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, 2021
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 Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 ☒

As of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, the registrant's securities were not publicly traded. The registrant's common stock began trading on The Nasdaq Stock Market LLC on November 10, 2020.

The registrant had 20,151,244 shares of the Common Stock outstanding at February 28, 2022.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders to be filed within 120 days of the registrant's fiscal year ended December 31, 2021 and is incorporated by reference in Part III 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 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 annual report on 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.

PART I

ITEM 1. BUSINESS

Overview

We are a late-stage pre-revenue company focused on improving patient outcomes through a more cost efficient, rapid, near patient product for triage, diagnosis and monitoring of disease progression. We believe there is a market need for an on-site and rapid diagnostic system that can be employed for testing and monitoring. Our diagnostic system, which we refer to as "Symphony," is an exclusively licensed, patented, low-cost, system that consists of a small footprint instrument and single-use indication specific test cartridges, that we believe, if cleared, authorized, or approved by the U.S. Food and Drug Administration ("FDA"), can provide a solution to this market need rapidly and with laboratory quality results in approximately 24 minutes, in the clinic, Intensive Care Unit ("ICU"), Emergency Room ("ER") and in other hospital and clinical setting settings where rapid and reliable results are required. Currently, testing is generally performed in a laboratory, and the transportation and logistics of transporting the samples to the lab and obtaining the result takes between 8-48 hours. Our platform is a sample-to-result system that has been shown in a clinical study to provide results in approximately 24 minutes. Our business model is to generate revenue from the sale of the table-top Symphony instrument, and from the sale of single-use indication specific cartridges that are used by the Symphony instrument for the diagnostic test. Once the test material (generally a small volume blood sample) is transferred to a single-use indication specific Symphony cartridge, no additional sample preparation or pre-processing is required. Based on the results of the clinical study described below, we believe Symphony may be able to eliminate the time required for transportation and logistics, and may be able to eliminate the number of operational 'touch-points' from 'sample-to-result' from six to two.

Our technology is the result of more than 12 years of development by our development partner and investor, Toray Industries, Inc. ("Toray"). For the past three years, Toray has used the technology successfully in Japan by selected clinical institutions for measurement of Interleukin-6 ("IL-6") in rheumatoid arthritis to monitor disease progression. Based in part on this extensive development, we believe we are now positioned to complete the last stages of development needed for commercialization in the US.

In a 2016 study conducted in Japan (the "Japan Study"), which was sponsored by Toray, it was shown that the Symphony system (known as the RAY-FAST system in Japan) can provide accurate results within 24 minutes. The Japan Study was conducted at the University of Yamanashi Hospital in Yamanashi, Japan to evaluate the accuracy and efficacy of the Symphony system in rheumatoid arthritis patients. The results of the study were published in Cytokine, "Development of a quick serum IL-6 measuring system in rheumatoid arthritis" (Volume 95. July 2017). In the Japan Study, 150 blood samples were collected from 76 rheumatoid arthritis patients, of which 16 samples were lower than the detection limit of the Symphony system. The Japan Study then examined the correlation between the results from the Symphony system and the chemiluminescent enzyme immunoassay (CLEIA) method. The serum IL-6 concentrations measured by the Symphony system were positively correlated with those measured by the CLEIA method. The correlation between the Symphony system and CLEIA method for IL-6 was $r = 0.941$ (the closer the r-value is to 1, the more closely the two variables are related). As such, the Japan Study concluded that the Symphony system was as accurate as CLEIA methods. In addition, the Japan Study confirmed the time required for the measurement of the IL-6 concentration to be 24 minutes.

Our first diagnostic test in development is for triage of sepsis in patients utilizing IL-6 as the target biomarker. According to a report by Market Data Forecast (February 2020), the total market for IL-6 testing for sepsis triage was $934 million in 2020 and is estimated to reach $1.4 billion by 2025 growing at a CAGR of 8.5%. IL-6 has important roles in both innate and adaptive immunity. It is an inflammatory biomarker, also considered as a 'first-responder,' that is elevated in patients with infection, sepsis, and septicemia. Reports have shown IL-6 concentrations correlate with severity of sepsis, progression of cancer, rheumatoid arthritis and many other severe conditions as defined by clinical and laboratory parameters. IL-6 is a clinically established biomarker for assessment of severity of infection and inflammation across many disease indications. IL-6 appears early in the blood circulation as a 'first responder' during infection or inflammation. One factor that is a challenge for healthcare professionals to overcome is the amount of time it takes to determine if a patient is septic. It usually takes about several hours to receive the lab results of a patient who may be in a very critical state, and the risk of dying increases every hour a patient is not treated for sepsis. We believe early measurement of IL-6 can enable physicians to make better therapeutic and treatment decisions. Due to its clinical significance hospital systems and centralized testing labs routinely utilize IL-6 testing.

The importance of IL-6 testing has been further highlighted during the COVID-19 pandemic, and IL-6 concentrations in blood have been found to be elevated in patients with COVID-19-associated systemic inflammation and hypoxic respiratory failure.

We are further developing a pipeline of diagnostic tests for Symphony including triage of myocardial infarction ("MI"), congestive heart failure ("CHF"), neutropenic sepsis in cancer, and other disease diagnostic indications using the same Symphony platform. We intend to pursue the general diagnostic marketplace following a sufficient clinical trial to support a 510(k) submission with the FDA, with the initial indication as a general diagnostic test for sepsis in triage of patients. We do not currently have any regulatory clearance for our Symphony products and our Symphony products will need to receive regulatory authorization from FDA, in order to be marketed as a diagnostic product in the United States.

Our operations to date have been funded primarily through sales of preferred stock and convertible notes. We expect to incur increasing expenses over the next two years to develop additional diagnostic tests, to expand our sales and marketing infrastructure, and our research and development activities. We believe the proceeds from our Initial Public Offering ("IPO") on November 10, 2021 will be sufficient to reach commercialization.

We were incorporated under the laws of Delaware on March 20, 2015. Our headquarters are located in Acton, Massachusetts.

Symphony Advantages

We believe there is a fast-growing market for near-patient, low-cost diagnostic platforms that are used for time-sensitive patient testing in life-threatening situation in hospitals, Long-Term Acute Care facilities ("LTACs"), intensive-care units ("ICUs") and clinics to replace legacy testing formats and processes. We believe our platform is well positioned to meet this need. Based on the results of the Japan Study, we believe Symphony may be able to provide results within approximately 24 minutes. In addition, based on the results of the Japan Study, we believe Symphony may be able to reduce test result time from days to minutes and to provide results that appear to be as accurate as those performed in a laboratory, allowing for more frequent testing, which we believe may lead to shortened hospital stays and improved patient outcomes, all of which also leads to reduced patient care costs.

Symphony is an automated diagnostic system, consisting of a fluorescence immuno-analyzer which uses a single-use diagnostic test cartridge with reagents integrated in the cartridge. Symphony utilizes a 'sample-to-result' format, which means that once a specimen is taken from the patient, it is placed in the cartridge and then the cartridge is placed inside the analyzer where the test is run without further technician intervention or additional reagent. This reduces test complexity and eliminates the need for highly trained and expensive laboratory technicians to run the tests. Our platform is designed to enable simple, rapid, and cost-effective analysis from a single clinical sample, which will allow LTACs, hospitals and clinics that traditionally could not afford more expensive or complex diagnostic testing platforms to modernize their laboratory testing and provide better patient testing at an affordable cost in time sensitive, life-threatening situations. We believe our on-site testing may also help avoid potential penalties often imposed on LTACs by insurance companies for failure to monitor for potential sepsis.

Based on the results of the Japan Study, we believe Symphony IL-6 can make a significant impact with turn-around time. As the whole blood samples do not need to be pre-processed, this medical device can be run at the patient's bedside, effectively eliminating the extended turn-around time for lab results.

If incorporated in the hospital workflow, this medical device can provide assistance with monitoring patients post-surgery, and monitoring patients admitted in the emergency room who are suspected to have acute symptoms of sepsis.

We believe our technology can provide the following advantages over traditional diagnostic systems:

- *Ease of Use*. Symphony is a sample-to-results system. No sample preparation or pre-processing is required. Once the samples are placed inside the cartridge and the cartridge is placed in the analyzer, the technician does not need to monitor the test and can complete other unrelated tasks.

- *Cost Savings*. We believe that the Symphony system and our expected pricing strategy will make it possible for LTACs, clinics and many types of hospitals that have cost constraints to adopt in-house testing. Our customers will be able to either purchase the analyzer or lease it at an affordable price through a third-party leasing company. A typical Symphony test would cost approximately $80 (the cost of the single-use cartridge to the health-care facility) compared to the approximately $275 per test charged by a third-party lab, excluding overhead and transportation cost.

- *Time Savings*. Saving pre-processing time for samples reduces time to test results by approximately 1-2 hours depending on the pre-processing required for a particular assay system. Furthermore, as current tests can only be performed in a laboratory, the transportation and logistics of transporting the samples to the lab and obtaining the result takes between 8-48 hours. Based on the results of the Japan Study, we believe Symphony may be able to eliminate the time required for transportation and logistics and may be able to eliminate the number of operational 'touch-points' from 'sample-to-result' from six to two.

- *Space Savings*. Symphony's significantly smaller tabletop design (14.5 inches by 10.5 inches), compared to the 100-200 square feet of space required by other diagnostic systems, will make it possible for many healthcare providers to perform in-house testing where there is limited available laboratory space.

- *Versatile Platform with the Capability to Deliver a Broad Test Menu*. Our Symphony platform has the potential for broad application across a number of areas in near-patient diagnostic testing. The same analyzer can be utilized for all of our planned future diagnostic tests.

- *Throughput and Multiple Testing Capability*. Our platform has been designed to provide the ability to analyze up to six distinct targets or six different patient samples simultaneously within approximately 24 minutes. This functionality will allow any organization to run multiple tests or panels on a single analyzer.

Our Market

According to research published by Allied Market Research (Global Invitro Diagnostics Market, 2020-2027), the global in vitro diagnostics market was $67.1 billion in 2019; projected to reach $91.1 billion by 2027, a compound annual growth rate ("CAGR") of 4.8% over 7 years driven by prevalence of chronic diseases including cancer, autoimmune diseases, and other inflammatory conditions. We believe the Symphony sample-to-result platform is well suited to address a subset of this market, including sepsis, cardio-metabolic diseases, cancer and other diseases that require time-sensitive, near-patient testing.

According to a report by Market Data Forecast (February 2020), the total market for IL-6 testing for sepsis triage was $934 million in 2020 and is estimated to reach $1.4 billion by 2025 growing at a CAGR of 8.51%. Our platform is designed to provide on-site and rapid test results, with no pre-processing of the blood, and as such, we intend to pursue the following markets for triage:

- *Sepsis Triage using IL-6*. According to the CDC, each year, at least 1.7 million adults in America develop sepsis and nearly 270,000 Americans die as a result of sepsis. In the United States, 1 in 3 patients who dies in a hospital has sepsis. In addition, in 2016, according to the National Center for Health Statistics, 8.3 million people were served by LTACs. A major responsibility of these LTAC facilities is to monitor sepsis. We estimate the potential total market for sepsis triage testing in LTACs is approximately $2–$3 billion annually. Septic shock and multi-organ failure were the most common cause of death in COVID-19 patients, often due to suppurative pulmonary infection.

- *Chest Pain Triage using hsTNT and NT-proBNP.* According to a Washington Post article in April 2019, there are 7.6 million people in the United States each year who visit or are admitted to the hospital with chest pain. Research suggests that about 50% of those patients are admitted for further observation and care of potential heart disease, and that approximately 3.6 million people annually needed cardiac triage. Two major biomarkers that are assessed to diagnose and monitor cardiac irregularities are hsTNT and NT-proBNP. These clinically established biomarkers generated approximately $4.6 billion in revenue in 2019 and will continue to grow with a CAGR of 11.2% through 2027. We are developing diagnostic tests for triage situations, using these cardiac biomarkers (hsTNT and NT pro-BNP), which were approximately a $3.6 billion market in 2020 and are estimated to be $5.5 billion by 2025, a CAGR of 8.9% (report by Markets and Markets, January 2021).

The CDC National Center for Health Statistics estimates that the market for the diagnostic cardiac triage tests will increase by more than 20% per year over the next several years. Many factors are driving the growth of these markets, particularly the accelerating adoption of near-patient testing inside hospitals, LTACs and ICUs. According to the 2021 edition of American Hospital Association Hospital Statistics, there were approximately 6,090 hospitals in the United States in 2019, approximately 5,000 of which are considered community hospitals. According to outside research, fewer than half of these facilities have the capabilities, technology and products for near-patient diagnoses for triage of either sepsis or cardiac conditions. We believe these facilities are candidates for our diagnostic platform.

Our Business Model

Our goal is to become a leading provider of sample-to-result, 'near-patient' diagnostic testing in infectious, inflammatory and metabolic diseases by leveraging the strengths of our Symphony platform. We intend to market the use of Symphony by targeting our sales and marketing to LTACs, clinics, and community hospitals in the United States. We believe that the format of our low-cost, 'near-patient' platform will be attractive to these institutions which may not otherwise have the financial resources, laboratory space, or trained personnel to justify the purchase of a diagnostic solution. Our business model relies on the following:

- *Attractive Financing Model*. We intend to provide our customers the ability to lease our analyzer at an affordable cost through third-party financial institutions. As such, our business model will not require a significant capital outlay by health care facility customers and, by moving testing in-house, will create a profit center for the facility.

