executives under any legal remedy available to the Company and applicable laws and regulations, including but not limited to the Sarbanes-Oxley Act of 2002, as amended, or pursuant to the terms of any other Company policy, employment agreement, equity award agreement, or similar agreement with a Covered Executive.

This Policy shall be binding and enforceable against all Covered Executives and their successors, beneficiaries, heirs, executors, administrators, or other legal representatives.

Amendment

This Policy may be amended from time to time by the Committee or the Board.

Governing Law; Dispute Resolution

To the extent not preempted by U.S. federal law, with respect to any Covered Executive subject to this Policy, this Policy will be governed by, construed, interpreted, and its validity determined under the laws of the state in which the applicable Covered Executive resides (the "*Governing Law State*"), as applied to agreements entered into and to be fully performed by residents of such Governing Law State. Such law of the Governing Law State shall govern regardless of the forum in which a dispute may be adjudicated. Subject to the following paragraph, all actions or proceedings for injunctive relief arising out of this Policy with respect to any Covered Executive shall exclusively be heard and determined in state or federal courts in the Governing Law State having appropriate jurisdiction. The Company and each Covered Executive expressly consent to the exclusive jurisdiction of such courts in any such action or proceeding and waive any objection to venue therein and any defense of forum non conveniens.

The Company and each Covered Executive hereby incorporate by reference into this Policy that certain Dispute Resolution Agreement previously entered into by the Company (or one of its current direct or indirect subsidiaries) and such Covered Executive, as such agreement may be amended from time-to-time (the "*Dispute Resolution Agreement*"), and agree that any and all disputes arising under this Policy are subject to and governed by the Dispute Resolution Agreement; provided, however, that Company and each Covered Executive reserve the right to seek temporary or preliminary injunctive relief in court, in which case such parties agree that such injunctive relief shall be granted in court to preserve the status quo pending a resolution on the merits in arbitration. Each Covered Executive agrees that in connection with any application for injunctive relief, discovery shall be conducted on an expedited basis. Each Covered Executive further agrees that, in any proceeding alleging application of this Policy, the Company shall have the right to conduct forensic examinations of any computers and/or electronic devices in the Covered Executive's possession or control, if the Company reasonably believes such devices contain Confidential Information (as defined in the Dispute Resolution Agreement).

BLUEJAY DIAGNOSTICS, INC.

INCENTIVE COMPENSATION RECOVERY POLICY

ACKNOWLEDGMENT AND AGREEMENT

This Acknowledgment and Agreement (this "*Agreement*") is entered into as of the [ ] day of [_____], between Bluejay Diagnostics, Inc., a Delaware corporation (the "*Company*"), and [_____] (the "*Executive*"), under the following circumstances:

WHEREAS, the Company has adopted the Bluejay Diagnostics, Inc. Incentive Compensation Recovery Policy (the "*Policy*");

WHEREAS, the Executive has been designated as a "*Covered Executive*" of the Company as defined in the Policy;

WHEREAS, in consideration of, and as a condition to the receipt of, future cash and equity-based awards, performance-based compensation, and other forms of cash or equity compensation made under the Company's Amended and Restated 2012 Long-Term Incentive Plan, as amended, or any other incentive compensation plan or program of the Company, the Executive and the Company are entering into this Agreement; and

WHEREAS, defined terms used but not defined in this Agreement shall have the meanings set forth in the Policy.

NOW, THEREFORE, the Company and the Executive hereby agree as follows:

1. The Executive hereby acknowledges receipt of the Policy, to which this Agreement is attached, and the terms of which are hereby incorporated into this Agreement by reference. The Executive has read and understands the Policy and has had the opportunity to ask questions to the Company regarding the Policy.

2. The Executive hereby acknowledges and agrees that the Policy shall apply to any Incentive Compensation as set forth in the Policy by the Committee and that all such Incentive Compensation shall be subject to recovery under the Policy.

3. Any applicable award agreement or other document setting forth the terms and conditions of any Incentive Compensation granted to the Executive by the Company's Board of Directors of the Committee shall be deemed to include the restrictions imposed by the Policy and shall incorporate it by reference. In the event of any inconsistency between the provisions of the Policy and the applicable award agreement or other document setting forth the terms and conditions of any Incentive Compensation award granted to the Executive, the terms of the Policy shall govern unless the terms of such other agreement or other document would result in a greater recovery by the Company.

4. The Executive hereby acknowledges that, notwithstanding any indemnification agreement or other arrangement between the Company and the Executive, the Company shall not indemnify the Executive against, or pay the premiums for any insurance policy to cover, losses incurred under the Policy.

5. In the event it is determined by the Company that any amounts granted, awarded, earned or paid to the Executive must be forfeited or reimbursed to the Company, the Executive will promptly take any action necessary to effectuate such forfeiture and/or reimbursement.

6. This Agreement and the Policy shall survive and continue in full force in accordance with their terms notwithstanding any termination of the Executive's employment with the Company and its affiliates.

7. This Agreement may be executed in two or more counterparts, and by facsimile or electronic transmission (such as PDF), each of which will be deemed to be an original but all of which, taken together, shall constitute one and the same Agreement.

8. To the extent not preempted by U.S. federal law, this Agreement and the Policy will be governed by, construed, interpreted, and its validity determined under the laws of the state in which the Executive resides (the "*Governing Law State*"), as applied to agreements entered into and to be fully performed by residents of such Governing Law State. Such law of the Governing Law State shall govern regardless of the forum in which a dispute may be adjudicated. Subject to the paragraph 9 below, all actions or proceedings for injunctive relief arising out of this Agreement and the Policy with respect to the Executive shall exclusively be heard and determined in state or federal courts in the Governing Law State having appropriate jurisdiction. The Company and the Executive expressly consent to the exclusive jurisdiction of such courts in any such action or proceeding and waive any objection to venue therein and any defense of forum non conveniens.

9. The Company and the Executive hereby incorporate by reference into this Agreement and the Policy that certain Dispute Resolution Agreement previously entered into by the Company (or one of its current direct or indirect subsidiaries) and the Executive, as such agreement may be amended from time-to-time (the "*Dispute Resolution Agreement*"), and agree that any and all disputes arising under this Agreement or the Policy are subject to and governed by the Dispute Resolution Agreement; provided, however, that Company and the Executive reserve the right to seek temporary or preliminary injunctive relief in court, in which case such parties agree that such injunctive relief shall be granted in court to preserve the status quo pending a resolution on the merits in arbitration. The Executive agrees that in connection with any application for injunctive relief, discovery shall be conducted on an expedited basis. The Executive further agrees that, in any proceeding alleging application of this Agreement or the Policy, the Company shall have the right to conduct forensic examinations of any computers and/or electronic devices in the Executive's possession or control, if the Company reasonably believes such devices contain Confidential Information (as defined in the Dispute Resolution Agreement).

10. No modifications or amendments of the terms of this Agreement shall be effective unless in writing and signed by the parties hereto or their respective duly authorized agents. The provisions of this Agreement shall inure to the benefit of, and be binding upon, the successors, administrators, heirs, legal representatives and assigns of the Executive, and the successors and assigns of the Company.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

BLUEJAY DIAGNOSTICS, INC.

By: _____
Name:
Title:

[INSERT EXECUTIVE'S NAME]

_____
Name:
Title: