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, 2022

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 $0.001 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. ☐

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, 2022, was approximately $21,361,484 based on the closing price of $1.06 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 February 28, 2023, there were 20,459,057 shares of the registrant's common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant's definitive proxy statement relating to its Annual Meeting of Stockholders will be filed within 120 days of the fiscal year ended December 31, 2022 and is incorporated by reference in Part III of the Form 10-K to the extent described therein.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other sections of this 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 may not be able to achieve significant revenues or profitability.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.
- 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 capita
- The License Agreement with Toray, which covers the license of the core technology used in our Symphony platform and test cartridge product candidates, contains significant risks that may threaten our viability or otherwise 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.
- Significant raw material shortages, supplier capacity constraints, supplier disruptions, and sourcing issues may adversely impact or limited 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 our initial public offering (the "IPO") on November 2021 (the "IPO Date"). 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 devices and cartridges through Contract Manufacturing Organizations ("CMOs"). We have contracts with Toray Industries, Inc ("Toray") to manufacture our cartridges and Sanyoseiko Co. Ltd ("Sanyoseiko") to manufacture both our device and cartridges. Each of our partners are well-established global manufacturing companies with capabilities to scale up, re-design and supply our devices and cartridges.

Sanyoseiko had been selected as our CMO, though in the near-term Toray will continue to develop, validate and manufacture our IL-6 cartridges as our pilot-manufacturing partner. 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.

Regulatory Strategy

Our current regulatory strategy is designed to support commercialization of Symphony in the United States pending authorization from the FDA. The FDA has identified Symphony as a de novo device, and we are subject to the *de novo* authorization regulatory pathway, which includes expansion of our clinical studies. We have several clinical studies currently active, all designed to support our *de novo* FDA submission. We have targeted large, well-known medical and academic institutions for our studies, which should also help support initial commercialization and market penetration. This clinical trial expansion could also support additional indications. The expansion also could delay obtaining marketing authorization for the product.

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). We also have a nonexclusive license for the same purposes in Japan. The agreement terminates in 2029 upon expiration of the last of the patents included in the license.

In connection with entering into the License Agreement, we are required to pay a 15% royalty fee for the period that any underlying patents exist or for five years after the first sale for the licensed technology after obtaining regulatory approval based on a percentage of our "Net Sales" of products using these technologies (as defined in the license Agreement) with a minimum royalty of $60,000 for the initial year that royalties are payable increasing to a minimum of $100,000 thereafter.

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 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 December 31, 2022, we have sixteen full-time employees. We also contract with several consultants and contractors performing regulatory advisory, investor relations and manufacturing scale-up support. None of our employees are represented by labor unions or covered by collective bargaining agreements.

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 are subject to the risks associated with new businesses.

We entered into a License Agreement with Toray in October 2020 and 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.

We have incurred significant losses since inception and may not be able to achieve significant revenues or profitability.

Since our inception, we have engaged primarily in development activities. We have funded our operations primarily through debt and equity financings, and have incurred losses since inception, including a net loss of $9.3 million and $3.5 million for the years ended December 31, 2022 and 2021, respectively. We do not know whether or when we will become profitable. 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 substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

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, 2022 and 2021, 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, 2022 and 2021, 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, 2022 and 2021 do not include any adjustments that may result from the outcome of this uncertainty. We anticipate that we will need to raise additional capital to fund our operations while we implement and execute our business plan. 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.

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. Failure to obtain such additional financing could result in delay or indefinite postponement of operations or the further development of our business with the possible loss of such properties or assets. If adequate funds are not available or are not available on acceptable terms, we may not be able to fund our business or the expansion thereof, take advantage of strategic acquisitions or investment opportunities or respond to competitive pressures. Such inability to obtain additional financing when needed could have a material adverse effect on our business, results of operations, cash flow, financial condition and prospects.

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 October 25, 2022, 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 April 24, 2023, 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. 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

The License Agreement with Toray, which covers the license of the core technology used in our Symphony Cartridges, contains 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 the same purposes in Japan. We have no contractual rights to the intellectual property covered in the 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 License Agreement:

- 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 cartridges for a three-year period ending in October 2024. If we are unable to extend this arrangement or activate a new CMO to produce cartridges, 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, increasing the time and cost of remediating product defects or impairing our ability to timely scale up cartridge manufacturing.

- The license is non-assignable and non-sublicensable (to third parties). 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 obtain market approval for the products in the United States and the European Union by October 2023 or the License Agreement could be terminated by Toray.

- Toray has the right to terminate the License Agreement or make it non-exclusive if we do not generate commercial sales by October 2025, or by April 2027 if the lack of commercial sales is not directly attributed to our actions.

- Except with respect to Toray's ownership of all intellectual property rights in respect of the licensed property, Toray provides no, and disclaims all, representations, warranties or covenants relating to the licensed intellectual property or any other matters under the License Agreement and in particular disclaims any fitness of the 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.

In addition, see the risks in "*Risks Related to Our Intellectual Property*" below. These risks are not the only risks inherent in the License Agreement. You are encouraged to read the complete text of the License Agreement, which is filed as an exhibit to this Form 10-K.

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.

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. In addition, we will 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. 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 limited our products sales and or impact our product margins.

In connection with effects related to the COVID-19 pandemic, we are operating in a supply-constrained environment and are facing, and may continue to face, supply-chain shortages, inflationary pressures, logistics challenges and manufacturing disruptions that impact our revenues, profitability, and timeliness in fulfilling customer orders. In addition, 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

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 or 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. In addition, the changing landscape related to the COVID-19 pandemic also could lead to delays in obtaining clinical data. The declining number of COVID patients with respiratory deterioration may impact our ability to meet the primary endpoint in our Symphony IL-6 Expanded Clinical Study. We are currently working with the FDA to expand this endpoint to better reflect the current standard of care and to make the number of study subjects more realistic in light of the decreasing number of COVID positive subjects needed in the study. 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 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.

The declining number of COVID patients with respiratory deterioration may impact our ability to meet the primary endpoint in our Symphony IL-6 Expanded Clinical Study. We are currently working with the FDA to expand this endpoint to better reflect the current standard of care and to make the number of study subjects more realistic in light of the decreasing number of COVID positive subjects needed in the study.

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 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 also could suffer. For so long as we are dependent on the intellectual property covered by the License Agreement for the pursuit of our business, any such disputes relating to the 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 intellectual property relating to our Symphony platform is owned by Toray. Under the 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 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 us from continuing to use the licensed intellectual property that we need to operate our business. 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 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 employees of Toray or us 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 will be 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 $1.07 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 incur increased costs as a result of operating as a public company, and our management will be 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 will 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 may 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 could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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 after we become 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 will 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.

