PROSPECTUS

Filed Pursuant to Rule 424(b)(4)
Registration Nos. 333-260029 and 333-260936

2,160,000 Units consisting of:

Common Stock
Class A Warrants
Class B Warrants

This is an initial public offering of units of our securities. Prior to this offering, there has been no public market for shares of our common stock.

Each Unit consists of (a) one share of our common stock (or, at the purchaser's election, one share of Series E Convertible Preferred Stock), (b) one Class A warrant (the "Class A Warrants") 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, and (c) one Class B warrant (the "Class B Warrants," and together with the Class A Warrants, the "Warrants") to purchase one share of our common stock at an exercise price equal to $10.00 per share (or 100% of the unit offering price), exercisable until the fifth anniversary of the issuance date. 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). The shares of our common stock and the Warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

We are also offering to those purchasers, if any, whose purchase of our common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to substitute Series E Convertible Preferred Stock, referred to as "Preferred Stock" for the shares of common stock included in the Units purchased by that investor. Each share of Preferred Stock is being sold together with the same Warrants described above being sold with each share of common stock. For each share of Preferred Stock purchased in this offering in lieu of common stock, we will reduce the number of shares of common stock being sold in the offering on a one-for-one basis. Pursuant to this prospectus, we are also offering the shares of common stock issuable upon conversion of the Preferred Stock.

Each share of Preferred Stock is convertible into one share of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the total number of shares of our common stock then issued and outstanding. However, any holder may increase such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. The shares of Preferred Stock will otherwise have the preferences, rights and limitations described under "Description of Capital Stock - Series E Convertible Preferred Stock Being Issued in this Offering" in this prospectus.

Prior to this offering, there has been no public market for our common stock. Our common stock is listed for trading on the NASDAQ Capital Market under the symbol "BJDX". We do not intend to apply for any listing of either of the Warrants on the Nasdaq Capital Market or any other securities exchange or nationally recognized trading system, and we do not expect a market to develop for the Class A Warrants or the Class B Warrants.

The registration statement of which this prospectus forms a part includes a separate prospectus to be used for the potential resale by a selling stockholder of 4,500,000 shares of common stock. Any shares sold by the selling stockholder until our common stock is listed or quoted on an established public trading market will take place at $10.00 per share, which is the public offering price of the Units we are selling in our initial public offering. Thereafter, any sales will occur at prevailing market prices or in privately negotiated prices.

Investing in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 11 for a discussion of certain risks that you should carefully consider in connection with an investment in our common stock.

	Per Unit[2]	Total[3]
Public offering price	$ 10.00	$ 21,600,000
Underwriting discounts[1]	$ 0.80	$ 1,728,000
Proceeds to us, before expenses	$ 9.20	$ 19,872,000

_____

(1) The underwriters will receive compensation in addition to the underwriting discounts and commissions. We refer you to "Underwriting" beginning on page 83 of this prospectus for additional information regarding underwriting compensation.

(2) The public offering corresponds to a public offering price per share of common stock or share of Series E Convertible Preferred Stock of $9.98, a public offering price per Class A warrant of $0.01, and a public offering price per Class B Warrant of $0.01.

(3) Persons affiliated with us may purchase our securities in this offering.

We have granted the underwriter an option, exercisable one or more times in whole or in part, to purchase up to 324,000 additional shares of common stock and/or Class A Warrants to purchase up to an aggregate of 324,000 shares of common stock and/or Class B Warrants to purchase up to an aggregate of 324,000 shares of common stock, in any combinations thereof, from us at the public offering price per security, less the underwriting discounts and commissions, for 45 days after the date of this prospectus to cover over-allotments, if any.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, and we have elected to comply with certain reduced public company reporting requirements.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the securities against payment on or about November 15, 2021.

Joint Book-Running Managers

Dawson James Securities, Inc. **I-Bankers Direct, LLC**

The date of this prospectus is November 9, 2021

ABOUT THIS PROSPECTUS

Neither we nor the underwriters have authorized anyone to provide you with any information or to make any representations other than as contained in this prospectus or in any free writing prospectuses we have prepared. Neither we nor the underwriters take responsibility for, and provide no assurance about the reliability of, any information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities. Our business, financial condition, results of operations and prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our securities or possession or distribution of this prospectus in any such jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions about this offering and the distribution of this prospectus applicable to those jurisdictions.