- *Recurring Revenue*. We intend to sell our customers disposable, single-use diagnostic test cartridges. Our single-use test cartridges will create a growing and recurring revenue stream for us as we sell more systems, 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.

- *Expand our Menu of Diagnostic Products.* If adoption increases, we believe the average customer use of the Symphony platform will begin to increase. As we expand our test menu, we believe we will be able to increase our annual revenue per customer through the resulting increase in utilization. To that end, we are in development on a broad menu of diagnostic tests that we believe will satisfy growing medical needs and present attractive commercial opportunities.

- *Increase our revenue and reduce our cost of sales through a 'waterfall' sales strategy*. Our proprietary test cartridges and Symphony analyzers are manufactured through our agreements with Toray and Sanyoseiko Co., Ltd. ("Sanyoseiko"), thus reducing the manufacturing cost structure. They currently build our Symphony system and test cartridges and currently purchase materials at high per unit cost due to low purchase volumes. We believe that by focusing our initial sales efforts on multi-location institutions, increased adoption and utilization of Symphony may lead to increasing sales within a relatively small customer base. We believe sales within those institutions may lower our salesforce costs. We believe the increased unit sales of our Symphony and cartridges will not only increase revenue, but will also allow us to reduce manufacturing costs and improve gross margins enhancing our ability to provide a lower cost solution to customers.

Our Symphony Platform

Symphony

The Symphony platform is an innovative and proprietary technology platform that in the Japan Study appeared to provide rapid and accurate measurements of key diagnostic biomarkers found in whole blood. Symphony is compact and portable as compared with current laboratory diagnostic platforms that we believe, based on the Japan Study, provide comparable sensitivity. In the Japan Study, Symphony appeared to provide lab-quality results in a near-patient setting. Symphony is designed for usability; all sample preparation and reagents are integrated into the disposable Symphony Cartridges. Symphony only needs a few hundred femtograms (10^{-10} grams) of the target to provide quantitation directly from whole blood. Therefore, Symphony only requires a few drops of blood to generate a result in approximately 24 minutes.

Symphony is comprised of the Symphony Fluorescence Immuno-analyzer and the Symphony Cartridge Library, shown in Figure 1. 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, enabling 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.

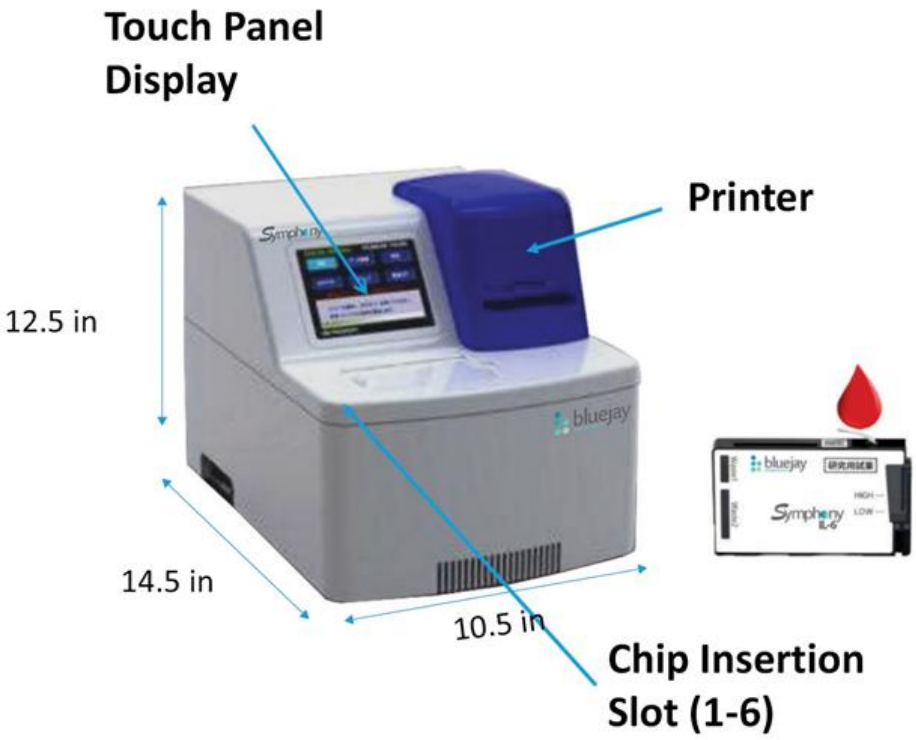

Figure 1. Photograph of the Symphony Fluorescence Immuno-analyzer and a Symphony IL-6 Cartridge. Barcode reader (not pictured) is included to streamline clinical workflow.

Although our first commercial offering will be focused on the detection and quantitation of IL-6, we believe the flexibility of our technology will allow us to deploy new biomarkers for additional indications. Every Symphony Cartridge inserted in the analyzer has a unique code which programs the Symphony to perform the specific test. This unique feature will enable the release of new tests without the need for system redesigns or updates. Furthermore, this automated feature will eliminate the need for system recalibrations for every product lot, further streamlining the clinical workflow and enhancing usability.

The Symphony IL-6 test principle employs direct sandwich Enzyme Linked Immunosorbent Assay (“ELISA”) for the quantitation of human IL-6 by fluorescence enzyme immunoassay (“FEIA”), as shown in Figure 2. Within the single-use Symphony IL-6 Cartridge, the assay separates plasma from whole blood and forms complexes through reaction of any IL-6 present in the sample with highly specific IL-6 binding antibodies. After the IL-6 sandwich is formed, a fluorescent substrate is enzymatically decomposed to generate fluorescent molecules. The fluorescence intensity is measured and converted to IL-6 concentration, and the entire process is enclosed within the Symphony IL-6 Cartridge and is controlled and measured by the Symphony Fluorescence Immuno-analyzer.

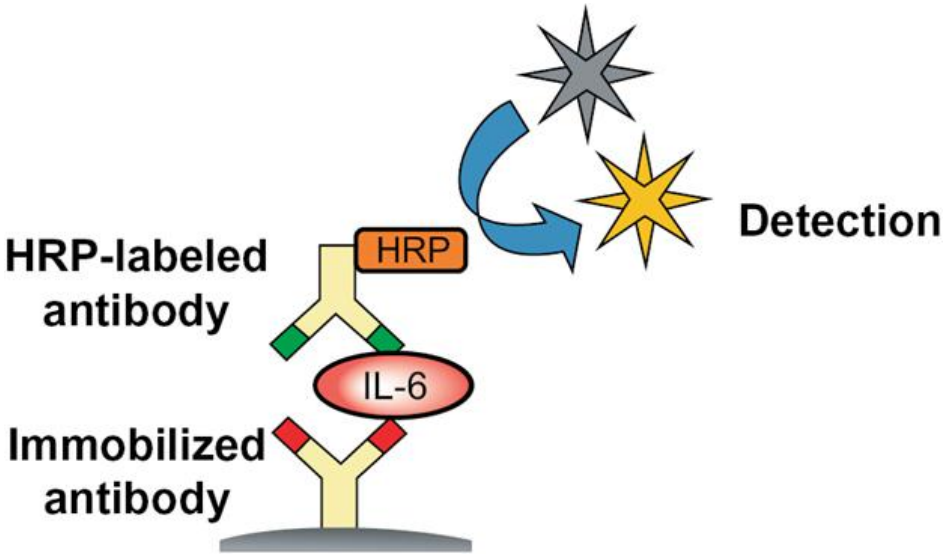

Figure 2. Overview of the Symphony IL-6 test principle.

The Symphony Test Cartridge

To perform a Symphony test, the test operator adds three drops of blood to the Symphony Cartridge. The volume does not have to be precise because the cartridge is able to work with a range of 0.1 — 0.2 cc, which can be visualized with a fill-gauge on the Symphony Cartridge as shown in Figure 3. After scanning in the patient ID, the Symphony Cartridge is inserted into the Symphony and the test proceeds automatically. Up to six Symphony Cartridges can be tested simultaneously, enabling up to six different patients or six different biomarkers to be tested at once on a single machine. In approximately 24 minutes, the measurement results are produced, and a clinical decision can be made.

The disposable cartridge contains the reagents required to run the applicable test. The three steps of the test (sample preparation, chemical reaction, and detection) are performed in chambers present on the cartridge. All waste is collected in a chamber in the cartridge significantly reducing the risk of lab contamination that is often cited as a concern of molecular diagnostic testing. After the test is completed and the result is obtained, the cartridge is disposed of with the hospital’s other medical waste.

Figure 3. Photograph of the Symphony IL-6 Cartridge loaded with a whole blood specimen.

Manufacturing

We plan to manufacture both our devices and cartridges through Contract Manufacturing Organizations ("CMOs"). We have contracts with Toray to manufacture our cartridges and Sanyoseiko to manufacture both our devices and cartridges. Pursuant to our agreement with Toray, we are required to use Toray to manufacture test cartridges for a period of three years. We believe both companies are well-known and well-established global manufacturing companies with capabilities to scale up, re-design and supply our devices and cartridges globally when needed. Therefore, we believe we will have the capability to supply globally, when required. Both Toray and Sanyoseiko facilities are located in Japan.

We outsource our manufacturing due to a number of factors; including,

- The cost of initiating and scaling in-house manufacturing is capital intensive,
- It would take significant time to establish our own manufacturing facilities,
- It would take significant time to obtain necessary certifications by regulatory authorities; and
- There would be a significant personnel and maintenance costs to maintain production in compliance with regulations.

In the first quarter of 2021, we established Sanyoseiko as our large-scale contract manufacturing organization. Toray will continue to develop, validate and manufacture our current IL-6 cartridges and other cartridges in our product pipeline as our pilot-manufacturing partner.

Regulatory Strategy

We license the technology for Symphony from Toray. Our license grants us exclusive world-wide use with the exception of Japan. Toray started developing the Symphony (known as RAY-FAST in Japan) to complement one of its sepsis related products for blood purification during sepsis. Development of RAY-FAST begin in 2006. For the past 3-4 years, RAY-FAST has been used successfully in Japan by selected clinical institutions for measurement of IL-6 in rheumatoid arthritis to monitor disease progression for the purpose of clinical validation, efficacy, monitoring potential adverse conditions reporting, robustness, durability and customer feedback on usability.

Our initial regulatory pathway is to label and distribute Symphony as an Research Use Only, or RUO product in the U.S. An RUO product is an in-vitro diagnostic device that is in the laboratory research phase of development. RUO devices are not authorized for use in clinical or diagnostic applications. However, it is possible that certain laboratories may choose to independently utilize the RUO Symphony as part of their own Laboratory Developed Test, or LDT. An LDT is a type of *in vitro* diagnostic test that is designed, manufactured and used within a single laboratory. In parallel, we are pursuing 510(k) clearance from FDA to use Symphony for *in vitro* diagnostic use.

Symphony IL-6

Our Symphony IL-6 product candidate is intended for early and rapid identification of sepsis during Emergency Department ("ED"), critical care triage, and neutropenic sepsis in oncology patients. Our Symphony IL-6 product candidate is also intended for monitoring disease progression during such treatment regimen.

We are conducting a multi-center clinical study at The University of Texas, Southwestern Medical Center (William P. Clements Jr. University Hospital (CUH) and Zale Lipshy Pavilion Hospital) and Parkland Memorial Hospital under a single protocol. Our clinical study will involve:

- A reference range study. For the reference range study, 120 subjects will be enrolled to achieve at a minimum 100 qualified data points for the statistical analysis. The reference range (2.5^{th} to 97.5^{th} centile) will be estimated using parametric methods. Parametric methods will be used to calculate the 95% confidence intervals for the reference limits. Nonparametric estimates of the reference limits with confidence intervals will be computed as a sensitivity analysis.

- A cutoff value study. For the cutoff value study, 96 subjects will be enrolled to achieve at a minimum 80 qualified data points for the statistical analysis. For the cutoff value study, the Receiver Operating Characteristic ("ROC") curve will be estimated. The ideal cutoff, which gives a point on the ROC curve that is closest to the (0.1) point, will be selected based on the results from this study.

- A cutoff validation study. For the cutoff validation study, 48 patients will be enrolled into the study to achieve at a minimum 40 qualified data points. Clinical sensitivity, clinical specificity, positive predictive value, negative predictive value, and corresponding 95% confidence intervals will be calculated using the cutoff value determined from the cutoff value study.

In parallel to these studies, we intend to capture the necessary analytical data required for FDA submission. These studies will be performed using patient samples with natural IL-6 and will be performed in accordance with the Clinical & Laboratory Standards Institute ("CLSI") guidelines.

We plan to start clinical studies at other clinical sites to support additional indications and possibly additional FDA premarket submissions. In addition to ICUs, we plan to add both adult and pediatric oncology patients. We plan to perform blood collections by both venipuncture and capillary collection, which includes both finger stick and heel stick, in our studies so we can support these indications for use.

Blood collection for pediatric patients is often faced with many challenges due to their limited supply of blood and the difficulty of performing venipuncture collections. We believe the small amount of blood needed for Symphony will be very attractive for pediatric healthcare. Furthermore, we have planned in our clinical studies to include finger stick and heel stick blood collection to further reduce the clinical burden of performing tests in pediatric patients.

We submitted a pre-submission application to the FDA presenting our study design and the data from our first set of studies. We will use their feedback, if necessary, to modify the ongoing studies and to construct the FDA clearance application. We plan to submit our FDA clearance application at the end of the third quarter of 2022.