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 2. PROPERTIES

We have leased two facilities in Acton, Massachusetts which will expire in 2024 and 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. On June 7, 2021, our Board of Directors declared a stock dividend of 2.15 shares of common stock for every share of common stock. This stock dividend was deemed a large stock dividend and was treated as a 1-for-3.15 stock split.

Holders of Common Stock

As of February 28, 2023, we had 20,459,057 shares of common stock outstanding held by approximately ten 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 $9.3 million and $3.5 million for the years ended December 31, 2022 and 2021, respectively. We had negative cash flow from operating activities of approximately $7.8 million and $4.4 million for the years ended December 31, 2022 and 2021, respectively, and had an accumulated deficit of approximately $17.0 million as of December 31, 2022.

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

The following table sets forth our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	**2021**
Revenue	$ 249,040	$ -
Cost of sales	200,129	-
Gross profit	48,911	-
Operating expenses:		
Research and development	4,152,152	1,147,955
General and administrative	4,763,114	1,792,482
Marketing and business development	451,421	289,726
Total operating expenses	9,366,687	3,230,163
Operating loss	(9,317,776)	(3,230,163)
Other income (expense):		
Interest expense, net of amortization of premium	-	(367,459)
Impairment of property and equipment	(237,309)	-
State grant revenue	-	75,000
Other income, net	258,137	34,324
Total other income (expense), net	20,828	(258,135)
Net loss	$ (9,296,948)	$ (3,488,298)

Revenue and Gross Profit

Revenue and gross profit increased approximately $250,000 and $49,000 respectively, for the year ended December 31, 2022, as compared to 2021. We recognized a small, non-recurring sale to a foreign development partner in the second quarter of 2022, which we do not consider an entry to the market or indicative of expected margins. As expected, there were no sales in the remainder of 2022.

Research and Development

Research and development expenses increased approximately $3.0 million, or 262%, for the year ended December 31, 2022, as compared to 2021. This was due primarily to an increase in personnel; costs incurred for clinical trials necessary to support or our *de novo* FDA submission; and product design, testing, and manufacturing scale-up related to our Symphony device and cartridges.

General and Administrative

General and administrative expenses increased approximately $3.0 million, or 166%, for the year ended December 31, 2022, as compared to 2021. The increase was primarily attributable to administrative costs necessary to operate as a public company, totaling approximately $1.6 million. In addition, employee compensation and benefits increased by $1.3 million due to an increase in personnel.

Marketing and Business Development

Marketing and business development expenses increased approximately $162,000, or 56%, for year ended December 31, 2022, as compared to 2021. The increase was primarily attributable to pre-launch activities, including the attendance of various industry conferences in 2022 introducing our Symphony platform to the market.

Total Other Income (Expense), net

Total other income (expense) increased approximately $279,000, or 108%, for the year ended December 31, 2022 as compared to 2021. The increase primarily related to income earned under the agreement with NanoHybrids, as discussed in Note 11, partially offset by an impairment charge recognized in September 2022 of $210,000 related to certain Allereye research and development equipment.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through proceeds from our IPO, debt financings, private placements, interest income earned on cash and cash equivalents, and grants. At December 31, 2022, we had cash and cash equivalents of approximately $10.1 million. As of February 28, 2023, we had cash and cash equivalents of approximately $7.6 million.

Primary Sources of and Uses of Cash

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,	
	2022	**2021**
Cash proceeds provided by (used in):		
Operating activities	$ (7,741,593)	$ (4,366,758)
Investing activities	(1,199,270)	(23,947)
Financing activities	8,075	22,526,122
Net (decrease) increase in cash and cash equivalents	$ (8,932,788)	$ 18,135,417

Net cash used in operating activities

During 2022, we used $7.7 million in cash for operating activities, an increase of $3.4 million from 2021. The increase in net cash used in operating activities was primarily due to increases in personnel costs, product development costs, and expenses incurred for public company operations.

Net cash used in investing activities

During 2022, we used $1.2 million in cash for investing activities, a $1.2 million increase from 2021. The increase in cash used in investing activities was primarily due to the purchase of lab and manufacturing equipment to support the development of the Symphony product line.

Net cash provided by financing activities

During 2022, we generated $8,000 in cash from financing activities, as compared to approximately $22.5 million in 2021. The $22.5 million decrease was primarily due to our IPO in November 2021, which provided net proceeds of $18.9 million. Additionally in 2021, we received $4.5 million from the issuance of convertible debentures, offset by issuance costs of approximately $563,000.

Contractual Obligations

See Note 12 to consolidated financial statements for our lease obligations and Note 13 to the consolidated financial statements for our other non-cancellable contractual obligations.

Liquidity and Going Concern

We had cash and cash equivalents of $10.1 million at December 31, 2022. We continue to develop the Symphony device and its first cartridge for the measurement of IL-6. We remain committed to obtaining FDA clearance and have expanded clinical trials to obtain additional data to support our *de novo* FDA submission, while also continuing to build our manufacturing operations with our CMOs. Current cash resources and expected operating expenses are considered in determining our liquidity requirement; as well as $1.6 million of current liabilities on our balance sheet at December 31, 2022 and capital commitments of approximately $2 million during 2023 (see Notes 12 and 13). As of the filing of this report, we expect to need additional capital to fund our planned operations for the next twelve months.

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

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

Recent Financings

Convertible Debentures

On June 8, 2021, we entered into an agreement to issue a total of $4.5 million of 7.5% Senior Secured Convertible Debentures (the "Convertible Debentures") to Sabby Volatility Master Fund, Ltd ("Sabby"), of which $3.0 million of the Convertible Debentures were issued at closing and $1.5 million in principal amount of the Convertible Debentures were issued in August 2021.

Initial Public Offering

We completed our IPO on November 10, 2021, whereby we sold 2,160,000 Units at a price of $10.00, with each Unit consisting of one share of common stock, one warrant to purchase one share of common stock at an exercise price of $7.00 per share ("Class A Warrant"), and one warrant to purchase one share of common stock at an exercise price of $10.00 ("Class B Warrant") (collectively, a "Unit"). Each warrant contained within the Units is exercisable until the fifth anniversary of the IPO Date, however, holders of Class B Warrants may 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 our common stock, if the volume weighted average price of our 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 Warrants (subject to adjustments as described in the warrant agreement). Additionally, the underwriter of the IPO exercised their overallotment option, solely with respect to the Class A Warrants and Class B Warrants, shortly after the IPO Date, which resulted in an additional issuance of 324,000 Class A Warrants and 324,000 Class B Warrants. The gross proceeds from the IPO were approximately $21.6 million and were offset by $2.8 million in offering costs.