INDUSTRY AND MARKET DATA

This prospectus contains estimates, projections and other information concerning our industry, our business, the science of our products and the markets for our products, including data regarding the incidence of certain medical conditions and the scientific basis of our products. We obtained the industry, science, market and similar data set forth in this prospectus from our internal estimates and research and from academic and industry research, publications, surveys, and studies conducted by third parties.

The content of the above sources, except to the extent specifically set forth in this prospectus, does not constitute a portion of this prospectus and is not incorporated herein. Information that is based on estimates, forecasts, projections, market research, scientific research, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information.

TABLE OF CONTENTS

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should read the entire prospectus carefully, including our financial statements and the related notes included in this prospectus and the information set forth under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

When used herein, unless the context requires otherwise, references to the "Company," "we," "our" and "us" refer to Bluejay Diagnostics, Inc., a Delaware corporation, collectively with its wholly owned subsidiary SpinCo, LLC.

Our Company

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 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. If our Symphony system is able to replicate the results from prior clinical studies and receives FDA clearance, we believe Symphony could eliminate the time required for transportation and logistics and will 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"). Toray holds 100,081 shares of our common stock, which they acquired in 2020 for approximately $1.0 million. The core technology used in our Symphony platform and test cartridge product candidates are licensed from Toray.

For the past three years, Toray has used the technology successfully as a Research Use Only ("RUO") product 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 of the Symphony platform, we believe we are positioned now to complete the last stages of development needed to move to commercialization in the United States. Our initial regulatory pathway is to label and distribute Symphony as an RUO product in the U.S. Certain laboratories may choose to utilize the RUO Symphony in laboratory developed tests, or LDTs. 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 the FDA to use Symphony for *in vitro* diagnostic use. In order to expedite the submission of our 510(k), we may seek to obtain data from laboratories using the RUO Symphony in LDTs.

Prior to seeking 510(k) clearance for Symphony, we will need to complete additional clinical trials, which commenced in September 2021. In January 2022, we plan to submit a pre-submission application to the FDA presenting our study design and the data from our first set of studies. We will use the FDA's feedback, if necessary, to modify the ongoing studies and to construct the 510(k) premarket notification clearance application. We plan to submit our 510(k) premarket notification at the end of the third quarter of 2022.

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. IL-6 is one of the principle inflammatory cytokines released during trauma or infection. Measuring IL-6 can serve as an early warning sign of a patient's prognosis and inform quicker and more accurate healthcare. Unlike the conventional downstream biomarkers typically used for sepsis, IL6 is

released hours to days before procalcitonin (“PCT”) and c-reactive protein (“CRP”). However, due to long wait times to receive lab results, IL-6 has had limited utility in healthcare. IL-6 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 is a biomarker that appears early on as a ‘first responder’ during infection or inflammation. We believe detection of IL-6 early on might allow physicians to make better therapeutic and treatment decisions. Due to the clinical significance of IL-6 testing, 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 heightened in patients with COVID-19-associated systemic inflammation and hypoxic respiratory failure. In addition, certain of the institutions that we are working with on our clinical studies have Clinical Laboratory Improvement Amendments (“CLIA”) certified labs. These CLIA certified laboratories might adopt Symphony IL-6 tests for their clinical testing as laboratory developed tests. We intend to submit an emergency use authorization (“EUA”) application with the FDA for this indication.

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 cleared products and our 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 this offering will be sufficient to reach commercialization.

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.

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) is able to 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 Fujirebio human chemiluminescent enzyme immunoassay (“CLEIA”) Lumipulse f system. The Lumipulse f system is a clinical system that has been approved by the Ministry of Health, Labour and Welfare (MHLW) of Japan for clinical use. Chemiluminescent assays are a common method for quantifying IL-6, and is the method used by all three current FDA Emergency Use Authorized tests: Roche’s Elecsys IL-6, Beckman Coulter’s Access IL-6, and Siemens Centaur Interleukin-6. Furthermore, a publication in Clinical Chemistry and Laboratory Medicine, “Interleukin-6 chemiluminescent immunoassay on Lumipulse G600II: analytical evaluation and comparison with three other laboratory analyzers” (Volume 58, Issue 10, 2020) did a comparison of a similar Lumipulse IL-6 test with Roche’s Elecsys IL-6, Beckman Coulter’s Access IL-6, and Siemens Centaur Interleukin-6 and measured comparable performance across all four systems. 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.

Based on the results of the Japan Study, we believe the Symphony system may be able to reduce test result time from days to minutes and may be able to provide results which, as shown in the Japan Study, 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 into 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.

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

- *Ease of Use*. Symphony is a sample-to-result 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 the Symphony system could eliminate the time required for transportation and logistics and 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 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 are expected to 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 increases, 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.