The importance of IL-6 testing has been further highlighted during the COVID-19 pandemic, and IL-6 concentrations in blood have been found to be heightened in patients with COVID-19-associated systemic inflammation and hypoxic respiratory failure. If clinical studies are successful, our Symphony IL-6 product candidate could also be used with confirmed COVID-19 illness to aid in determining the risk of intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing. In our ongoing clinical studies, we have performed prospective Symphony IL-6 tests on the whole blood of 90 subjects admitted to either William P. Clements Jr. University Hospital, Zale Lipshy Pavilion Hospital, or Parkland Memorial Hospital with confirmed COVID-19, confirmed by an FDA Emergency Use Authorization, or EUA PCR SARS-CoV-2 test. Once completed, we believe our planned study design can be used to apply for an EUA for use with confirmed COVID-19 illness to aid in determining the risk of intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing. There is no assurance that we will be successful in obtaining EUA for this indication.

Symphony hsTNT/I and NT-proBNP

We have two other product candidates that are in development: (i) hsTNT/I for myocardial injury or myocardial infarction (MI) and (ii) NT-proBNP for cardiac heart failure ("CHF"). These product candidates will follow a similar regulatory pathway as identified for our Symphony IL-6 product candidate which we believe will result in obtaining 510(k) clearance for diagnostic use.

For the clinical trial, we plan to have both retrospective samples and prospective subjects to power the study to have a statistically significant result. For retrospectively collected samples, we will utilize clinical information recorded during the original sample collection. For prospectively collected samples, clinical information will be collected initially during admission or ER triage, and will be considered as baseline samples. Clinical information will also be collected on discharge, shift or admission to ICU. Our clinical plan also allows us to monitor ER or admitted patients during their treatment regimen.

Sales and Marketing

Initially, we plan to have four major sales territories; Northeast, Northwest, Central (South central and North central) and West (North west and South west). These territories will be served and supported by territory sales managers and technical sales support managers. A centralized sales and technical support team will support the regional groups. We intend to focus our initial sales efforts on the large institutions, hospitals, and LTACs that operate multiple facilities and therefore might purchase multiple units. This 'Waterfall' strategy, focusing on sales within those institutions, may lower salesforce costs.

Our sales representatives will typically have experience in molecular diagnostic testing and a network of customer contacts within their respective territories. We will utilize our teams' knowledge along with market research databases to target and qualify our customers. We intend to execute a variety of sales campaigns and strategies to meet the buying criteria of the different customer segments we intend to pursue.

In the United States, our sales cycle will typically include customer evaluations, a decision to use our platform and then validation of our platform. Upon successful validation a hospital or reference lab may choose to become a customer. The analyzer will be available to the customer by purchase or third-party lease for their use with our diagnostic test. The customer will buy our proprietary test cartridge from us and utilize one disposable test cartridge each time they run a diagnostic test.

We have deployed the Symphony and test cartridges in the United States in selected medical institutions and LTAC facilities for evaluation. Our goal is to convert these facilities into paying customers if we receive FDA authorization.

Customers

Our initial focus is on the following types of customers:

Medical Institution and Hospitals with Intensive Care Unit (ICUs): ICUs treat patients with severe or life-threatening illnesses and injuries, which require constant care, close supervision from life support equipment and medication to ensure normal bodily functions. ICUs are staffed by highly trained physicians, nurses and respiratory therapists who specialize in caring for critically ill patients. ICUs are also distinguished from general hospital wards by a higher staff-to-patient ratio and access to advanced medical resources and equipment that is not routinely available elsewhere. The types of patients typically seen in ICUs are those with acute and advanced respiratory distress syndrome, septic shock, and patients requiring support for an acute reversible failure of one or more organs.

Long-term Acute Care facilities (LTACs): LTACs are facilities that specialize in the treatment of patients with serious medical conditions that require care on an on-going basis but no longer require intensive care or extensive diagnostic procedures. These patients are typically discharged from the intensive care units and require more care than they can receive in a rehabilitation center, skilled nursing facility, or at home. The types of patients typically seen in LTACs include those requiring prolonged ventilator use or weaning, ongoing dialysis for chronic renal failure, intensive respiratory care, multiple IV medications or transfusions, and complex wound care/care for burns.

Outpatient Clinics: A clinic (or outpatient or ambulatory care clinic) is a health care facility that is primarily focused on the care of outpatients. Clinics can be privately operated or publicly managed and funded. They typically cover the primary care needs of populations in local communities. Typical large outpatient clinics house general medical practitioners such as doctors and nurses to provide ambulatory care and some acute care services including patient triage for sepsis and cardiac patients. The types of patient care they perform include blood tests, triage with chest pain complaints, triage with septic shock, biopsies, chemotherapy, colonoscopy, CT scan, mammograms, minor surgical procedures, radiation treatments, ultrasound imaging and x-rays.

License Agreement

We have an exclusive license with Toray for the entire world, excluding Japan, to use their patents and know-how related to Symphony and the detection cartridges for the manufacturing, marketing and sale of the products (as defined in the agreement). We also have a nonexclusive license for the same purposes in Japan. The term of this license agreement extends until the expiration of all the patents associated with the licensed patent rights, which are between 2029 and 2036. If we do not generate commercial sales within five years of the date of the license, Toray has the right to terminate the agreement or make it non-exclusive. In addition, we are required to make commercially reasonable efforts to obtain market approval for the products in the United States and the European Union by October 2023. Pursuant to the agreement, we are required to use Toray to manufacture the sample cartridges. The agreement terminates upon expiration of the last of the patents included in the license.

In connection with entering into the agreement, we paid Toray $240,000 in licensing fees. We are required to pay a 15% royalty fee for the period that any underlying patents exist or for 5 years after the first sale for the licensing of this technology 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 our license agreement with Toray of patent, copyright, trade secret, trademark, confidentiality agreements, and contractual protection to establish and protect our proprietary rights. We have licensed U.S. Patent Nos. 8,409,447 (“the ‘447 patent”) and 8,821,813 (“the ‘813 patent”). The ‘447 patent is valid through at least February 2029 and is generally directed to a separation chip and a method for separating an insoluble component from a suspension with the separation chip. The ‘813 patent is valid through at least March 2028 and is generally directed to a liquid-feeding chip, a liquid feeding method and analysis method. We have also licensed use or process patents covering the inventions and/or subject matter of the ‘447 and ‘813 patents in various international territories including Japan, Canada, China, Europe and South Korea, which are valid through at least February 2027.

These measures may not be adequate to safeguard the technology underlying our products. For example, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries, as many countries do not offer the same level of legal protection for intellectual property as the United States. Furthermore, for a variety of reasons, we may decide not to file for patent, copyright or trademark protection outside of the United States. Our trade secrets could become known through other unforeseen means. Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology. Our competitors may also develop similar products without infringing on any of our intellectual property rights or design around our proprietary technologies. Furthermore, any efforts to enforce our proprietary rights could result in disputes and legal proceedings that could be costly and divert attention from our business. We could also be subject to third-party claims that we require additional licenses for our products, and such claims could interfere with our business. If our products infringe the intellectual property rights of others, we could face costly litigation, which could cause us to pay substantial damages and limit our ability to sell some or all of our products. Even if our products were determined not to infringe the intellectual property rights of others, we could incur substantial costs in defending any such claims.

Competition

Our primary competition is laboratory size equipment including the Roche Cobas®, Siemens ADVIA Centaur® and Beckman Coulter Access 2®.

Our competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales and distribution organizations than we do. Our competitors also offer broader product lines and have greater brand recognition than we do. Moreover, our existing and new competitors may make rapid technological developments that may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue. We may encounter potential customers that, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. There can be no assurance that competitors, many of which have made substantial investments in competing technologies, will not prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

Government Regulation

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

FDA Regulation

Research Use Only Technologies

Symphony will initially be commercialized as an RUO tool in the United States. RUO products belong to a separate regulatory classification under a long-standing FDA regulation. From an FDA perspective, products that are intended for research use only and are labeled as RUO are not regulated by the FDA as *in vitro* diagnostic devices and are therefore not subject to the regulatory requirements discussed below for clinical diagnostic products. Thus, RUO products may be used or distributed for research use without first obtaining FDA clearance, authorization or approval. The products must bear the statement: "For Research Use Only. Not for Use in Diagnostic Procedures." RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and they cannot be intended by the manufacturer for human clinical diagnostic use. Accordingly, a product labeled RUO but intended or promoted for clinical diagnostic use may be viewed by the FDA as false or misleading and thereby adulterated and misbranded products under the Federal Food, Drug, and Cosmetic Act ("FDCA") and subject to FDA enforcement action. The FDA's 2013 Guidance for Industry and Food and Drug Administration Staff on "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only," explains that the FDA will consider the totality of the circumstances surrounding distribution and use of an RUO product, including how the product is marketed and to whom, when determining its intended use. Merely including a labeling statement that a product is intended for research use only will not necessarily exempt the device from the FDA's 510(k) clearance, premarket approval, or other requirements, if the circumstances surrounding the distribution of the product indicate that the manufacturer intends its product to be used for clinical diagnostic use. These circumstances may include written or verbal marketing claims or links to articles regarding a product's performance in clinical applications, a manufacturer's provision of technical support for clinical validation or clinical applications, or solicitation of business from clinical laboratories, all of which could be considered evidence of intended uses that conflict with RUO labeling. If the FDA disagrees with a company's RUO status for its product, the company may be subject to FDA enforcement activities, including, without limitation, removal of the product, or requiring the company to seek clearance, authorization or approval for the products.

Medical Devices

Generally, *in vitro* diagnostic 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 *in vitro* diagnostic devices ("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 approval of a premarket approval ("PMA") application.

After a medical device is placed on the market, numerous regulatory requirements apply. These include:

- compliance with the FDA's QSR, which requires manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;

- labeling regulations, which prohibit the promotion of products for uncleared, or unapproved uses, or "off-label" uses, and impose other restrictions on labeling; and

- obligations to investigate and report to the FDA adverse events, including deaths, or serious injuries that may have been or were caused by a medical device and malfunctions in the device that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include sanctions, including but not limited to, warning letters; fines, injunctions, and civil penalties; recall or seizure of the device; operating restrictions, partial suspension or total shutdown of production; refusal to grant 510(k) clearance, *de novo* authorization, or approval of a PMA application for new devices; withdrawal of clearance, authorization, or approval; and civil or criminal prosecution.

Premarket Authorization and Notification

While most Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a PMA application prior to marketing, generally applicable to Class III devices; or (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class II and some Class I devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because FDA has not yet called for PMAs for these devices. Other less common regulatory pathways to market medical devices include Emergency Use Authorization or the EUA process which is only available during public health emergencies, humanitarian device exception ("HDE") or a product development protocol ("PDP").

510(k) Notification

Product development in the U.S. for most Class II and limited Class I devices typically follows a 510(k) pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the predicate device. A predicate device may be a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications. The manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

There are three types of 510(k)s: traditional; special, for devices that are modified and the modification needs a new 510(k) but the modification does not affect the intended use or alter the fundamental scientific technology of the device; and abbreviated, for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review. The FDA intends to process special 510(k)s within 30 FDA days of receipt, and abbreviated 510(k)s within 90 FDA days of receipt. The clearance pathway for traditional 510(k)s can, however, take from four to 12 months, or even longer if FDA has questions during the review.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a *de novo* authorization approval of a PMA application. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance, *de novo* authorization, or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance, *de novo* authorization, or PMA approval is obtained.

During the review of a 510(k) submission, the FDA may request more information or additional studies and may decide the indications for which we seek clearance should be limited. In addition, laws and regulations and the interpretation of those laws and regulations by the FDA may change in the future. We cannot foresee what effect, if any, such changes may have on us.

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.

PMA Application

A product not eligible for 510(k) clearance or de novo authorization must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction.

Results from adequate and well-controlled clinical trials are required to establish the safety and effectiveness of a Class III PMA device for each indication for which FDA approval is sought. After completion of the required clinical testing, a PMA including the results of all preclinical, clinical, and other testing, and information relating to the product's marketing history, design, labeling, manufacture, and controls, is prepared and submitted to the FDA.

The PMA approval process is generally more expensive, rigorous, lengthy, and uncertain than the 510(k) premarket notification process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the QSR requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The FDA's review of a PMA application typically takes one to three years, but may last longer. If the FDA's evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and/or placement of restrictions on the sale of the device until the conditions are satisfied.

Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

EUA Process

The program for authorizations of products through an Emergency Use Authorization ("EUA") is established when the Secretary of Health and Human Services declares a public health emergency. This process remains in effect only as long the declared public health emergency is in effect. An EUA authorization is granted by FDA using similar analytical and clinical validation metrics similar to what may be required for 510(k), PMA or de novo authorizations but are based on a reduced amount of data. The process to obtain an EUA typically consists of two phases, an initial Pre-EUA submission that is used to identify and resolve any significant problems that would preclude issuance of an EUA and a final EUA submission. The final EUA submission addresses the details that the FDA will require to demonstrate that the Symphony IL-6 test will have acceptable analytical and clinical performance. FDA has granted EUA for the Roche Elecsys IL-6 test, the Siemens ADVIA Centaur IL-6 test and the Beckman Coulter Access IL-6 test. FDA publishes summaries of the testing performed to support these EUAs, which will serve as guidance as we prepare our EUA. There are no required timelines for review and authorization of an EUA. Moreover, FDA has prioritized those IVD EUA that the agency will review to include molecular and antigen tests that may be used at the POC or completely at home; the manufacturer has the capacity to scale up to a production of >500,00 tests per week within 3 months of authorization; or tests that are from or supported by US government stakeholder, e.g. BARDA or NIH's RADx program. For serology tests, FDA intends to focus on quantitative and neutralizing antibody tests. There is no guarantee that the Symphony IL-6 assay will be a priority for FDA review.