Indemnification

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

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-21.

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 Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. 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 Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022.

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 Chief Executive Officer and our Chief Financial Officer assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, our Chief Executive Officer and our 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 Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2022, 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 year ended December 31, 2022, 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 2023 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2023 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

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 2023 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2022.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans at December 31, 2022:

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)	719,835	$ 1.96	1,601,990
Equity compensation plans not approved by security holders (2)	559,599	$ 4.20	-

(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 629,440 and 1,960,000, respectively. At December 31, 2022 there were 262,269 and 1,339,721 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 2023 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

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 2023 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

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	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 Class A Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-41031), filed on November 16, 2021).
4.3	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).
4.4	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).
4.5	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).
4.6	Description of Securities of Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 4.6 to the Company's annual report on Form 10-K for the year ended December 31, 2021.
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	License and Supply Agreement, dated October 6, 2020, by and between Toray Industries, Inc. and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.3**	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).
10.4**	Employment Agreement, dated July 1, 2021, between Gordon Kinder and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.5**	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).
10.6**	Employment Agreement, dated July 1, 2021, between Kevin Vance and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
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	Amendment to License and Supply Agreement, dated July 21, 2021, by and between Toray Industries, Inc. and Bluejay Diagnostics, Inc. (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-260029), filed on October 4, 2021).
10.10**	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 (File No. 001-41031), filed on January 27, 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
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 20, 2023.

Bluejay Diagnostics, Inc.

By: /s/ Neil Dey
Neil Dey
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	Director and Chief Executive Officer (Principal Executive Officer)	March 20, 2023
/s/ Kenneth Fisher Kenneth Fisher	Chief Financial Officer (Principal Financial and Accounting Officer)	March 20, 2023
/s/ Douglas C. Wurth Douglas C. Wurth	Chairman of the Board of Directors	March 20, 2023
/s/ Donald R. Chase Donald R. Chase	Director	March 20, 2023
/s/ Svetlana Dey Svetlana Dey	Director	March 20, 2023
/s/ Fred S. Zeidman Fred S. Zeidman	Director	March 20, 2023
/s/ Gary Gemignani Gary Gemignani	Director	March 20, 2023

Index to Consolidated Financial Statements

Contents

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, 2022 and 2021, the related consolidated statements of operations, stockholders' equity (deficit) 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, 2022 and 2021, 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.

Uncertainty Relating to 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.
Wolf & Company, P.C.

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

Boston, Massachusetts
March 20, 2023

Bluejay Diagnostics, Inc.
Consolidated Balance Sheets

	December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,114,990	$ 19,047,778
Prepaid expenses and other current assets	1,673,480	1,612,708
Total current assets	11,788,470	20,660,486
Property and equipment, net	1,232,070	337,366
Operating lease right-of-use assets	465,514	-
Other non-current assets	35,211	21,019
Total assets	$ 13,521,265	$ 21,018,871
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 635,818	$ 295,778
Operating lease liability, current	168,706	-
Accrued expenses and other current liabilities	835,730	341,384
Total current liabilities	1,640,254	637,162
Operating lease liability, non-current	323,915	-
Other non-current liabilities	15,823	-
Total liabilities	1,979,992	637,162
Commitments and Contingencies (See Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value; 100,000,000 shares authorized; 20,215,288 and 20,112,244 shares issued and outstanding at December 31, 2022 and 2021, respectively	2,022	2,011
Additional paid-in capital	28,536,353	28,074,484
Accumulated deficit	(16,997,102)	(7,694,786)
Total stockholders' equity	11,541,273	20,381,709
Total liabilities and stockholders' equity	$ 13,521,265	$ 21,018,871

See notes to consolidated financial statements.

Bluejay Diagnostics, Inc.
Consolidated Statements of Operations

	For the Years Ended December 31,	
	2022	**2021**
Revenue	$ 249,040	$ -
Cost of sales	200,129	-
Gross profit	48,911	-
Operating expenses:		
Research and development	4,152,152	1,147,955
General and administrative	4,763,114	1,792,482
Marketing and business development	451,421	289,726
Total operating expenses	9,366,687	3,230,163
Operating loss	(9,317,776)	(3,230,163)
Other income (expense):		
Interest expense, net of amortization of premium	-	(367,459)
Impairment of property and equipment	(237,309)	-
State grant income	-	75,000
Other income, net	258,137	34,324
Total other income (expense), net	20,828	(258,135)
Net loss	$ (9,296,948)	$ (3,488,298)
Net loss per share - Basic and diluted	$ (0.46)	$ (0.41)
Weighted average common shares outstanding:		
Basic and diluted	20,163,915	8,522,422

See notes to consolidated financial statements.

Bluejay Diagnostics, Inc.
Statements of Changes in Redeemable Preferred Stock and Stockholders' Equity (Deficit)

	Redeemable, Convertible Preferred Stock								Stockholders' Equity (Deficit)				
	Series A		Series B		Series C		Series D		Common Stock		Additional Paid-In	Accumulated	Total Stockholder's Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2020	**10,600**	**$ 1,077,303**	**5,187**	**$ 1,800,347**	**636**	**$ 1,000,465**			**3,147,200**	**$ 315**	**$ -**	**$ (4,206,488)**	**$ (4,206,173)**
Exercise of common stock warrants	-	-	-	-	-	-	-	-	4,715,836	471	140,990	-	141,461
Accretion of redeemable, convertible preferred stock to redemption value	-	73,912	-	33,994		19,961	-	-	-	-	(127,866)	-	(127,866)
Conversion of convertible debentures into Series D preferred stock	-	-	-	-	-	-	4,500	4,036,535	-		-	-	-
Conversion of redeemable, convertible preferred stock into common stock	(10,600)	(1,151,215)	(5,187)	(1,834,341)	(636)	(1,020,426)	(4,500)	(4,036,535)	7,084,323	708	8,041,809	-	8,042,517
Fair value of warrants issued for services	-	-	-	-	-	-	-	-	-	-	180,339	-	180,339
Fair value of warrants issued to placement agent in relation to the Convertible debentures	-	-		-	-	-	-	-	-	-	166,816		166,816
Conversion of Amended 2017 Convertible Notes into common stock	-	-	-	-	-	-	-	-	580,000	58	579,942	-	580,000
Reclassification of Series B Warrants	-	-	-	-	-	-	-	-	-	-	145,953	-	145,953
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	68,458	-	68,458
Issuance of common stock from exercise of stock options	-	-	-	-	-	-	-	-	56,385	6	22,617	-	22,623
Issuance of common stock in initial public offering, net of offering costs of $2,750,601	-	-	-	-	-	-	-	-	2,160,000	216	18,855,663	-	18,855,879
Issuance of common stock from exercise of warrants	-	-	-	-	-	-	-	-	2,368,500	237	(237)	-	-
Net loss	-	-	-	-	-	-		-	-		-	(3,488,298)	(3,488,298)
Balance at December 31, 2021	**-**	**$ -**	**-**	**$ -**	**-**	**$ -**		**-**	**20,112,244**	**$ 2,011**	**$28,074,484**	**$ (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	-	-	-	-	-	-	-	-	62,944	7	28,869	-	28,876
Exercise of common stock Series B Warrants	-	-	-	-	-	-	-	-	40,100	4	(4)	-	-
Net loss	-	-	-	-	-	-		-	-		-	(9,296,948)	(9,296,948)
Balance at December 31, 2022	**-**	**$ -**	**-**	**$ -**	**-**	**$ -**		**-**	**20,215,288**	**$ 2,022**	**$28,536,353**	**$ (16,997,102)**	**$ 11,541,273**