Risks We Face

Our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our securities. In particular, you should consider the following risks, which are discussed more fully in the section entitled "Risk Factors":

- We expect to incur losses for the foreseeable future, until we are able to generate sufficient revenue from product sales.
- Our losses from operations could continue to raise substantial doubt regarding our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.
- All of our product candidates are dependent on our license agreement with the Toray. The license agreement imposes significant obligations on us, including the potential obligation to pay the minimum royalties upon regulatory approval. If our license agreement with Toray is terminated for any reason, we will not be able to generate revenues and our business will likely cease.
- The regulatory approval pathway we must navigate may be expensive, time-consuming and uncertain, and may prevent us from obtaining approval for the marketing of our product candidates.
- There can be no assurance that we will successfully complete any clinical evaluation studies necessary to receive regulatory approvals.
- Our success is highly dependent on our IL-6 product candidates, which are yet to be approved and, even if approved, may not be accepted by the marketplace.
- We intend to rely solely on third parties to manufacture our product candidates.
- If Toray is unable to successfully protect or enforce its intellectual property and proprietary rights or elects to not do so, our competitive position will be harmed.
- If others claim we or Toray are infringing on their intellectual property rights, we may be subject to costly and time-consuming litigation.
- We face competition from companies that have greater resources than we do, and we may not be able to effectively compete against these companies.
- Given our lack of revenue, we may need to raise additional capital, which may not be available to us on acceptable terms, or at all.

Corporate Information

We were incorporated under the laws of Delaware on March 20, 2015. Our principal executive offices are located at 360 Massachusetts Avenue, Suite 203, Acton, MA 01720 and our telephone number is (844) 327-7078. Our corporate website address is *bluejaydx.com.* Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

Implications of being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act ("JOBS Act"). An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. We intend 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 of 2002, as amended, or 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.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

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) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (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.

The Offering

Securities offered by us:	Each Unit consists of (a) one share of our common stock (or, at the purchaser's election, one share of Series E Convertible Preferred Stock), (b) one Class A warrant (the "Class A Warrants") 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, and (c) one Class B warrant (the "Class B Warrants," and together with the Class A Warrants, the "Warrants") to purchase one share of our common stock at an exercise price equal to $10.00 per share (or 100% of the unit offering price), exercisable until the fifth anniversary of the issuance date and subject to certain adjustment and cashless exercise provisions as described herein. The shares of our common stock and the Warrants are immediately separable and will be issued separately, but will be purchased together in this offering. We are also offering to those purchasers, if any, whose purchase of common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to substitute Series E Convertible Preferred Stock, referred to as "Preferred Stock" for the shares of common stock included in the Units purchased by that investor. This prospectus also relates to the offering of shares of common stock issuable upon conversion of the Preferred Stock. Each share of Preferred Stock is convertible into one share of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the total number of shares of our common stock then issued and outstanding. However, any holder may increase such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. In the event of our liquidation, dissolution, or winding up, holders of our Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to any beneficial ownership limitation), subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily. The holders of the Preferred Stock have no voting rights, except as required by law. Any amendment to our certificate of incorporation that adversely affects the powers, preferences and rights of the Preferred Stock requires the approval of the holders of a majority of the shares of Preferred Stock then outstanding.

	The holders of our Preferred Stock are entitled to receive dividends on shares of Preferred Stock equal (on an as-if-converted-to-common-stock basis, without giving effect for such purposes to any beneficial ownership limitation) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by our board of directors.
Common stock outstanding prior to this offering:	10,534,265 shares
Common stock outstanding after this offering:	12,694,265 shares (assuming no purchaser elects to purchase shares of Series E Convertible Preferred Stock in lieu of shares of common stock).
Over-allotment option:	We have granted the underwriter an option, exercisable one or more times in whole or in part, to purchase up to 324,000 additional shares of common stock and/or Class A Warrants to purchase up to an aggregate of 324,000 shares of common stock, and/or Class B Warrants to purchase up to an aggregate of 324,000 shares of common stock, in any combinations thereof, from us at the public offering price per security, less the underwriting discounts and commissions, for 45 days after the date of this prospectus to cover over-allotments, if any. See "*Underwriting*" for additional information. Because the warrants will not be listed on a national securities exchange or other nationally recognized trading market, the underwriters will be unable to satisfy any overallotment of shares and warrants without exercising the underwriters' overallotment option with respect to the warrants. As a result, the underwriters will exercise their overallotment option for all of the warrants which are over-allotted, if any, at the time of the initial offering of the shares and the warrants. However, because our common stock is publicly traded, the underwriters may satisfy some or all of the overallotment of shares of our common stock, if any, by purchasing shares in the open market and will have no obligation to exercise the overallotment option with respect to our common stock.
Use of proceeds:	We intend to use the net proceeds received from this offering (i) to obtain regulatory approvals of our product candidates, including completing any product development required to meet such regulatory requirements; and (ii) to market our products. The remaining net proceeds, if any, are expected to be used for working capital and other general corporate purposes. See "*Use of Proceeds*."
Lockups	Our executive officers, directors, and stockholders holding 5% or more of our common stock prior to the offering, collectively, have agreed with the underwriters not to sell, transfer or dispose of any shares or similar securities for a period of six months following the closing of this offering. We have also agreed, for a period of twelve months after the closing of this offering, not to sell, transfer or dispose of any shares or similar securities, subject to certain exceptions.