Clinical Trials of Medical Devices

Clinical trials are almost always required to support a PMA, are often required for a de novo authorization, and are sometimes required for 510(k) clearance. Clinical trials may also be conducted or continued to satisfy post-approval requirements for devices with PMAs. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an Investigational Device Exemption ("IDE") application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing it is safe to test the device on humans and 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 the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board ("IRB") has approved the study.

During any study, the sponsor must comply with the applicable portions of FDA's IDE requirements. These requirements include investigator selection, trial monitoring, adverse event reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements.

A nonsignificant risk device does not require FDA approval of an IDE; however, the clinical trial must still be conducted in compliance with various requirements of FDA's IDE regulations and be approved by an IRB at the clinical trials sites. We, the FDA, or the IRB at each institution at which a clinical trial is being conducted may suspend a clinical trial at any time for various reasons, including a belief the subjects are being exposed to an unacceptable risk. During the approval, authorization, or clearance process, the FDA may inspect the records relating to the conduct of one or more investigational sites participating in the study supporting the application.

Even if a trial is completed, the results of clinical testing may not demonstrate the safety and effectiveness of the device, may be equivocal or may otherwise not be sufficient to obtain approval, authorization, or clearance of the product.

Sponsors of applicable clinical trials of devices 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. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Post-Approval Regulation of Medical Devices

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

- the FDA QSR, which applies to manufacturers, developers, and contract manufacturers, and governs, among other things, how manufacturers design, test manufacture, exercise quality control over, and document manufacturing of their products;
- establishment registration and device listing
- corrections and removal reporting regulations, which require that manufactures report to FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a risk to health;
- labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- the Medical Device Reporting regulation, which requires reporting to the FDA of certain adverse experience associated with use of the product.

We will continue to be subject to inspection by the FDA to determine our compliance with regulatory requirements. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted; and
- criminal prosecution.

QSR Requirements

Manufacturers of medical devices are required to comply with FDA quality system requirements set forth the QSR. The QSR requires, among other things, establishment of a quality system and processes for design and development and manufacturing controls as well as the corresponding maintenance of records and documentation. Certain adverse events and malfunctions with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or in product withdrawal. Product approvals, authorizations, or clearances may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or effectiveness of the product occurs following the approval, authorization, or clearance. We will use contract manufacturers to manufacture our products for the foreseeable future. We will, therefore, be dependent on their compliance with these requirements to market our products. We work closely with our contract manufacturers to assure our products are in strict compliance with these regulations.

Export Regulations

Medical devices that are legally marketed in the United States may be exported anywhere in the world without prior FDA notification or approval. Devices that have not been approved or cleared in the United States must follow the export provisions of the FDCA. Depending on which section of the FDCA we may export under, we may need to request an export permit letter or export certificate, or we may need to submit a simple notification. Export certificates may be requested by foreign customers or foreign governments to provide proof of the products' status as regulated by the FDA. The export certificate is prepared by FDA and contains information about a product's regulatory or marketing status in the United States.

Clinical Laboratory Improvement Amendments of 1988

The use of our products is also affected by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and related federal and state regulations, which provide for regulation of laboratory testing. Any customers using our products for clinical use in the United States will be regulated under CLIA, which establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. In particular, these regulations mandate that clinical laboratories must be certified by the federal government or a federally approved accreditation agency, or must be located in a state that has been deemed exempt from CLIA requirements because the state has in effect laws that provide for requirements equal to or more stringent than CLIA requirements. Moreover, these laboratories must meet quality assurance, quality control and personnel standards, and they must undergo proficiency testing and inspections. The CLIA standards applicable to clinical laboratories are based on the complexity of the method of testing performed by the laboratory, which range from "waived" to "moderate complexity" to "high complexity."

Laboratory-developed tests.

The FDA considers LDTs to be tests that are designed, developed, validated and used within a single laboratory. The FDA historically has taken the position that it has the authority to regulate such tests as medical devices under the FDC Act but has for the most part exercised enforcement discretion and has not required clearance, authorization, or approval of LDTs prior to marketing. Rather, in place of premarket clearance or approval and other medical device general and special controls, the agency has relied on the certification of the laboratory under CLIA to ensure the quality and validity of the tests.

Under present FDA enforcement discretion, most LDTs currently do not require premarket clearance or approval. Instead, LDTs are generally subject to CLIA regulations, provided that:

1. the tests must be developed and validated by a laboratory certified by CLIA as capable of performing high complexity tests;

2. the developed LDT may be requested only on the order of a physician or other licensed health care provider;

3. the technological characteristics of the LDT are not so complex or potentially misunderstood by users such that the technology alone creates a significant health risk to patients;

4. the LDT is not marketed directly to consumers; and

5. the LDT does not present a specific patient or population risk such that FDA determines that enforcement discretion is not warranted or appropriate.

Foreign Government Regulation

We intend to market our products in European and other select international markets. The regulatory pre-market requirements for molecular devices vary from country to country. Some countries impose product standards, packaging requirements, labeling requirements and import restrictions on devices. Each country has its own tariff regulations, duties and tax requirements. Failure to comply with applicable foreign regulatory requirements may subject us to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. For products sold in the European Economic Area, we have self-declared a Declaration of Conformity under the relevant sections of the applicable European Community standards and other normative documents.

Fraud and Abuse Regulations

We are subject to numerous federal and state health care anti-fraud laws, including the federal anti-kickback statute and False Claims Act that are intended to reduce waste, fraud and abuse in the health care industry. These laws are broad and subject to evolving interpretations. They prohibit many arrangements and practices that are lawful in industries other than health care, including certain payments for consulting and other personal services, some discounting arrangements, the provision of gifts and business courtesies, the furnishing of free supplies and services, and waivers of payments. In addition, many states have enacted or are considering laws that limit arrangements between medical device manufacturers and physicians and other health care providers and require significant public disclosure concerning permitted arrangements. These laws are vigorously enforced against medical device manufacturers and have resulted in manufacturers paying significant fines and penalties and being subject to stringent corrective action plans and reporting obligations. If we are ever accused of violating them, we could be forced to expend significant resources on investigation, remediation and monetary penalties.

Patient Protection and Affordable Care Act

Our operations will be affected by the federal Patient Protection and Affordable Care Act of 2010, as modified by the Health Care and Education Reconciliation Act of 2010, which we refer to as the Health Care Act. Among other things, the Health Care Act requires manufacturers to report to HHS detailed information about financial arrangements with physicians, teaching hospitals and certain other categories of health care providers. These reporting provisions preempt state laws that require reporting of the same information, but not those that require reports of different or additional information. Failure to comply subjects the manufacturer to significant civil monetary penalties.

Health Insurance Coverage and Reimbursement

Our ability to successfully commercialize our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidates.

In the United States, third-party payors continue to implement initiatives that restrict the use of certain technologies to those that meet certain clinical evidentiary requirements. In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used.

Employees

As of December 31, 2021, we have nine full-time employees. We also contract with several consultants and contractors performing public relations, investor relations, and accounting functions. 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. We make available free of charge through the Investors Relations section of our website 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 as soon as reasonably practicable after such material is electronically filed with or furnished to the U.S. Securities and Exchange Commission. 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.

ITEM 1A. RISK FACTORS

Risk Factor Summary

The following summary highlights the material risks that may affect our business, operating results, financial condition and prospects, as more fully described in the pages that follow this summary.

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 preparation for commencing regulatory trials. We have no approved products, have not yet generated revenue, and we cannot guarantee we will ever be able to generate 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 $3.5 million and $1.2 million for the years ended December 31, 2021 and 2020, 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. We expect that our current cash position will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. Thereafter, unless we achieve profitability, 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 shareholders. 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.

Risks Related to Our Business

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 have an exclusive license with Toray for the entire world, excluding Japan, to use their patents and know-how related to our Symphony platform and 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.

- For a period of three years, we are required to purchase test cartridges from Toray. Accordingly, we will not have unfettered right to select our suppliers, regardless of whether an unauthorized supplier could provide products on better pricing, delivery, quality or other terms, thus potentially materially and adversely impacting those aspects of our business, economies, profitability and prospects.

- 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.

- If we do not generate commercial sales within five years of the date of the license, Toray has the right to terminate the agreement or make it non-exclusive.

- 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 annual report.

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.

Our future performance will depend on the continued engagement of key members of our management team.

Our future performance depends to a large extent on the continued services of members of our current management. 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 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. 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.

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 contract manufacturers 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 an approved 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 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 clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations.

Our Symphony IL-6 product candidate is currently being distributed as a research use only product. The FDA could disagree with this distribution 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, our Symphony IL-6 is currently labeled and sold 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 the 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 business model 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.

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 are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain Good Manufacturing Practices ("cGMP"), 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.

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 may not be able to satisfy the continued listing requirements of the NASDAQ Capital Market in order to maintain the listing of our common stock.

We must meet certain financial and liquidity criteria to maintain the listing of our common stock on the NASDAQ Capital Market. If we fail to meet any of continued listing standards, our common stock may be delisted. In addition, while we have no present intention to do so, our Board of Directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A 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.

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.

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 directors, officers and certain existing stockholders entered into lock-up agreements pursuant to which, subject to certain exceptions, such persons will not sell shares of our common stock (including common stock underlying options and warrants) that they own for six months after the date of our IPO. As of December 31, 2021 the shares covered by the lock-up these agreements totaled 9,837,737. Notwithstanding the foregoing, the lock-up provisions in these agreements may be waived, at any time and without notice by the representative of the underwriter of our IPO.

Subject to the lock-up agreements, 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 are be obligated to develop and maintain a system of effective internal control over financial reporting. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may harm investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in the annual report we file with the SEC for the year ending December 31, 2022. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, our auditors will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act, if we take advantage of the exemptions available to us through the JOBS Act. Even after we cease to be an "emerging growth company," our auditors will not be required to formally attest to the effectiveness of our internal control over financial reporting unless we are an accelerated filer or a large accelerated filer (as defined under the Exchange Act).

We are in the very early stages of the costly and challenging process of compiling the system and process documentation necessary to perform the evaluation needed to comply with Section 404. In this regard, we will need to continue to dedicate internal resources, 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. As we transition to the requirements of reporting as a public company, we may need to add additional finance staff. We may not be able to complete our evaluation and testing in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. We may not be able to remediate any material weaknesses in a timely fashion. If we are unable to complete our evaluation and testing, or if we are unable to assert that our internal control over financial reporting is effective, particularly if we have been unable to remediate any material weaknesses identified, or if or our auditors, when required to do so, are unable to express an opinion that our internal controls are effective, investors could lose confidence in the accuracy and completeness of our financial reports, which could harm our stock price.

We have incurred increased costs as a result of operating as a public company and our management has been required to devote substantial time to new compliance initiatives and corporate governance practices. Moreover, our ability to comply with all applicable laws, rules and regulations is uncertain given our management's relative inexperience with operating United States public companies.

As a public company, and particularly after we are no longer an "emerging growth company," we have incurred significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the listing requirements of the NASDAQ Market and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. Furthermore, new or changing laws, regulations and standards are 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, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

Moreover, our executive officers have little experience in operating a United States public company, which makes our ability to comply with applicable laws, rules and regulations uncertain. Our failure to company with all laws, rules and regulations applicable to United States public companies could subject us or our management to regulatory scrutiny or sanction, which could harm our reputation and stock price.

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 the board deems relevant. 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 ("Stock Split").

Holders of Common Stock

As of February 28, 2022, we had 20,151,244 shares of common stock outstanding held by approximately 10 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.

Recent Sales of Unregistered Securities

The following sets forth information regarding all unregistered securities sold by us during the year ended December 31, 2021. In June 2021, we entered into an agreement to issue a total of $4.5 million of 7.5% Senior Secured Convertible Debentures (the "Debentures"), of which $3.0 million in principal amount of the Debentures were issued at closing and $1.5 million in principal amount of the Debentures were issued in August 2021. At the time of our initial public offering, the Debentures were converted into our Series D Preferred Stock at a conversion price of $1,000 per share which were subsequently converted in common stock shares prior to December 31, 2001. The foregoing issuances were made to an accredited investor in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act.

Use of Proceeds from Initial Public Offering

On November 15, 2021, we closed our initial public offering of 2,160,000 units at a price to the public of $10.00 per unit. The gross proceeds from our initial public offering, before deducting underwriting discounts and commissions, were $21.6 million. We granted the underwriter in the offering a 45-day option to purchase up to an additional 324,000 shares of common stock and/or Class A Warrants and/or Class B Warrants from the Company. The underwriter partially exercised the foregoing option to purchase an additional 324,000 Class A Warrants and 324,000 Class B Warrants. The offer and sale of all of the securities in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-260029), which was declared effective by the SEC on November 9, 2021. Dawson James Securities, Inc. acted as underwriter for the offering.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on November 12, 2021 pursuant to Rule 424(b).