See notes to consolidated financial statements.

Bluejay Diagnostics, Inc.
Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (9,296,948)	$ (3,488,298)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	156,598	145,719
Stock-based compensation expense	433,004	68,458
Amortization of right-of-use assets	149,770	-
Impairment of property and equipment	237,309	-
Loss on disposal of property and equipment	137	-
Issuance of warrants for service	-	180,339
Gain on forgiveness of note payable, Paycheck Protection Program	-	(5,000)
Non-cash interest expense	-	227,007
Gain on revaluation of derivative warrant liability	-	(9,676)
Changes in operating assets and liabilities:		
Inventory	-	84,762
Prepaid expenses and other current assets	(40,772)	(1,551,637)
Non-current assets	(14,192)	(21,019)
Accounts payable	298,881	(79,150)
Due to related party	(2,000)	(123,102)
Accrued expenses	336,620	204,839
Net cash used in operating activities	**(7,741,593)**	**(4,366,758)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,199,270)	(23,947)
Net cash used in investing activities	**(1,199,270)**	**(23,947)**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of principal on notes payable	-	(289,617)
Payments of convertible debenture issuance costs	-	(562,842)
Proceeds from initial public offering, net of offering costs	-	18,855,879
Proceeds from issuance of convertible debentures	-	4,500,000
Payments on note payable, Paycheck Protection Program	-	(9,000)
Proceeds from exercise of common stock warrants	-	9,079
Payments of deferred offering costs	(20,000)	-
Payment of finance lease	(801)	-
Proceeds from exercise of stock options	28,876	22,623
Net cash provided by financing activities	**8,075**	**22,526,122**
(Decrease) increase in cash and cash equivalents	(8,932,788)	18,135,417
Cash and cash equivalents, beginning of year	19,047,778	912,361
Cash and cash equivalents, end of year	$ 10,114,990	$ 19,047,778
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH FINANCING ACTIVITIES		
Interest paid	$ 364	$ 150,228
Accretion of Series A redeemable, convertible preferred stock dividend	$ -	$ 17,667
Accretion of Series A redeemable, convertible preferred stock issuance costs and fair value adjustment	$ -	$ 56,245
Accretion of Series B redeemable, convertible preferred stock dividend	$ -	$ 31,258
Accretion of Series B redeemable, convertible preferred stock issuance costs	$ -	$ 2,736
Accretion of Series C redeemable, convertible preferred stock dividend	$ -	$ 16,727
Accretion of Series C redeemable, convertible preferred stock issuance costs	$ -	$ 3,234
Exercise of warrants through debt principal conversion	$ -	$ 132,383
Conversion of convertible debentures into preferred stock	$ -	$ 4,500,000
Conversion of preferred stock into common stock	$ -	$ 8,505,982
Conversion of amended 2017 convertible notes	$ -	$ 580,000
Reclassification of derivative warrant liability into additional paid-in capital	$ -	$ 145,953
Fair value of warrants issued to placement agent in relation to the Convertible debentures	$ -	$ 166,816
Fair value of warrants for common stock issued for services	$ -	$ 180,339
Fair value of warrants issued to underwriters	$ -	$ 2,939,327
Liabilities incurred for the purchase of property and equipment	$ 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 our Symphony technology platform ("Symphony") to improve patient outcomes in critical care settings. The Company's Symphony platform is a combination of Bluejay's intellectual property ("IP") and exclusively licensed and patented IP that consists of a mobile device and single-use test cartridges that if cleared, authorized, or approved by the U.S. Food and Drug Administration (the "FDA"), can provide a solution to a significant market need in the United States. Clinical trials indicate the Symphony device produces laboratory-quality results in less than 20 minutes in critical care settings, including Intensive Care Units ("ICUs") and Emergency Rooms ("ERs"), where rapid and reliable results are required.

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

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

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

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

Initial Public Offering

The Company completed its initial public offering (the "IPO") in November 2021 ("IPO Date"), whereby it sold 2,160,000 Units at a price of $10.00, with each Unit consisting of one share of the Company's common stock, one warrant to purchase one share of common stock at an exercise price of $7.00 per share ("Class A Warrant"), and one warrant to purchase one share of common stock at an exercise price of $10.00 ("Class B Warrant") (collectively, a "Unit"). Each warrant contained within the Units is exercisable until the fifth anniversary of the IPO Date, however, holders of Class B Warrants may 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). Additionally, the underwriter of the IPO exercised their overallotment option, solely with respect to the Class A Warrants and Class B Warrants, shortly after the IPO Date which resulted in an additional issuance of 324,000 Class A Warrants and 324,000 Class B Warrants. The gross proceeds from the IPO were approximately $21.6 million and were offset by $2.8 million in offering costs.

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). 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.

Going Concern

The Consolidated Financial Statements for the years ended December 31, 2022 and 2021 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. However, the Company has incurred net losses since its inception, and has negative cash flows from operations and will need additional funding to complete planned development efforts. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company had cash and cash equivalents of $10.1 million at December 31, 2022. It continues to develop the Symphony device and its first test for the measurement of IL-6. It remains committed to obtaining FDA clearance and has expanded clinical trials to obtain additional data to support its *de novo* FDA submission, while also continuing to build its manufacturing operations with its CMOs. Current cash resources and expected operating expenses are considered in determining its liquidity requirement; as well as $1.6 million of current liabilities on its balance sheet at December 31, 2022 and capital commitments of approximately $2 million during 2023 (see Notes 12 and 13). Given the Company's current plans, the Company estimates cash resources will be sufficient to fund its operations through the fourth quarter of 2023. The Company will need additional capital to fund its planned operations for the next 12 months.