Underwriters' warrants	Upon the closing of this offering, we will issue to Dawson James, as representative of the underwriters, warrants entitling the representative to purchase 5% of the aggregate number of shares of common stock issued in this offering (including the shares of common stock issuable upon conversion of the Series E Convertible Preferred Stock). The warrants shall be exercisable at an exercise price of 125% of the public offering price per unit for a period of five years from the commencement of sales in this offering. For additional information, please refer to the "Underwriting" section on page 83.
Listing:	Our common stock is listed on the NASDAQ Capital Market under the symbol "BJDX."
Risk factors:	An investment in our company is highly speculative and involves a high degree of risk. See "*Risk Factors*" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

The number of shares of common stock outstanding is based on 10,534,265 shares of common stock issued and outstanding as of October 20, 2021 and excludes the following:

- 4,500,000 shares of common stock issuable upon the conversion of our Series D Convertible Preferred Stock;
- 1,255,775 shares of common stock issuable upon the exercise of our outstanding warrants to purchase common stock at a weighted average price of $1.03 per share;
- 500,786 shares of common stock issuable upon the exercise of our outstanding options to purchase common stock at a weighted average price of $2.98 per share;
- 1,770,000 shares of common stock that are available for future issuance under our 2021 Stock Plan;
- 2,160,000 shares of common stock issuable upon the exercise of Class A warrants to be issued in this offering;
- 2,160,000 shares of common stock issuable upon the exercise (including the cashless exercise) of Class B warrants to be issued in this offering; and
- 108,000 shares of common stock issuable upon the exercise of warrants to be issued to the underwriters upon the closing of this offering.

Unless expressly indicated or the context requires otherwise, (i) all information in this prospectus assumes no exercise by the representative of the over-allotment option; and (ii) all common stock share and per share amounts reported in the following analysis reflect the stock dividend of 2.15 share of common stock for each outstanding share of common stock, effected June 7, 2021.

Summary Financial Data

You should read the following summary financial data together with our financial statements and the related notes appearing at the end of this prospectus, "*Capitalization*," and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*." We have derived the financial data for the six months ended to June 30, 2021 from our unaudited condensed financial statements appearing elsewhere in this prospectus. We have derived the financial data for the fiscal years ended December 31, 2020 and 2019 from our audited financial statements included in this prospectus.

	For the Fiscal Year Ended December 31, 2019	For the Fiscal Year Ended December 31, 2020	For the Six Month Period Ending June 30, 2021	Pro Forma for the Six Month Period Ending June 30, 2021[1]
Results of Operations Data:				
Net loss	$ (819,842)	$ (1,158,285)	$ (834,421)	$ (834,421)
Basic and diluted net loss per common share	(0.26)	(0.37)	(0.20)	(0.20)
Weighted average number of common shares outstanding	3,147,200	3,147,200	4,201,688	4,201,688

	As of December 31, 2019	As of December 31, 2020	As of June 30, 2021	Pro Forma as of June 30, 2021[1]	Pro Forma as adjusted as of June 30, 2021[2]
Balance Sheet Data:					
Cash	$ 96,011	$ 912,361	$ 2,400,457	$ 3,765,457	$ 22,649,457
Working capital	(276,197)	(787,196)	(516,185)	3,461,930	22,078,039
Total assets	916,518	1,517,332	3,125,544	4,490,544	23,106,653
Total liabilities	1,380,826	1,845,390	3,249,029	635,914	635,914
Total redeemable preferred stock	2,468,130	3,878,115	—	—	—
Total stockholders' equity (deficit)	(2,932,438)	(4,206,173)	(123,485)	3,854,630	22,470,739

(1) Reflects issuance on August 4, 2021 of an additional $1.5 million in principal amount of convertible debentures, after deducting the origination fees and estimated offering expenses payable by us, and the mandatory conversion of the total $4.5 million in principal amount of debentures into Series D convertible preferred stock.