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 Annual Report on 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 late-stage pre-revenue company focused on improving patient outcomes through a more cost efficient, rapid, near patient product for triage, diagnosis and monitoring of disease progression. We believe there is a market need for an on-site and rapid diagnostic system that can be employed for testing and monitoring. Our diagnostic system, which we refer to as "Symphony," is an exclusively licensed, patented, low-cost, system that consists of a small footprint instrument and single-use indication specific test cartridges, that we believe, if cleared, authorized, or approved by the U.S. Food and Drug Administration ("FDA"), can provide a solution to this market need with rapid laboratory quality results in approximately 24 minutes, in the clinic, Intensive Care Unit ("ICU"), Emergency Room ("ER") and in other hospital and clinical setting settings where rapid and reliable results are required. Currently, testing is generally performed in a laboratory, and we estimate that the transportation and logistics of transporting the samples to the lab and obtaining the result takes between 8-48 hours. Our platform is a sample-to-result system that has been shown in a clinical study to provide results in 24 minutes. Our business model is to generate revenue from the sale of the table-top Symphony instrument, and from the sale of single-use indication specific cartridges that are used by the Symphony instrument for the diagnostic test. Once the test material (generally a small volume blood sample) is transferred to a single-use indication specific Symphony cartridge, no additional sample preparation or pre-processing is 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 $3.5 million, and $1.2 million for the years ended December 31, 2021 and 2020, respectively. We had negative cash flow from operating activities of approximately $4.4 million and $0.5 million for the years ended December 31, 2021 and 2020, respectively, and had an accumulated deficit of approximately $7.8 million as of December 31, 2021.

Results of Operations

Comparison of Years Ended December 31, 2021 and 2020

The following table sets forth our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 1,147,955	$ 527,253
General and administrative	1,792,482	596,116
Marketing and business development	289,726	73,022
Total operating expenses	3,230,163	1,196,391
Operating loss	(3,230,163)	(1,196,391)
Other income (expense):		
Gain on forgiveness of note payable, Paycheck Protection Program	5,000	102,000
Derivative warrant liability gain (loss)	9,676	(42,434)
Interest expense, net of amortization of premium	(367,459)	(26,997)
State grant revenue	75,000	-
Other income	19,648	5,537
Total other income (expense), net	(258,135)	38,106
Net loss	$ (3,488,298)	$ (1,158,285)

Research and Development

Research and development expenses increased approximately $621,000, or 118%, for the year ended December 31, 2021, as compared to the same period of 2020. The increase was primarily due to expenses incurred totaling approximately $522,000 in connection with the clinical trials and manufacturing costs related to the Symphony analyzers.

General and Administrative

General and administrative expenses increased approximately $1.2 million, or 201%, for the year ended December 31, 2021, as compared to the same period of 2020. The increase was primarily attributable to increased operating expenses related to the company's transition from a private to public company, including the addition of accounting, legal and audit related expenses totaling approximately $670,000. In addition, expenses related to employee compensation and benefits increased by approximately $309,000 due to an increase in general and administrative headcount. Expense for expiring inventory of approximately $85,000 was recorded in 2021, versus no such expense recorded during 2020.

Marketing and Business Development

Marketing and business development expenses increased approximately $217,000, or 297%, for year end December 31, 2021, as compared to the same period of 2020. The increase was primarily attributable to increased expenses of approximately $218,000 paid to employees and consultants to expand the commercialization of our Symphony platform.

Derivative Warrant Liability Gain (Loss)

Derivative warrant liability gain (loss) increased by approximately $52,000, or 123%, for the year ended December 31, 2021 as compared to the same period of 2020, resulting from the revaluation of the Series B Warrants accounted for as liability until their reclassification into equity in June 2021.

Interest Expense, Net of Amortization of Premium

Interest expense increased by approximately $340,000, or 1,261%, for the year ended December 31, 2021 as compared to the same period of 2020. The increase was primarily related to the amortization of discount and accrued interest on the Convertible Debentures issued in 2021 totaling approximately $266,000 and $125,000, respectively. This was partially offset by the lower interest expense recognized on the note payable issued in 2017 of $51,000 and increased premium amortization on the note payable issued in 2017 of approximately $29,000 driven by the conversion of those notes payable into common stock.

Grant Income

Grant income increased by approximately $75,000, or 100%, for the year ended December 31, 2021 as compared to the same period of 2020. The increase was due to a $75,000 grant received from Massachusetts Growth Capital Corporation

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, 2021, we had cash and cash equivalents of approximately $19.0 million. As of February 28, 2022, we had cash and cash equivalents of approximately $18.0 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,	
	2021	**2020**
Cash proceeds provided by (used in):		
Operating activities	$ (4,366,758)	$ (508,710)
Investing activities	(23,947)	-
Financing activities	22,526,122	1,325,060
Net increase in cash and cash equivalents	$ 18,135,417	$ 816,350

Net cash used in operating activities

During 2021, we used $4.4 million in cash for operating activities, an increase of $3.9 million, as compared to approximately $509,000 in 2020. The increase in the net cash used in operations was primarily due to approximately $500,000 increase in cash paid for personnel costs, approximately $600,000 increase in cash paid for certain design services for the Symphony machine, $240,000 increase in cash paid to Toray for licensing fees, and $1.6 million increase in cash spent on Directors and Officers insurance premiums due to our change from a private to a public company.

Net cash used in investing activities

During 2021, we used approximately $24,000 in cash for investing activities, a 100% increase from 2020. The increase in cash used in investing activities was primarily due to the purchase of lab equipment to support the development of the symphony product line.

Net cash provided by financing activities

During 2021, we generated $22.5 million in cash from financing activities, as compared to $1.3 million in 2020. The $21.2 million increase in cash generated from financing activities was primarily due to our initial public offering 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.

Liquidity

We believe that our available cash resources will be sufficient to fund our planned operations and capital expenditure requirements for at least twelve months from the date of this Annual Report on Form 10-K is filed with the SEC. This evaluation is based on relevant conditions and events that are currently known or reasonably knowable. However, our forecast is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Our future capital requirements will depend on many factors, including:

- the costs and timing associated with the development and commercialization of our Symphony analyzers and additional diagnostic tests;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights; and
- the costs and any production constraints of our key contract manufacturers.

As a result, we could deplete our available capital resources sooner than we currently expect. We expect to continue to incur net losses for the foreseeable future and believe we will need to raise substantial additional capital to accomplish our business plan over the next several years. In order to fund continued business development, to generate sales, to invest in further research and development and to otherwise satisfy obligations as they mature, we may need to seek additional financing equity and/or debt financing. Additional funding, however, may not be available to us on acceptable terms, or at all. If we are unable to access additional funds when needed, we will not be able to continue the development of our platform and our tests, or we could be required to delay, scale back or eliminate some or all of our research and development programs and other operations. Any additional equity financing, if available to us, may not be available on favorable terms, will most likely be dilutive to our current stockholders, and debt financing, if available, may involve restrictive covenants. Any of these events could harm our business, financial condition and prospects.

Recent Financings

Series B Redeemable, Preferred Stock

In 2020, we issued 456 shares of Series B redeemable, preferred stock ("Series B") and 68 Series B warrants for gross proceeds of $50,000.

Subordinated Notes

On October 22, 2020, we issued $154,000 of 8% subordinated promissory notes ("Subordinated Notes") to related party shareholders, as well as warrants to purchase 1,154,000 (prior to the stock dividend) shares of common stock at $0.10 per share, exercisable in cash or through cancellation of the notes.

Series C Redeemable, Preferred Stock

In November 2020, we issued 636 shares of Series C redeemable, convertible preferred stock ("Series C") at a purchase price of $1,578.50 per share and received proceeds, net of issuance costs of approximately $995,000.

Paycheck Protection Program Loan

In 2020, we received loan proceeds of $116,000 from a Paycheck Protection Program loan ("PPP loan"). In November 2020, we received notice of forgiveness of $102,000 of principal of the PPP loan and, in February 2021, we received an adjustment which increased the forgiven balance by approximately $5,000 and repaid the $9,000 related to the unforgiven balance.

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 "Debentures") to Sabby Volatility Master Fund, Ltd ("Sabby"), of which $3.0 million of the Debentures were issued at closing. The agreement provides for the purchase by Sabby of an additional $1.5 million of the Debentures after we file a registration statement for an initial public offering. On August 4, 2021 we issued an additional $1.5 million in principal amount of the Debentures to Sabby.

Initial Public Offering

We completed our initial public offering ("IPO") on November 10, 2021 ("IPO Date"), whereby we sold 2,160,000 Units, 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 Unit was sold at a price of $10.00. Each warrant contained within the Units is exercisable until the fifth anniversary of the IPO date. Additionally, the underwriter exercised its overallotment option to purchase 324,000 of Class A and Class B Warrants. The gross proceeds from the IPO were approximately $21.6 million. The offering costs related to the IPO were approximately $2.8 million.

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. The Company recognizes 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

In August 2020, FASB issued ASU 2020-06, Debt — *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity,* which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, this ASU modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in this ASU are effective for public companies for fiscal years beginning on or after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company elected to adopt early this guidance in the first quarter of 2021. The adoption of this standard had no material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

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 Company is currently evaluating the adoption date of this ASU and the impact, if any, adoption will have on its financial position and results of operations.

In February 2016, the Financial Accounting Standards Board ("FASB") issued 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. We 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 our consolidated statements of operations or cash flows.

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 Annual Report on Form 10-K on pages F-1 through F-22.

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, 2021. 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, 2021.

Management's Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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, 2021, 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 2022 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

Our Board of Directors has adopted a written Code of Business Conduct and Ethics applicable to all officers, directors and employees, which is available on our website (bluejaydx.com) under "Governance Overview" within the "Investor Relations" section. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of this Code and by posting such information on the website address and location specified above.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is hereby incorporated by reference to our definitive proxy statement for our 2022 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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 2022 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans at December 31, 2021:

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)	589,786	$ 1.86	1,943,269
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 and 2021 Stock Plans.
(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 2022 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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 2022 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2021.

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 Annual Report on 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 Annual Report, which list is incorporated by reference in this Item.

(b) See the accompanying Index to Exhibits filed as a part of this Annual Report.

(c) Other schedules are not applicable.

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 10, 2022.

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 10, 2022
/s/ Gordon Kinder Gordon Kinder	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2022
/s/ Douglas C. Wurth Douglas C. Wurth	Chairman of the Board of Directors	March 10, 2022
/s/ Donald R. Chase Donald R. Chase	Director	March 10, 2022
/s/Svetlana Dey Svetlana Dey	Director	March 10, 2022
/s/Fred S. Zeidman Fred S. Zeidman	Director	March 10, 2022
/s/ Gary Gemignani Gary Gemignani	Director	March 10, 2022

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, 2021 and 2020, 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, 2021 and 2020, 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.

Basis for Opinion

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

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

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

/s/ Wolf & Company, P.C.

We have served as the Company's auditor since 2017.
Boston, Massachusetts
March 10, 2022

Bluejay Diagnostics, Inc.
Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,047,778	$ 912,361
Inventory	-	84,762
Prepaid expenses and other current assets	1,612,708	61,071
Total current assets	20,660,486	1,058,194
Property and equipment, net	337,366	459,138
Other non-current assets	21,019	-
Total assets	$ 21,018,871	$ 1,517,332
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 295,778	$ 374,928
Due to related party	2,000	125,102
Accrued expenses and other current liabilities	339,384	133,820
Notes payable, net	-	1,041,186
Note payable, Paycheck Protection Program	-	14,725
Derivative warrant liability	-	155,629
Total liabilities	637,162	1,845,390
Commitments and Contingencies (See Note 13)		
Series A redeemable, convertible preferred stock, $0.0001 par value; 10,600 shares authorized; 0 and 10,600 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	1,077,303
Series B redeemable, convertible preferred stock, $0.0001 par value; 5,918 shares authorized; 0 and 5,187 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	1,800,347
Series C redeemable, convertible preferred stock, $0.0001 par value; 636 shares authorized; 0 and 636 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	1,000,465
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 100,000,000 shares authorized; 20,112,244 and 3,147,200 shares issued and outstanding at December 31, 2021 and 2020, respectively	2,011	315
Additional paid-in capital	28,074,484	-
Accumulated deficit	(7,694,786)	(4,206,488)
Total stockholders' equity (deficit)	20,381,709	(4,206,173)
Total liabilities, redeemable, convertible preferred stocks and stockholders' equity (deficit)	$ 21,018,871	$ 1,517,332

See notes to consolidated financial statements.
Reflects a 1-for-3.15 stock dividend effective June 7, 2021.

Bluejay Diagnostics, Inc.
Consolidated Statements of Operations

	For the Years Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 1,147,955	$ 527,253
General and administrative	1,792,482	596,116
Marketing and business development	289,726	73,022
Total operating expenses	3,230,163	1,196,391
Operating loss	(3,230,163)	(1,196,391)
Other income (expense):		
Gain on forgiveness of note payable, Paycheck Protection Program	5,000	102,000
Derivative warrant liability gain (loss)	9,676	(42,434)
Interest expense, net of amortization of premium	(367,459)	(26,997)
State grant income	75,000	-
Other income	19,648	5,537
Total other income (expense), net	(258,135)	38,106
Net loss	$ (3,488,298)	$ (1,158,285)
Net loss per share - Basic and diluted	$ (0.41)	$ (0.37)
Weighted average common shares outstanding:		
Basic and diluted	8,522,422	3,147,200

See notes to consolidated financial statements.
Reflects a 1-for-3.15 stock dividend effective June 7, 2021.