The Company may 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 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.

On June 7, 2021, the Company's Board of Directors declared a stock dividend of 2.15 shares of common stock for every share of common stock. This stock dividend was deemed a large stock dividend and was treated as a 1-for-3.15 stock split. The common stock shares and per share amounts (other than authorized shares) in these consolidated financial statements and related notes have been retroactively restated to reflect the stock dividend for all periods presented.

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

Financial Statement Reclassifications

Certain balances in the prior year consolidated financial statements have been reclassified to conform to the presentation in the current year 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 are carried at fair market value which approximates cost.

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

Effective January 1, 2022, the Company adopted the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") ASC 842, *Leases* ("ASC 842"). The Company has adopted ASC 842 using the optional transition method and, as a result, there have been no reclassification of prior comparable periods due to this adoption.

The Company has arrangements involving the lease of facilities. 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 to the economic benefits or outputs from the asset.

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. 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 leases include both lease and non-lease components. Consideration is allocated to the lease and non-lease components based on estimated standalone prices. The Company has elected to exclude non-lease components from the calculation of its ROU assets and lease liabilities.

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.

Finance leases are not material to the Company's consolidated financial statements.

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. As of December 31, 2022 and 2021, respectively, the Company had $371,000 and $0 capitalized in property and equipment related to pre-production molds and tooling related to the Symphony device.

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. Forfeited share-based awards are recorded as a reduction to stock compensation expense.

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, 2022. Any interest or penalties are charged to expense. During the years ended December 31, 2022 and 2021, the Company had no significant interest and penalties. Tax years subsequent to December 31, 2018 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.

Net Loss per Share

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

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

	December 31	
	2022	**2021**
Options to purchase common stock	719,835	503,433
Warrants for common stock	811,882	811,882
Class A Warrants for common stock	2,484,000	2,484,000
Class B Warrants for common stock	75,400	115,500

Recently Adopted Accounting Standards

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, *Leases*. The new guidance requires the recognition of lease liabilities, representing future minimum lease payments, on a discounted basis, and corresponding right-of-use assets on a balance sheet for most leases, along with requirements for enhanced disclosures to give financial statement users the ability to assess the amount, timing, and uncertainty of cash flows arising from leasing arrangements. The Company adopted the provisions of ASU 2016-02 on January 1, 2022 and elected to implement the transition package of practical expedients permitted within the new standard, which included (i) not reassessing whether expired or existing contract contain leases, (ii) not reassessing lease classification, and (iii) not revaluing initial direct costs for existing leases. Adoption of the new standard resulted in the recording of initial right-of-use assets and lease liabilities of approximately $200,000 as of January 1, 2022. The new standard did not materially impact the Company's consolidated statements of operations or cash flows.

In May 2021, the FASB issued ASU 2021-04 *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force)*. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early application is permitted, including in an interim period as of the beginning of the fiscal year that includes that interim period. The adoption date of this ASU did not have a material impact on the Company's financial position and results of operations.

Recently Issued 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. This ASU is effective for fiscal years beginning after December 15, 2022, with early adoption permitted, including adoption in an interim period. The Company is currently evaluating the effect that this standard may have on its financial position and related disclosures.

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. There were no sales of or revenues from the Cartridges during the 12-month periods ended December 31, 2022 and 2021.

At December 31, 2022 and 2021, there were no amounts accrued related to the License Agreement.

4. NOTES PAYABLE

2017 Notes Payable

In 2017, the Company entered into multiple Unit Purchase Agreements (the "Financing") whereby the Company issued 106 Units. Each Unit consisted of 100 shares of Series A redeemable, convertible preferred stock ("Series A") at a purchase price of $100 per share and $10,000 in notes payable (the "Notes"). The Company defaulted on certain Notes issued in 2017 with aggregate principal amount of $1,060,000 in January 2021. On February 17, 2021, the Company repaid in cash $268,000 in principal and $2,010 in accrued interest on the Notes. On May 26, 2021, the remaining Notes of $580,000 were amended and restated (the "Amended Notes"). The Amended Notes accrue no interest and were due in May 2023. On June 8, 2021, the Amended Notes were automatically convertible into 580,000 shares of common stock at the conversion rate of $1.00 per share upon the issuance by the Company of securities to Sabby Volatility Warrant Master Fund, Ltd ("Sabby") (the "Sabby Agreement"). The amendment and subsequent conversion of the Notes was accounted for as the debt settlement in equity under ASC 470-60 *Troubled Debt Restructurings by Debtors*. The Company recognized a gain on extinguishment of $6,360, equal to the difference between the carrying amount of the Amended Notes at the conversion date, totaling $586,360, and the fair value of the common stock shares issued to the noteholders of $580,000. This gain on extinguishment is included in other income on the consolidated statement of operations for the year ended December 31, 2021. For the year ended December 31, 2021 the interest expense on the Notes was $6,360.

The allocation of the gross proceeds from the Financing resulted in recording a premium on the Notes of $583,349. The premium is amortized over the term of the Notes. As a result of the event of default in January 2021 and the Notes becoming due on demand, the Company accelerated the amortization of the premium and discount and amortized the remaining balances during the three-month period ended March 31, 2021. The Company recognized the amortization of the premium of $145,837 as a reduction to non-cash interest expense during the year ended December 31, 2021. The premium amortization was included within interest income (expense) on the consolidated statements of operations.

In connection with the Financing, the Company paid $183,194 in issuance costs of which $91,597 was recorded as a discount on the Notes and is being amortized over the term of the Notes. The remaining $91,597 was netted with the proceeds allocated to Series A (see Note 7). The Company recognized the amortization of the discount of $22,899 as non-cash interest expense during the year ended December 31, 2021. The discount amortization was included in the interest income (expense) on the consolidated statements of operations.

2020 Subordinated Notes

On October 22, 2020, the Company issued $154,000 in subordinated promissory notes ("Subordinated Notes") to the Company's stockholders, including $30,000 to Lana Management and Business Research International, LLC ("LMBRI"). The Subordinated Notes accrued interest at 8% payable at each quarter end and had a maturity date of March 31, 2021. The Company defaulted on the Subordinated Notes on March 31, 2021, and the Subordinated Notes started to accrue 15% penalty interest starting on the date of default. For the year ended December 31, 2021 interest expense on the Subordinated Notes was $7,443. In conjunction with the issuance of the Subordinated Notes, the Company issued to each noteholder warrants to purchase shares of the Company's common stock ("Subordinated Note Warrants") totaling 4,846,688 Common Stock Warrants, of which 944,160 were issued to LMBRI. The allocation of the proceeds to the Subordinated Note Warrants resulted in a discount to the Subordinated Notes of $148,892. The Company amortized this discount through non-cash interest expense using the effective interest method, of which $83,752 was amortized during the year ended December 31, 2021, and included in the interest income (expense) in the consolidated statement of operations.