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, 2019	**10,600**	**$ 892,809**	**4,732**	**$ 1,575,321**	**-**	**$ -**	**-**	**$ -**	**3,147,200**	**$ 315**	**$ -**	**$ (2,932,753)**	**$ (2,932,438)**
Issuance of Series B redeemable, convertible preferred stock, net of issuance costs of $4,570	-	-	455	160,228	-	-	-	-	-	-	-	-	-
Issuance of Series C redeemable, convertible preferred stock, net of issuance costs of $8,776	-	-	-	-	636	994,832	-	-	-	-	-	-	-
Reclassification of derivative warrant liability	-	-	-	(16,787)	-	-	-	-	-	-	-	-	-
Accretion of redeemable, convertible preferred stock to redemption value	-	184,494	-	81,585	-	5,633	-	-	-	-	(156,262)	(115,450)	(271,712)
Allocation of proceeds to common stock warrants	-	-	-	-	-	-	-	-			148,892		148,892
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	7,370	-	3,730
Net loss	-	-	-	-	-	-		-	-	-	-	(1,158,285)	(1,158,285)
Balance at December 31, 2020	**10,600**	**$ 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	-	-	-	-	-	-	-	-	2,160,000	216	18,855,663	-	18,855,879

in initial public offering, net of offering costs of $2,750,601													
Issuance of common stock from exercise of warrants	-	-	-	-	-	-	-	-	2,368,500	237	(237)	-	-
Net loss	-	-	-	-	-	-	-	-	-		-	(3,488,298)	(3,488,298)
Balance at December 31, 2021	**-**	**$ -**	**-**	**$ -**	**-**	**$ -**		**-**	**20,112,244**	**$ 2,011**	**$28,074,484**	**$ (7,694,786)**	**$ 20,381,709**

See notes to consolidated financial statements.
Reflects a 1-for-3.15 stock dividend effective June 7, 2021.

Bluejay Diagnostics, Inc.
Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (3,488,298)	$ (1,158,285)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	145,719	157,039
Stock-based compensation expense	68,458	7,370
Issuance of warrants for service	180,339	-
Gain on forgiveness of note payable, Paycheck Protection Program	(5,000)	(102,000)
Non-cash interest expense	227,007	(51,530)
(Gain) loss on revaluation of derivative warrant liability	(9,676)	42,434
Changes in operating assets and liabilities:		
Accounts receivable	-	645
Inventory	84,762	38,746
Prepaid expenses and other current assets	(1,551,637)	19,106
Non-current assets	(21,019)	-
Accounts payable	(79,150)	345,803
Due to related party	(123,102)	39,097
Accrued expenses	204,839	152,865
Net cash used in operating activities	**(4,366,758)**	**(508,710)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(23,947)	-
Net cash used in investing activities	(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	-
Proceeds from issuance of Series B redeemable, convertible preferred stock, net of issuance costs	-	60,228
Proceeds from issuance of Series C redeemable, convertible preferred stock, net of issuance costs	-	994,832
Proceeds from subscription to the 2020 Promissory Notes	-	154,000
Proceeds (payments) on note payable, Paycheck Protection Program	(9,000)	116,000
Proceeds from exercise of common stock warrants	9,079	-
Proceeds from exercise of stock options	22,623	-
Net cash provided by financing activities	**22,526,122**	**1,325,060**
Increase in cash and cash equivalents	18,135,417	816,350
Cash and cash equivalents, beginning of year	912,361	96,011
Cash and cash equivalents, end of year	$ 19,047,778	$ 912,361
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH FINANCING ACTIVITIES		
Interest paid	$ 150,228	$ 53,240
Accretion of Series A redeemable, convertible preferred stock dividend	$ 17,667	$ 42,400
Accretion of Series A redeemable, convertible preferred stock issuance costs and fair value adjustment	$ 56,245	$ 143,094
Accretion of Series B redeemable, convertible preferred stock dividend	$ 31,258	$ 74,018
Accretion of Series B redeemable, convertible preferred stock issuance costs	$ 2,736	$ 6,567
Accretion of Series C redeemable, convertible preferred stock dividend	$ 16,727	$ 4,619
Accretion of Series C redeemable, convertible preferred stock issuance costs	$ 3,234	$ 1,014
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	$ 16,787
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	$ -
Relative fair value of warrants for common stock issued in connection with notes payable	$ -	$ 148,892
Fair value of warrants issued to underwriters	$ 2,939,327	$

See notes to consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Bluejay Diagnostics, Inc. (the "Company"), which commenced its activities on March 20, 2015, is incorporated under the laws of the State of Delaware.

The Company is a diagnostic company that aims to develop and market a more cost efficient, rapid, near patient product for triage, diagnosis and monitoring of disease progression

The Company is utilizing the Symphony technology platform and Symphony IL-6 test licensed from Toray Industries, Inc. of Japan (see Note 3). The Company is also developing biomarkers for detection of other diseases such as hsTNT/I for myocardial injury and NT-proBNP for cardiac heart failure .

The Company's ALLEREYE diagnostic test ("ALLEREYE") is a POC device that offers healthcare providers a cost effective, reliable, easy to use solution for diagnosis of Allergic Conjunctivitis. ALLEREYE received clearance by the U.S. Food and Drug Administration (the "FDA") in October 2017.

On June 4, 2021, the Company created Bluejay Spinco, LLC, ("SpinCo") a wholly owned subsidiary of the Company, for purposes of further development of ALLEREYE. The Company transferred assets and liabilities related to ALLEREY to SpinCo in accordance with the Contribution and Assumption Agreement. The assets and liabilities were transferred from the Company to SpinCo at their carrying value. The Company is responsible for the operational activities of SpinCo and bears all costs necessary to operate SpinCo. The Company's CEO is also the CEO of SpinCo and oversees the business strategy and operations of SpinCo.

Initial Public Offering

The Company completed its initial public offering ("IPO") on November 10, 2021 ("IPO Date"), whereby it sold 2,160,000 Units, 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 Unit was sold at a price of $10.00. 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 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 resulting 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 industries, including rapid technological change, competition from larger biotechnology companies and dependence on key personnel.

The extent of the impact of the COVID-19 pandemic on the Company's business continues to be highly uncertain and difficult to predict, as the responses that the Company, other businesses and governments are taking continue to evolve. Furthermore, capital markets and economies worldwide have also been negatively impacted by the COVID-19 pandemic, and it is possible that it could cause a lasting national and/or global economic recession. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole. The extent to which the COVID-19 pandemic may in the future materially impact the Company's financial condition, liquidity or results of operations is uncertain.

Liquidity

Since its inception, the Company has devoted substantially all of its efforts to business planning, business development, research and development, and raising capital. The income potential of the Company's business and market are unproven. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. As of December 31, 2021, the Company had $19.0 million in cash and cash equivalents.

The Company believes it has sufficient cash to meet its funding requirements for at least the next 12 months from the issuance of this report. However, the Company has experienced net losses and negative cash flows from operating activities since its inception and has an accumulated deficit of $7.7 million as of December 31, 2021. The Company expects to continue to incur net losses for the foreseeable future and believes it will need to raise substantial additional capital to accomplish its business plan over the next several years. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of equity offerings, debt financings and generating revenue from sales to customers. If the Company is not able to secure adequate additional funding or generate sufficient revenue, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future.

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 (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 ("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 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 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. The Company maintains its cash in bank deposit accounts which, at times, may exceed the federal insurance limit.

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

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

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

Derivative instruments

The Company does not use derivative instruments to hedge exposures to cash flow or market risks; however, certain warrants to purchase preferred stock that do not meet the requirements for classification as equity are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net -cash settlement. Such financial instruments are initially recorded at fair value with subsequent changes in value charged (credited) to operations each reporting period. If these instruments subsequently meet the requirements for classification as equity, the Company reclassifies the then fair value to equity.

The Company values its outstanding warrants using the Black-Scholes option pricing model.

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 options are recorded as a reduction to stock compensation expense.

Fair Value Measurements

The Company applies a three-level valuation hierarchy for fair value measurements. The categorization of assets and liabilities within the valuation hierarchy is based on the lowest level of input that is significant to the measurement of fair value.

Level 1 inputs to the valuation methodology utilize unadjusted quoted market prices in active markets for identical assets and liabilities.
Level 2 inputs to the valuation methodology are other observable inputs, including quoted market prices for similar assets and liabilities, quoted prices for identical and similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.
Level 3 inputs to the valuation methodology are unobservable inputs based on management's best estimate of the inputs that market participants would use in pricing the asset or liability at the measurement date, including assumptions about risk.

A change to the level of an asset or liability within the fair value hierarchy is determined at the end of a reporting period.

Fair Values of Financial Instruments

The fair value of cash, cash equivalent, and accounts payable approximates the carrying value of these financial instruments because of the short-term nature of any maturities. The Company determines the estimated fair values of other financial instruments, using available market information and valuation methodologies, primarily input from independent third-party pricing sources.

Redeemable Convertible Preferred Stock

The Company has classified Series A, Series B, and Series C redeemable, convertible preferred stock ("Preferred Stock") as temporary equity in the accompanying consolidated balance sheet at December 31, 2020 due to terms that allow for redemption of the shares upon certain events that are outside of the Company's control. On June 1, 2021, the Company's outstanding Preferred Stock was converted into common stock (see Note 8).

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. As of December 31, 2021 and 2020, all of the Company's assets were located in the United States.

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, 2021. Any interest or penalties are charged to expense. During the years ended December 31, 2021 and 2020, the Company did not recognize any interest and penalties. Tax years subsequent to December 31, 2017 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	
	2021	2020
Redeemable, convertible preferred stock	-	2,584,323
Options to purchase common stock	503,433	375,826
Warrants for common stock	811,882	4,846,688
Warrants for Series B redeemable, convertible preferred stock	-	115,030
Class A warrants for common stock	2,484,000	-
Class B warrants for common stock	115,500	-

Newly Adopted Accounting Standards

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This guidance changes how entities account for convertible instruments and contracts in an entity's own equity and simplifies the accounting for convertible instruments by removing certain separation models for convertible instruments. This guidance also modifies the guidance on diluted earnings per share calculations. This new guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company elected to early adopt this guidance in the first quarter of 2021. The adoption of this standard had no material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

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 Company is currently evaluating the adoption date of this ASU and the impact, if any, adoption will have on its financial position and results of operations.

In February 2016, the Financial Accounting Standards Board ("FASB") issued 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.

3. LICENSE AND SUPPLY AGREEMENT WITH TORAY INDUSTRIES

On October 6, 2020, the Company entered into a license and supply agreement ("Toray Agreement") with Toray Industries, Inc. ("Toray"). Under the Toray Agreement, the Company received the exclusive license to make and distribute the protein detection chips that has a function of automatic stepwise feeding of reagent ("Toray Chips") outside of Japan. In exchange for the license, the Company committed to make two payments of $120,000 each. The first payment was made in January 2021, and the second payment was made in October 2021. In addition, following the first sale of Toray Chips, the Company will also make royalty payments to Toray equal to 15% of the net sales of the Toray Chips 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 Toray Chips during the twelve-month periods ended December 31, 2021 and 2020.

At December 31, 2020, $240,000 were accrued related to the Toray Agreement and was included in current liabilities on the consolidated balance sheet. No amounts were accrued at December 31, 2021.

4. FAIR VALUE MEASUREMENTS

The assets and liabilities measured at fair value on a recurring basis at December 31, 2021 and 2021 are summarized in the tables below.

	December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Cash equivalents - money market funds	$ 8,795,293	$ -	$ -	$ -
	$ 8,795,293	$ -	$ -	$ -

	December 31, 2020			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Derivative warrant liability	$ -	$ -	$ 155,629	$ -
	$ -	$ -	$ 155,629	$ -

The table below presents the changes in Level 3 liabilities measured at fair value on a recurring basis.

	Warrant Liability
Balance at December 31, 2019	$ 96,408
Unrealized loss	42,434
Issuance of Series B warrants	16,787
Balance at December 31, 2020	$ 155,629
Unrealized gain	(9,676)
Fair value of Series B warrants converted into warrants for common stock	(145,953)
Balance at December 31, 2021	$ -

Unrealized gain (loss) on revaluation of derivative warrant liability is included in derivative warrant liability gain (loss) in the consolidated statements of operations.

There were no assets or liabilities measured at fair value on a non-recurring basis at December 31, 2021 or 2020.

5. NOTES PAYABLE

2017 Notes Payable

In 2017, the Company entered into multiple Unit Purchase Agreements. In connection with this financing (the "Financing"), the Company issued 106 Units at a purchase price of $20,000 each. A Unit consisted of 100 shares of Series A redeemable, convertible preferred stock ("Series A") at a purchase price of $100 per share ("Original Offering Price") and $10,000 in notes payable (the "Notes"). Gross proceeds from the Financing were $2,120,000 and were allocated between the Notes and Series A based on their relative fair values with $1,643,349 allocated to the Notes and $476,651 to the Series A. The Notes are secured by all business assets of the Company and are fully guaranteed by Lana Management and Business Research International, LLC ("LMBRI"), a related party (see Note 10).

Certain Notes with aggregate principal amount of $930,000 mature on March 20, 2022 while $130,000 of the Notes mature on June 22, 2022. The Notes bear interest at 5% per annum, increasing to 7% on the amounts in default. For the first twelve months following issuance of the Notes, interest accrued on the Notes of approximately $53,000 was added to the principal balance of the Notes and not paid out to investors. The Notes require principal payments of $265,000 per year commencing in 2019 on the second anniversary of the Notes' issuance and annually thereafter, until the final principal payment upon maturity. For the year ended December 31, 2020, no principal payments were made to investors and the remaining unpaid balance on the Notes became immediately due and was classified as short-term at December 31, 2020. The Company defaulted on the Notes 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 are 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") (see Note 6). 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 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 years ended December 31, 2021 and 2020 the interest expense on the Notes was $6,360 and $59,274, respectively.

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 and $116,670 as a reduction to non-cash interest expense during the years ended December 31, 2021 and 2020, respectively. 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 8). The Company recognized the amortization of the discount of $22,899 and $18,319 as non-cash interest expense during the year ended December 31, 2021 and 2020, respectively. 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 shareholders, including $30,000 to 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 years ended December 31, 2021 and 2020 interest expense on the Subordinated Notes was $7,443 and $2,396 respectively.

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 Subordinated Note Warrants have an exercise price of $0.03 per share, and are exercisable upon issuance date and have a 5-year term. The Subordinated Note Warrants may be exercised for cash or through cancellation of the Subordinated Notes. The terms of the Common Stock Warrants were amended in November 2021 to provide for cashless exercise (see Note 7). The fair value of the Subordinated Note Warrants at the issuance date was estimated to be $4,488,570 using a Black-Scholes option pricing model.

The Subordinated Note Warrants were accounted for as equity under ASC 815 – *Derivatives and Hedging*. The proceeds from the issuance of the Subordinated Notes were allocated between the Subordinated Notes and the Subordinated Note Warrants based on their relative fair values, with $5,108 allocated to the Subordinated Notes and $148,892 allocated to the Common Stock Warrants. The proceeds allocated to the Subordinated Note Warrants were recorded in additional paid-in capital on the accompanying consolidated balance sheet as of December 31, 2020.

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 and $65,140 was amortized during the years ended December 31, 2021 and 2020, respectively, 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 those 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.

6. 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 an Initial Public Offering, which was filed on July 22, 2021. The Convertible Debentures were due on May 31, 2022 and secured by all of the Company's assets except for the assets transferred to SpinCo. 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. The Company was obligated to pay interest on the Convertible Debentures at the rate of 7.5% per annum, payable quarterly beginning on July 1, 2021, on each Conversion Date (as to that principal amount then being converted), on the Forced Conversion Date (as to that principal amount then being converted) and on the Maturity Date in cash. For the year ended December 31, 2021, interest expense on the Convertible Debentures was $124,829.

In connection with the IPO, on November 10, 2021, all of the Company's outstanding Convertible Debentures automatically converted into 4,500 shares of Series D Preferred Stock. Subsequently the holder of all the 4,500 outstanding shares of Series D Preferred Stock exercised their option to convert their Series D preferred stock 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 ("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. These 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.

7. WARRANTS

The following table summarizes information with regard to warrants outstanding at December 31, 2021:

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)
Common Stock Warrants	811,882	Common Stock	$ 3.24	4.1
Class A Warrants	2,484,000	Common Stock	$ 7.00	4.9
Class B Warrants	115,500	Common Stock	$ 10.00	4.9

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 to a financial advisor warrants to purchase 226,599 shares of the Company's common stock ("Advisor Warrants") as consideration for services in connection with the planned initial public offering ("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 under ASC 815 – *Derivatives and Hedging*, and the grant date fair value was estimated to be $180,339 using a Black-Scholes option pricing model 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, 2021, all of the Advisor Warrants remain outstanding.

In August 2021, the Company granted 225,000 warrants ("Dawson Warrants") to its placement agent for compensation for their services in relation to the issuance of the Convertible Debentures (see Note 6). As of December 31, 2021, all of the Dawson Warrants remain outstanding.

In November 2021, the Company granted 108,000 warrants ("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, 2021, all of the Underwriter Warrants remain outstanding.

In October 2020, in conjunction with the issuance of the Subordinated Notes, the Company granted 4,846,688 warrants ("Subordinated Note Warrants") to the noteholders, of which 944,160 warrants were issued to LMBRI (see Note 5). 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, 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, 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 our 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). In such event, the aggregate number of shares of common stock issuable in such cashless exercise shall equal the product of (x) the aggregate number of shares of common stock that would be issuable upon exercise of the Class B Warrant in accordance with its terms if such exercise were by means of a cash exercise rather than a cashless exercise and (y) 1.00. During 2021, 2,368,500 Class B Warrants were exercised, all on a cashless basis. As of December 31, 2021, 115,500 Class B Warrants were outstanding.

Warrants for Series B Redeemable, Convertible Preferred Stock

The 643 Series B Warrants issued in conjunction with the Series B Preferred Stock (see Note 8) were accounted for as a derivative liability under ASC 480 – *Distinguishing Liabilities from Equity* and adjusted to their fair valued of at $155,629 as of December 31, 2020. 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 Series B redeemable preferred stock warrants at June 1, 2021 and December 31, 2020 was based on the assumptions as follows:

	June 1, 2021	**December 31, 2020**
Risk-free interest rate	0.31% - 0.56%	0.17% - 0.36%
Dividend rate	0%	0%
Volatility	88.60%	88.60%
Expected life (in years)	2.81– 4.22	3.23 – 4.64

8. PREFERRED STOCK

Series A, B and C Preferred Stock

The Company's Certificate of Incorporation, as amended on June 7, 2021, provided authorization for issuance of up to 35,000,000 shares, par value of $0.0001, of which 30,000,000 shares shall be common stock and 5,000,000 shares shall be preferred stock. The Certificate of Incorporation was amended on October 22, 2021, to increase the authorized shares for preferred and common stock to 5,000,000 and 100,000,000, respectively.

In 2017 in connection with the Financing (see Note 5), 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. The Series A were being accreted to the redemption value through December 31, 2021, the redemption date. Accretion of the Series A to redemption value, including the accretion of dividends and issuance costs, was $73,912 and $184,494 for years ended December, 2021 and 2020, respectively.

In 2019, the Company entered into Subscription Agreements, as amended, for the issuance of 4,455 shares of Series B (the "Series B Financing") plus the committed future issuance of 415 of additional shares. Combined, 4,732 shares of Series B at a purchase price of $361.50 per share were issued in 2019. Gross proceeds from the Series B Financing were approximately $1,710,000 in 2019. The Subscription Agreements, as amended, also specified that purchasers investing $150,000 or more in Series B were to be issued a five year stock purchase warrant ("Series B Warrants") exercisable into a total number of Series B shares equal to 15% of the purchase price divided by $361.50. A total of 663 Series B Warrants were issued in 2019 in connection with the Series B Financing. The remaining Series B committed shares were drawn in January 2020 and the Company issued 138 shares of Series B and 21 Series B Warrants. In July and August 2020, the Company issued an additional 317 shares of Series B and 47 warrants to purchase Series B at an exercise price of $361.50 per share for gross proceeds of approximately $115,000.

The Series B were subject to accretion to the redemption value through December 31, 2024, the redemption date. Accretion of the Series B to redemption value, including the accretion of dividends and issuance costs, was $33,994 and $81,585 for the years ended December, 2021, respectively.

On November 19, 2020, the Company entered into a Subscription Agreement for the issuance of Series C (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. The Series C were being accreted to the redemption value through December 31, 2021, the redemption date. Accretion of the 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 debt financing by Sabby (see Note 6), the Company's 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 effected through the joint consent of the Company's Board of Directors and shareholders 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.

The Series A ranked senior to Series B and Series C. Series B was pari passu with the Series C. Significant terms of the Series A, Series B and Series C (collectively, "Voting Preferred Stock") were as follows:

- *Voting* - The holder of each share of Voting Preferred Stock has the right to vote for each share of common stock into which such Preferred Stock could convert. Except as otherwise provided, the holders of Voting Preferred Stock and Common Stock shall vote together as a single class.

- *Dividends* - The holders of Voting Preferred Stock shall be entitled to receive dividends at a rate per annum of 4%. Dividends shall accrue whether or not declared and are cumulative. The dividends shall be paid quarterly on the first day of March, June, September, and December only if and when declared by the Board of Directors. No dividends have been declared by the Company to date.

- *Liquidation Preference*- In the event of any liquidation, dissolution or winding up of the Company, the holders of Series A shall be entitled to be paid out of the assets of the Company, after all creditors of the Company have been paid, before any payments shall be made to the holders of Series B, Series C and common stock, in the amount of the Original Offering Price per share, plus all accrued but unpaid dividends thereon. If insufficient assets and funds are available to permit payment to the Series A holders, then all available assets and funds shall be distributed to the Series A holders on a pro rata basis. All dividends accrued and unpaid to the date of such distribution shall be paid out of the assets of the Company before any distribution is made to the holders of any junior stock of the Company.

- In the event of any liquidation, dissolution or winding up of the Company, the holders of Series B and Series C, which are pari passu stocks, shall be entitled to be paid out of the assets of the Company before any payments shall be made to the holders of the common stock, in the amount of the Original Offering Price per share, plus all accrued but unpaid dividends thereon. If insufficient assets and funds are available to permit payment to the Series B and Series C holders, then all available assets and funds shall be distributed to the Series B and Series C holders on a pro rata basis. All dividends accrued and unpaid to the date of such distribution shall be paid out of the assets of the Company before any distribution is made to the holders of any junior stock of the Company.

- *Conversion* - Each share of Voting Preferred Stock is entitled to convert into 157.36 shares of common stock at $0.64, $2.30 and $10.03 per share, respectively, at any time by the holder following issuance.

- *Redemption* - If the Company has not had an Initial Public Offering, or has not been acquired by December 31, 2024, the Company will be required, upon request of the holders of at least two thirds of the outstanding shares, to redeem the outstanding Preferred Stock at the greater of (i) Original Offering Price, plus accrued dividends, or (ii) the fair market value as determined by an appraiser selected by Company who is reasonably acceptable to the holders of a majority of the outstanding Preferred Stock and paid for by the Company.

Series D Preferred Stock

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"). Each share of Series D shall have a par value of $0.0001 per share and a stated value equal to $1,000. Series D has no voting rights, and is convertible into 1,000 shares of Common Stock at $1.00 per share at any time following issuance. In connection with the IPO, on November 10, 2021, all of the Company's outstanding Convertible Debentures automatically converted into 4,500 shares of Series D Preferred Stock. In November 2021, all Series D Preferred stock was converted into 4,500,000 shares of common stock. There were no Series D outstanding as of December 31, 2021.

9. STOCK COMPENSATION

In 2018, the Company adopted the 2018 Stock Incentive Plan (the "2018 Plan") for employees, consultants, and directors. The 2018 Plan, which is administered by the Board of Directors, permits the Company to grant incentive and nonqualified stock options for the purchase of common stock, and restricted stock awards. The maximum number of shares reserved for issuance under the 2018 Plan is 629,440.

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. The Company can continue to issue shares under the 2018 Plan. At December 31, 2021, there were 1,681,000 and 262,269 shares available for grants under the 2021 and 2018 Plans, respectively.

The Company calculated the grant-date fair value of share-based awards granted during the years ended December 31, 2021 and 2020 using the Black-Scholes model with the following assumptions:

	Year Ended December 31,	
	2021	**2020**
Risk-free interest rate	0.78% – 1.27%	0.27% – 0.28%
Expected dividend yield	0.00%	0.00%
Volatility factor	106.00% – 114.76%	88.60%
Expected life of option (in years)	5.00 – 6.00	5.00

The following is a summary of stock option activity for the year ended December 31, 2021:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2020	375,826	$ 0.59	8.0	$ 194,950
Granted	279,000	3.25		
Exercised	(56,385)	0.40		
Cancelled and forfeited	(8,655)	0.95		
Outstanding at December 31, 2021	589,786	$ 1.86	8.3	$ 605,187
Exercisable at December 31, 2021	259,104	$ 1.02	7.5	$ 444,049

The weighted average grant date fair value of options granted during the years ended December 31, 2021 and 2020 was $1.16 per share and $0.65 per share, respectively

For the years ended December 31, 2021 and 2020, the Company recorded stock-based compensation expense as follows:

	Year ended December 31,	
	2021	2020
Research and development	$ 29,543	$ -
General and administrative	17,315	7,370
Marketing and business development	21,600	-
Total stock-based compensation	$ 68,458	$ 7,370

At December 31, 2021, there was approximately $222,307 of unrecognized compensation expense related to non-vested stock option awards that are expected to be recognized over a weighted-average period of 3.0 years.

10. RELATED PARTY TRANSACTIONS

Lana Management and Business Research International, LLC

LMBRI has board members in common with the Company. Funds were advanced to the Company by LMBRI for operational and Food and Drug Administration (“FDA”) pre-submission funding purposes since inception. The outstanding balance due to LMBRI is payable upon demand.

The Company and LMBRI have 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 is billed $4,000 monthly for these expenses. Such amounts are included in general and administrative expenses on the accompanying consolidated statements of operations. The Company also issued Subordinated Notes and Common Stock Warrants to LMBRI in October 2020 as described in Note 5.

The table below summarizes the amounts incurred, paid, and balances due to LMBRI as of and for year’s ended December 31, 2021 and 2020.

	2021	2020
Expenses from LMBRI	$ 48,000	$ 55,097
Expense Sharing Agreement payments to LMBRI	$ 171,102	$ 16,000
Amounts payable to LMBRI	$ 2,000	$ 125,102
Interest Incurred and Payments on Subordinated Notes to LMBRI (Note 5)	$ 3,303	$ -
Portion of Subordinated Notes payable to LMBRI (Note 5)	$ -	$ 995

NanoHybrids, LLC

In December 2021, the Company entered into an agreement with NanoHybids, 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 NanoHyrids 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. There were no amounts incurred, paid or balances due related to this agreement for the year ended and as of December 31, 2021.