On June 7, 2021, the holders of $132,383 in principal of the Subordinated Notes elected to exercise their warrants into 4,166,357 shares of common stock, with the principal from the Subordinated Notes applied to the exercise price of the warrants. The remaining $21,617 principal amount of the Subordinated Notes was repaid in cash in 2021.

5. CONVERTIBLE DEBENTURES

On June 7, 2021, the Company entered into a Securities Purchase Agreement with Sabby, under which the Company committed to sell, and Sabby agreed to purchase, an aggregate of $4,500,000 principal amount of debentures, of which $3,000,000 upon execution of the agreement and the remaining $1,500,000 within three trading days of the later of (i) the date that the Company files the Registration Statement with the SEC and (ii) the date that the Company files the registration statement registering the shares of common stock to be issued in the IPO.

On June 8, 2021, the Company issued a total of $3,000,000 of 7.5% Senior Secured Convertible Debentures (the "Convertible Debentures") to Sabby. On August 4, 2021, the Company issued an additional $1,500,000 of Convertible Debentures upon the filing of a registration statement in connection to the IPO, which was filed on July 22, 2021. The Convertible Debentures' principal amount was convertible, at the holder's option, into the Company's Series D Convertible Preferred Stock (Series D) at $1,000 conversion price per share. The Convertible Debenture was automatically converted into Series D upon the effectiveness of an IPO. For the year ended December 31, 2021, interest expense on the Convertible Debentures was $124,829.

In connection with the IPO, all of the Company's outstanding Convertible Debentures automatically converted into 4,500 shares of Series D Preferred Stock on the IPO Date. Subsequently, the holder of the 4,500 outstanding shares of Series D Preferred Stock exercised their option to convert their shares into 4,500,000 shares of common stock.

The Company incurred $729,658 in issuance costs consisting of cash payments and 225,000 warrants (the "Dawson Warrants") issued to the placement agent for compensation for their services in relation to the issuance of the Convertible Debentures. The Dawson Warrants are exercisable after May 10, 2022 at the exercise price of $1.25 per share of common stock and have a 5-year term. The Dawson Warrants were accounted for as equity under ASC 815 – *Derivatives and Hedging*, and the grant date fair value was estimated to be $166,816 using Black-Scholes option pricing model and is included in issuance costs related to the Convertible Debentures.

The resulting discount is amortized over the term of the Convertible Debentures using the effective interest method. The Company recognized $266,193 of amortization of the discount during the year ended December 31, 2021, which was included within interest income (expense) in the consolidated statement of operations. The remaining $463,465 of unamortized discount was credited to the capital accounts at the time of conversion.

6. WARRANTS

The following table summarizes information with regard to warrants outstanding at December 31, 2022:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
Common Stock Warrants	811,882	Common Stock	$ 3.24	3.1
Class A Warrants	2,484,000	Common Stock	$ 7.00	3.8
Class B Warrants	75,400	Common Stock	$ 10.001	3.8

1 Class B Warrants may also exercise such warrants on a "cashless" basis. See Class A Warrants and Class B Warrants subsection below.

No warrants were issued during the year ended December 31, 2022. The following assumptions were used in the Black-Scholes option pricing model to estimate the fair value of the warrants granted during the year ended December 31, 2021:

Risk-free interest rate	0.37% - 0.73%
Dividend rate	0%
Volatility	106.00% - 142.46%
Expected life (in years)	5

Common Stock Warrants

In March 2021, the Company granted a financial advisor warrants to purchase 226,599 shares of the Company's common stock (the "Advisor Warrants") as consideration for services in connection with the IPO. The warrants are exercisable at any time from the issuance date at the exercise price of $3.177 per share of common stock, subject to adjustment based on the amounts raised in the IPO, and have a 5-year term. These warrants were accounted for as equity and the grant date fair value was estimated to be $180,339 and were netted against the IPO proceeds. The terms of the advisory services agreement also provide for an incentive bonus of $200,000 payable upon closing of the IPO if such a closing occurs on or before January 31, 2022. This amount was netted against the IPO proceeds. As of December 31, 2022 and 2021, all of the Advisor Warrants remained outstanding.

In August 2021, the Company granted the Dawson Warrants to its placement agent for compensation for their services in relation to the issuance of the Convertible Debentures (see Note 5). As of December 31, 2022 and 2021, all of the Dawson Warrants remained outstanding.

In November 2021, the Company granted 108,000 warrants (the "Underwriter Warrants") with an exercise price of $12.50, and a fair value of approximately $356,000, to the underwriter of the IPO which is in addition to the cash fees paid for underwriting the Company's IPO. As of December 31, 2022 and 2021, all of the Underwriter Warrants remained outstanding.

In October 2020, in conjunction with the issuance of the Subordinated Notes, the Company granted 4,846,688 warrants (the "Subordinated Note Warrants") to the noteholders, of which 944,160 were issued to LMBRI (see Note 4). In November 2021, the terms of some of the Subordinated Note Warrants were amended to provide for cashless exercise. During 2021, 4,718,251 of the Subordinated Note Warrants were exercised. As of December 31, 2022 and 2021, 128,438 of the Subordinated Note Warrants were outstanding.

Class A Warrants and Class B Warrants

In conjunction with the Company's IPO as described in Note 1 the Company issued 2,160,000 Class A Warrants and 2,160,000 Class B Warrants. Additionally, the underwriter of the IPO exercised their overallotment option, solely with respect to the Class A Warrants and Class B Warrants, shortly after the IPO Date resulting in an additional issuance of 324,000 Class A Warrants and 324,000 Class B Warrants. From the net IPO proceeds, $5,164,751 and $7,323,161, respectively, were apportioned to the Class A Warrants and Class B Warrants.

Class A Warrants entitle the holder to purchase one share of common stock at an exercise price of $7.00 per share. As of December 31, 2022 and 2021 all Class A Warrants were outstanding.