11. SUPPLEMENTAL BALANCE SHEET INFORMATION

Prepaid expenses and other current assets consist of the following:

	December 31, 2021	December 31, 2020
Prepaid insurance	$ 1,127,062	$ -
Prepaid clinical trial expenses	160,467	-
Prepaid other	325,179	61,071
Total prepaid expenses and other current assets	$ 1,612,708	$ 61,071

Accrued expenses and other current liabilities consist of the following:

	December 31, 2021	December 31, 2020
Accrued personnel costs	$ 157,938	$ -
Accrued other	181,446	133,820
Total accrued expenses and other current liabilities	$ 339,384	$ 133,820

12. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2021 and 2020:

		December 31,	
	Depreciable lives	2021	2020
Construction in process		$ 15,078	$ -
Furniture, fixtures, and equipment	5 years	24,915	16,046
Website	5 years	4,619	4,619
Lab equipment	5 years	741,591	741,591
		786,203	762,256
Less: accumulated depreciation		(448,837)	(303,118)
Property and equipment, net		$ 337,366	$ 459,138

13. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

As of December 31, 2021, the Company has entered into non-cancelable purchase commitments primarily for inventory and key advisory services. The purchase commitments covered by these agreements are for less than one year and aggregate to approximately $1.5 million.

Lease Commitments

In October 2021, the Company entered into a lease for laboratory space that expires on October 31, 2024. Additionally in 2021, we signed a lease for office space that is expected to commence in April 2022 when the buildout of the space is expected to be completed. The office space lease expires on March 30, 2027.

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

Year	
2022	$ 144,402
2023	172,954
2024	160,803
2025	100,000
2026	100,000
Thereafter	16,667
Total future lease payments	694,826

Minimum Royalties

As required under the Toray Agreement (see Note 3), following the first sale of Toray Chips, the Company will also make royalty payments to Toray equal to 15% of the net sales of the Toray Chips 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 Toray Chips through December 31, 2021.

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, 2021 and 2020 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,	
	2021	2020
Deferred tax assets:		
Net operating losses	$ 1,791,043	$ 957,902
Tax credits	3,659	31,017
Intangible assets	68,564	73,815
Other	97,945	7,432
Total deferred tax assets	1,961,211	1,070,166
Valuation allowance	(1,934,351)	(996,934)
Net deferred tax assets	$ 26,860	$ 73,232
Deferred tax liabilities:		
Note premium amortization	$ -	$ (46,583)
Fixed assets	(26,860)	(26,649)
Net deferred tax assets	$ (26,860)	$ (73,232)

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 2021 and 2020 is as follows:

	Year Ended December 31,	
	2021	2020
Federal statutory rate	21.00%	21.00%
State income taxes, net of federal benefit and tax credits	5.41%	6.77%
Change in valuation allowance	(25.88)%	(28.49)%
Permanent differences	(0.53)%	0.72%
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, 2021 and 2020, 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, 2020 and 2019 will not be realized given the Company's history of operating losses. The valuation allowance against deferred tax assets increased by approximately $937,000 and $335,000 and during 2021 and 2020, respectively, related mainly to a full valuation allowance recorded against additional net operating losses and tax credits generated in the year.

At December 31, 2021, the Company had federal net operating loss carryforwards of approximately $6.6 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 2021 totaling $5.9 million have no expiration date as a result of the December 22, 2017 Tax Cuts and Jobs Act tax reform legislation.

As of December 31, 2021, the Company had post-apportioned state net operating losses of $6.3 million that can generally be carried forward 20 years and will expire at various dates through 2041. As of December 31, 2020, the Company had post-apportioned Massachusetts net operating losses of $3.2 million that can generally be carried forward 20 years and will expire at various dates through 2040.

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 Form S-1 file no. 333-260029)
3.2	Amended and Restated Bylaws. (incorporated by reference to exhibit 3.2 to the Company's Form S-1 file no. 333-260029)
4.1	Specimen Common Stock Certificate. (incorporated by reference to exhibit 4.1 to the Company's Form S-1 file no. 333-260029)
4.2	Form of Class A Warrant. (incorporated by reference to exhibit 4.1 to the Company's Form 8-K filed November 16, 2021)
4.3	Form of Class B Warrant. (incorporated by reference to exhibit 4.3 to the Company's Form S-1 file no. 333-260029)
4.4	Form of Warrant Agency Agreement. (incorporated by reference to exhibit 4.4 to the Company's Form S-1 file no. 333-260029)
4.5	Form of IPO Underwriters' Warrant. (incorporated by reference to exhibit 4.5 to the Company's Form S-1 file no. 333-260029)
4.6 *	Description of Securities of Bluejay Diagnostics, Inc.
10.1 **	2021 Stock Plan. (incorporated by reference to exhibit 10.1 to the Company's Form S-1 file no. 333-260029)
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 Form S-1 file no. 333-260029)
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 Form S-1 file no. 333-260029)
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 Form S-1 file no. 333-260029)
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 Form S-1 file no. 333-260029)
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 Form S-1 file no. 333-260029)
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 Form S-1 file no. 333-260029)
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 Form S-1 file no. 333-260029)
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 Form S-1 file no. 333-260029)
14.1	Code of Ethics. (incorporated by reference to exhibit 14.1 to the Company's Form S-1 file no. 333-260029)
21.1	List of Subsidiaries. (incorporated by reference to exhibit 21.1 to the Company's Form S-1 file no. 333-260029)
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 in IXBRL, and included in exhibit 101).

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

Exhibit 4.6

DESCRIPTION OF THE COMPANY'S SECURITIES

The following summary is a description of the material terms of our capital stock. This summary is not complete, and is qualified by reference to our amended and restated certificate of incorporation, and our amended and restated bylaws, which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of the Delaware General Corporations Law for additional information.

Our amended and restated certificate of incorporation authorize us to issue up to 100,000,000 shares of common stock and 5,000,000 shares of preferred stock.

Common Stock

Shares of our common stock have the following rights, preferences and privileges:

Voting

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

Dividends

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

Liquidation Rights

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

Other

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

Preferred Stock

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

Warrants Issued in IPO

The Class A Warrants and Class B Warrants issued in our IPO were in registered form under separate warrant agent agreements (each a "Warrant Agent Agreement") between us and our warrant agent, Continental Stock Transfer & Trust Company (the "Warrant Agent"). The material provisions of the warrants are set forth herein and a copy of each of the Warrant Agent Agreements are filed as exhibits to this report. The Company and the Warrant Agent may amend or supplement each of the Warrant Agent Agreements without the consent of any holder for the purpose of curing any ambiguity, or curing, correcting or supplementing any defective provision contained therein or adding or changing any other provisions with respect to matters or questions arising under each of the Warrant Agent Agreements as the parties thereto may deem necessary or desirable and that the parties determine, in good faith, shall not adversely affect the interest of the Class A Warrant or Class B Warrant holders, respectively. All other amendments and supplements to each of the Warrant Agent Agreement shall require the vote or written consent of holders of at least 50.1% of each of the Class A Warrants and Class B Warrants, as applicable.

Class A Warrants

The Class A Warrants entitle the registered holder to purchase one share of our common stock at an exercise price equal to $7.00 per share, exercisable until the fifth anniversary of the issuance date. The exercise price and number of shares of common stock issuable upon exercise of the Class A Warrants may be adjusted in certain circumstances, including in the event of a stock dividend, extraordinary dividend, recapitalization, reorganization, merger or consolidation.

The Class A Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the Warrant Agent, with the exercise form attached to the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. The Class A Warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their Class A Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the Class A Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No Class A Warrants will be exercisable for cash unless at the time of the exercise a prospectus or prospectus relating to common stock issuable upon exercise of the Class A Warrants is current and the common stock has been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the Class A Warrant Agent Agreement, we have agreed to use our best efforts to maintain a current prospectus or prospectus relating to common stock issuable upon exercise of the Class A Warrants until the expiration of the Class A Warrants. Additionally, the market for the Class A Warrants may be limited if the prospectus or prospectus relating to the common stock issuable upon exercise of the Class A Warrants is not current or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of such Class A Warrants reside. If we fail to maintain a current prospectus or prospectus relating to the common stock issuable upon the exercise of the Class A Warrants, such holders may exercise their Class A Warrants on a "cashless" basis pursuant to a formula set forth in the terms of the Class A Warrants. In no event will the registered holders of a Class A Warrant be entitled to receive a net-cash settlement in lieu of physical settlement in shares of our common stock.

No fractional shares of common stock will be issued upon exercise of the Class A Warrants. If, upon exercise of the Class A Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number the number of shares of common stock to be issued to the Warrant holder. If multiple Class A Warrants are exercised by the holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all the Class A Warrants.

Class B Warrants Offered Hereby

The Class B Warrants entitle each holder to purchase one share of our common stock at an exercise price equal to $10.00 per share, exercisable until the fifth anniversary of the issuance date and subject to certain adjustment and cashless exercise provisions as described herein. The exercise price and number of shares of common stock issuable upon exercise of the Class B Warrants may be adjusted in certain circumstances, including in the event of a stock dividend, extraordinary dividend on or recapitalization, reorganization, merger or consolidation.

The Class B Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the Warrant Agent, with the exercise form attached to the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. The Class B Warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their Class B Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the Class B Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No Class B Warrants will be exercisable for cash unless at the time of the exercise a prospectus or prospectus relating to common stock issuable upon exercise of the Class B Warrants is current and the common stock has been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the Class B Warrant Agent Agreement, we have agreed to use our best efforts to maintain a current prospectus or prospectus relating to common stock issuable upon exercise of the Class B Warrants until the expiration of the Class B Warrants. Additionally, the market for the Class B Warrants may be limited if the prospectus or prospectus relating to the common stock issuable upon exercise of the Class B Warrants is not current or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of such Class B Warrants reside. In no event will the registered holders of a Class B Warrant be entitled to receive a net-cash settlement in lieu of physical settlement in shares of our common stock. If we fail to maintain a current prospectus or prospectus relating to the common stock issuable upon the exercise of the Class B Warrants, such holders may exercise their Class B Warrants on a “cashless” basis pursuant to a formula set forth in the terms of the Class B Warrants.

Additionally, holders of Class B Warrants may exercise such warrants on a “cashless” basis upon the earlier of (i) 10 trading days from the issuance date of such warrant or (ii) the time when $10.0 million of volume is traded in our common stock, if the volume weighted average price (“VWAP”) of our common stock on any trading day on or after the date of issuance fails to exceed the exercise price of the Class B Warrant (subject to adjustment for any stock splits, stock dividends, stock combinations, recapitalizations and similar events). In such event, the aggregate number of shares of common stock issuable in such cashless exercise shall equal the product of (x) the aggregate number of shares of common stock that would be issuable upon exercise of the Class B Warrant in accordance with its terms if such exercise were by means of a cash exercise rather than a cashless exercise and (y) 1.00.

No fractional shares of common stock will be issued upon exercise of the Class B Warrants. If, upon exercise of the Class B Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number the number of shares of common stock to be issued to the Warrant holder. If multiple Class B Warrants are exercised by the holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all the Class B Warrants.

Warrants

We have the following warrants outstanding:

- warrants to purchase an aggregate of 115,190 shares of our common stock having an exercise price per share equal to $2.30, which warrants expire on April 5, 2024;
- warrants to purchase an aggregate of 128,438 shares of our common stock having an exercise price per share equal to $0.03, which warrants expire on October 22, 2025;
- a warrant to purchase 226,599 shares of our common stock having an exercise price per share equal to $3.18, which warrant expires on March 15, 2026;
- placement agent warrants to purchase 150,000 shares of our common stock having an exercise price per share equal to $1.25, which warrants expire on July 7, 2026;

- placement agent warrants to purchase 75,000 shares of our common stock having an exercise price per share equal to $1.25, which warrants expire on August 4, 2026;
- warrants to purchase an aggregate of 8,655 shares of our common stock having an exercise price per share equal to $0.95, which warrants expire on July 22, 2030;
- underwriter warrants to purchase an aggregate of 108,000 shares of our common stock having an exercise price per share equal to $12.50, which warrants expire on November 9, 2026.

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

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

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

Delaware Anti-Takeover Statute

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

Undesignated Preferred Stock

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

Authorized Common Stock

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

Advance Notice Requirements for Shareholder Proposals and Director Nominations

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

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

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

Exclusive Forum Selection

Our amended and restated certificate of incorporation 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 provides that the Court of Chancery and the federal district court for the District of Delaware will have concurrent jurisdiction over any action arising under the Securities Act or the rules and regulations thereunder, and the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction. To the extent the exclusive forum provision restricts the courts in which our stockholders may bring claims arising under the Securities Act and the rules and regulations thereunder, there is uncertainty as to whether a court would enforce such provision. Investors cannot waive compliance with the federal securities laws and the rules and regulations promulgated thereunder.

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

Transfer Agent and Registrar

The transfer agent for our common stock is Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York 10004.

Listing of Common Stock

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

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)) 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. [Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942];

   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 10, 2022

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, Gordon Kinder, certify that:

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

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

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

4. The registrant's other certifying 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)) 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. [Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942];

   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 10, 2022

By: /s/ Gordon Kinder
Gordon Kinder
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, 2021, 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 10, 2022

/s/ Neil Dey

Name: Neil Dey
Title: 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, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gordon Kinder, 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 10, 2022

/s/ Gordon Kinder

Name: Gordon Kinder
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)