Class B Warrants entitle the holder to purchase one share of common stock at an exercise price of $10.00 per share. Holders of Class B Warrants may also exercise such warrants on a "cashless" basis after the earlier of (i) 10 trading days from closing date of the offering or (ii) the time when $10.0 million of volume is traded in the Company's common stock, if the volume weighted average price of the Company's common stock on any trading day on or after the closing date of the offering fails to exceed the exercise price of the Class B Warrant (subject to adjustment as described in the warrant agreement). During 2022 and 2021, respectively, 40,100 and 2,368,500 Class B Warrants were exercised, all on a cashless basis. As of December 31, 2022 and 2021, respectively, 75,400 and 115,500 Class B Warrants were outstanding.

Warrants for Series B Redeemable, Convertible Preferred Stock

The 643 Series B Warrants (defined below) issued in conjunction with the Series B redeemable, convertible preferred stock (see Note 7) were accounted for as a derivative liability under ASC 480 – *Distinguishing Liabilities from Equity.* On June 1, 2021, the Series B Warrants were amended ("Amended Series B Warrants") to become exercisable into 115,190 shares of common stock at an exercise price of $2.30 per share and are now reflected as common stock warrants in the table of outstanding warrants above. The Amended Series B Warrants were accounted for as equity and reclassified from liabilities into additional paid-in capital at the fair value determined as of the amendment date of $145,953.

The fair value of the outstanding the Amended Series B Warrants at June 1, 2021 was based on the assumptions as follows:

	June 1, 2021
Risk-free interest rate	0.31% - 0.56%
Dividend rate	0%
Volatility	88.60%
Expected life (in years)	2.81– 4.22

7. PREFERRED STOCK

In 2017 in connection with the Financing (see Note 4), the Company issued 10,600 shares of Series A. The allocation of proceeds from the Financing was based on the relative fair values of the Notes and Series A resulting in the Series A being recorded at $476,651, net of $91,597 of issuance costs. Series A were being accreted to the redemption value through December 31, 2021, the redemption date. Accretion of Series A to redemption value, including the accretion of dividends and issuance costs, was $73,912 for year ended December 31, 2021.

In 2019, the Company entered into Subscription Agreements, as amended, for the issuance of 4,455 shares of Series B plus the committed future issuance of 415 of additional shares (the "Series B Financing"). The Series B Financing also resulted in the issuance of a total of 848 warrants (the "Series B Warrants"). Series B were subject to accretion to the redemption value through the redemption date. Accretion of Series B to redemption value, including the accretion of dividends and issuance costs, was $33,993 for the year ended December 31, 2021.

On November 19, 2020, the Company entered into a Subscription Agreement for the issuance of Series C redeemable, convertible preferred stock (the "Series C Financing") with Toray. In connection with the Series C Financing, the Company issued 636 shares of Series C at a purchase price of $1,578.50 per share. Proceeds from the Series C Financing, net of issuance costs, were $994,832. Series C were being accreted to the redemption value through December 31, 2021, the redemption date. Accretion of Series C to redemption value, including the accretion of dividends and issuance costs, was $19,961 for the year December 31, 2021.

On June 1, 2021, in connection with the Sabby Agreement (see Note 5), Series A were converted into 1,668,016 shares of common stock, Series B were converted into 816,226 shares of common stock, and Series C were converted into 100,081 shares of common stock. The conversion was affected through the joint consent of the Company's Board of Directors and stockholders and was subject to and in accordance with the terms of the Certificates of Designation. As a result of the conversion, the temporary equity balances at the conversion date were reclassified into the stockholders' equity.

On June 7, 2021, the Company filed a certificate of designation of preferences, rights, and limitations with the state of Delaware for up to 4,500 shares of Series D convertible preferred stock ("Series D"). In connection with the IPO, all of the outstanding Convertible Debentures automatically converted into 4,500 shares of Series D on the IPO Date. In November 2021, all Series D was converted into 4,500,000 shares of common stock. There were no Series D outstanding as of December 31, 2022.

8. 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 629,440. At December 31, 2022 there were 262,269 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 1,960,000 shares of common stock were approved to be initially reserved for issuance under the 2021 Stock Plan. At December 31, 2022 there were 1,339,721 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, 2022:

	Non-vested Restricted Stock Awards	
	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	-	$ -
Granted	105,000	1.29
Vested	-	-
Forfeited	(45,000)	1.29
Outstanding at December, 2022	60,000	$ 1.29

The following is a summary of stock option activity for the year ended December 31, 2022:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2021	589,786	$ 1.86	8.3	$ 605,187
Granted	236,279	1.80		
Exercised	(62,944)	0.46		21,354
Cancelled and forfeited	(43,286)	1.86		
Outstanding at December 31, 2022	719,835	$ 1.96	6.5	$ 20,578
Exercisable at December 31, 2022	495,101	$ 1.97	7.6	$ 20,578

The weighted average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $1.42 per share and $1.16 per share, respectively. The Company calculated the grant-date fair value of stock option awards granted during the years ended December 31, 2022 and 2021 using the Black-Scholes model with the following assumptions:

	2022	2021
Risk-free interest rate	1.58% – 4.35%	0.78% – 1.27%
Expected dividend yield	0.00%	0.00%
Volatility factor	102.03% – 107.36%	106.00% – 114.76%
Expected life of option (in years)	5.40 – 6.00	5.00 – 6.00

Stock-Based Compensation Expense

For the years ended December 31, 2022 and 2021, the Company recorded stock-based compensation expense as follows:

	Year ended December 31,	
	2022	2021
Research and development	$ 64,352	$ 29,543
General and administrative	367,702	17,315
Marketing and business development	950	21,600
Total stock-based compensation	$ 433,004	$ 68,458

At December 31, 2022, there was approximately $111,357 of unrecognized compensation expense related to non-vested stock option awards that are expected to be recognized over a weighted-average period of 2.2 years. At December 31, 2022, there was approximately $50,859 of unrecognized compensation expense related to non-vested restricted stock awards that are expected to be recognized over a weighted-average period of 2.1 years.

9. RELATED PARTY TRANSACTIONS

Lana Management and Business Research International, LLC

Lana Management and Business Research International, LLC ("LMBRI") has board members in common with the Company. The Company and LMBRI entered into an Expense Sharing Agreement, whereby the Company will reimburse LMBRI monthly for certain shared expenses including insurance, rent, salaries, telephone, and other miscellaneous expenses. The Company was billed $4,000 monthly for these expenses through December 31, 2021. On January 1, 2022, the Company moved into its own leased facility and no longer shared expenses with LMBRI Such amounts are included in general and administrative expenses on the accompanying consolidated statements of operations. The Company also issued Subordinated Notes and Warrants to LMBRI in October 2020 as described in Note 4.

The table below summarizes the amounts incurred, paid, and balances due to LMBRI as of and for year's ended December 31, 2022 and 2021.

	2022	2021
Expenses from LMBRI	$ -	$ 48,000
Expense Sharing Agreement payments to LMBRI	$ -	$ 171,102
Amounts payable to LMBRI	$ 2,000	$ 2,000
Interest Incurred and Payments on Subordinated Notes to LMBRI (Note 4)	$ -	$ 3,303

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%. NanoHybrids is wholly owned by the Company's Chief Technology Officer. The table below summarizes the amounts earned and due from NanoHybrids for the years ended December 31, 2022 and 2021 and balances due as of December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Income from NanoHybrids included in Other Income	$ 163,256	$ -
Cash receipts from NanoHybrids	$ 143,525	$ -

	As of December 31,	
	2022	2021
Amounts receivable from NanoHybrids included in Prepaids and Other Current Assets	$ 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.

10. SUPPLEMENTAL BALANCE SHEET INFORMATION

Prepaid expenses and other current assets consist of the following:

	December 31, 2022	December 31, 2021
Prepaid insurance	$ 751,979	$ 1,127,062
Prepaid clinical trial expenses	-	160,467
Vendor prepayments	681,218	160,000
Prepaid other	240,283	165,179
Total prepaid expenses and other current assets	$ 1,673,480	$ 1,612,708

Accrued expenses and other current liabilities consist of the following:

	December 31, 2022	December 31, 2021
Accrued personnel costs	$ 533,577	$ 157,938
Accrued other	302,153	181,446
Total accrued expenses and other current liabilities	$ 835,730	$ 339,384

11. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2022 and 2021:

		December 31,	
	Depreciable lives	2022	2021
Construction in process		$ 375,466	$ 15,078
Furniture, fixtures, and equipment	3-5 years	136,942	24,915
Software	3 years	4,457	4,619
Lab equipment	3-5 years	1,268,380	741,591
Leasehold improvements	Life of lease	43,231	-
		1,828,476	786,203
Less: accumulated depreciation		(596,406)	(448,837)
Property and equipment, net		$ 1,232,070	$ 337,366

12. LEASES

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

	Year ended December 31, 2022
Weighted average remaining lease term – operating leases (in years)	3.7
Weighted average remaining lease term – finance leases (in years)	5.1
Weighted average discount rate	7.0%
Operating cash flows from operating leases	$ 149,770

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

	December 31, 2022
Operating lease right-of-use asset	$ 465,514
Finance lease asset included in property & equipment, net	21,067
Total lease assets	486,581
Current portion of operating lease liability	168,706
Current portion of finance lease liability included in accrued expenses	4,807
Non-current operating lease liabilities	323,915
Non-current finance lease liabilities included in other non-current liabilities	15,823
Total lease liabilities	$ 513,251

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

Year	
2023	$ 168,706
2024	162,991
2025	100,000
2026	100,000
2027	25,000
Thereafter	-
Total future lease payments	556,697
Less: Imputed interest	64,076
Present value of lease liability	$ 492,621

13. 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. No goods have been received under this arrangement as of December 31, 2022.

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, the total open non-cancellable commitments for the manufacturing line buildout totaled approximately $375,000.

As of December 31, 2022, the Company has entered into other non-cancelable purchase commitments primarily for R&D supplies and key advisory services. The purchase commitments covered by these agreements are for less than one year and aggregate to approximately $700,000.

Minimum Royalties

As required under the License Agreement (see Note 3), following the first sale of Cartridges, the Company will also make royalty payments to Toray equal to 15% of the net sales of the Cartridges for the period that any underlying patents exist or for 5 years after the first sale. Following the first sale, the Company will pay a one-time minimum royalty of $60,000, which shall be creditable against any royalties owed to Toray in such calendar year. The Company will pay a minimum royalty of $100,000 in each year thereafter, which are creditable against any royalties owed to Toray in such calendar year. There were no sales of or revenues from the Cartridges through December 31, 2022.

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.

14. INCOME TAX

No provision for federal income taxes has been recorded for the years ended December 31, 2022 and 2021 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,	
	2022	**2021**
Deferred tax assets:		
Net operating losses	$ 3,043,585	$ 1,791,043
Tax credits	190,489	3,659
Intangible assets	66,716	68,564
Capitalized R&D expenses	1,018,165	-
Fixed assets	37,580	-
Other	272,106	97,945
Total deferred tax assets	4,628,641	1,961,211
Valuation allowance	(4,628,641)	(1,934,351)
Net deferred tax assets	$ -	$ 26,860
Deferred tax liabilities:		
Fixed assets	-	(26,860)
Net deferred tax assets	$ -	$ (26,860)

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 2022 and 2021 is as follows:

	Year Ended December 31,	
	2022	**2021**
Federal statutory rate	21.00%	21.00%
State income taxes, net of federal benefit and tax credits	6.86%	5.41%
Change in valuation allowance	(29.06)%	(25.88)%
Permanent differences	1.20%	(0.53)%
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 net deferred tax assets. During the years ended December 31, 2022 and 2021, 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, 2022 and 2021 will not be realized given the Company's history of operating losses. The valuation allowance against deferred tax assets increased by approximately $2.7 million and $900,000 and during 2022 and 2021, respectively, related mainly to a full valuation allowance recorded against capitalized research expenditures, additional net operating losses and tax credits generated in the year.

At December 31, 2022, the Company had federal net operating loss carryforwards of approximately $11.2 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 2022 totaling $10.5 million can be carried forward indefinitely.

As of December 31, 2022, the Company had post-apportioned state net operating losses of $10.9 million that can generally be carried forward 20 years and will expire at various dates through 2042. As of December 31, 2021, the Company had post-apportioned Massachusetts net operating losses of $6.3 million that can generally be carried forward 20 years and will expire at various dates through 2041.

The Tax Cuts and Jobs Act resulted in significant changes to the treatment of research or experimental ("R&E") expenditures under Section 174. For tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize all R&E expenditures that are paid or incurred in connection with their trade or business which represent costs in the experimental or laboratory sense. Specifically, costs for U.S. based R&E activities must be amortized over five years and costs for foreign R&E activities must be amortized over 15 years; both using a midyear convention. The Company has implemented this standard on January 1, 2022, noting that the impact on the Company's consolidated financial statements was immaterial.

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 20, 2023

By:/s/ Neil Dey
Neil Dey
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, Kenneth Fisher, 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 20, 2023

By:/s/ Kenneth Fisher
Kenneth Fisher
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, 2022, 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 20, 2023

By:/s/ Neil Dey
Neil Dey
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, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kenneth Fisher, 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 20, 2023

By:/s/ Kenneth Fisher
Kenneth Fisher
Chief Financial Officer
(Principal Financial and Accounting Officer)