(2) Reflects the sale and issuance of all the shares of common stock offered hereby, at the public offering price of $10.00 per unit, after deducting the underwriting discounts and estimated offering expenses payable by us.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including the financial statements and the related notes included elsewhere in this prospectus, before deciding whether to invest in shares of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

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 financed our operations primarily through financing from private capital raising, and have incurred losses since inception, including a net loss of $1.2 million for the fiscal year ended December 31, 2020 and a net loss of $834,421 for the six months ended June 30, 2021. 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.

Our losses from operations could continue to raise substantial doubt regarding our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.

We had cash and cash equivalents of approximately $1.9 million at October 20, 2021. We estimate that our existing cash resources, without giving effect to the proceeds from this offering, will not be sufficient to fund operations into 2022. Our financial statements included with this prospectus have been prepared assuming that we will continue as a going concern. We have concluded that substantial doubt about our ability to continue as a going concern exists and our auditors have made reference to this in their audit report on our audited financial statements for the year ended December 31, 2020. If we are unable to obtain sufficient funding, we could be forced to delay the commercialization of our product candidates, and our financial condition and results of operations will be materially and adversely affected. After the completion of this offering, future financial statements may continue to disclose substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

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 the net proceeds from this offering, along with 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 the registration statement of which this prospectus is a part.

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, or maintained if 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.

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.

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.

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, than those of other competitors. 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 this Offering and the Ownership of Our Common Stock

We have broad discretion in the use of the net proceeds from this offering and may use the net proceeds in ways with which you may not agree.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not advance our business plan, achieve proposed objectives, improve our financial condition, generate revenue or enhance the value of our common stock. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending the application of these funds, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We may not be able to satisfy the continued listing requirements of the NASDAQ Global 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.

Investors in this offering will experience immediate and substantial dilution in net tangible book value.

The difference between the public offering price per share of our common stock and the pro forma net tangible assets per share of our common stock after this offering constitutes the dilution to the investors in this offering. You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of all 2,160,000 shares of common stock in this offering at the public offering price of $10.00 per share, investors in this offering can expect an immediate dilution to net tangible assets of $8.22 per share, based on a pro forma as adjusted net tangible book value per share after the offering of $1.78. This dilution is due in large part to the fact that our existing investors acquired their securities prior to this offering at substantially less than investors are paying in this offering. If any outstanding warrants to purchase shares of our common stock are exercised, there would be further dilution.

If any outstanding warrants to purchase shares of our common stock are exercised, there would be further dilution. In addition, if upon the earlier of (i) 10 trading days from the issuance date of the Class B Warrants or (ii) the time when $10.0 million of volume is traded in our common stock, if the volume weighted average price of our common stock on any trading day on or after the date of issuance fails to exceed the exercise price of the Class B Warrants, the Class B Warrants can be exercised on a "cashless" basis for shares of common stock on a one-for-one basis, regardless of whether the market price of our common stock is above the exercise price, which may result in additional dilution and no additional proceeds to us in connection with such exercises. See "Dilution" for a more complete description of how the value of your investment in our common stock will be diluted upon the completion of this offering.

The market price of our common stock may be significantly volatile.

The market price for our common stock may be significantly volatile and subject to wide fluctuations in response to factors including the following:

- developments prior to commercial sales relating to regulatory approval, manufacturing and distribution of our products;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices for securities of medical device companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- any delay in or the results of our clinical evaluations;
- any delay in manufacturing of our products;
- any delay with the approval for reimbursement for the patients from their insurance companies;
- our failure to comply with regulatory requirements;
- the announcements of clinical evaluation data, and the investment community's perception of and reaction to those data;
- the results of clinical evaluations conducted by others on products that would compete with ours;
- any delay or failure to receive clearance or approval from regulatory agencies or bodies;
- our inability to commercially launch products or market and generate sales of our products;
- failure of our products, even if approved for marketing, to achieve any level of commercial success;
- our failure to obtain intellectual property protection for any of our technologies and products or the issuance of third-party intellectual property that cover our proposed technologies or products;
- developments or disputes concerning our future products intellectual property rights;
- our or our competitors' technological innovations;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or intellectual property;
- failure to adequately manufacture our products through third parties;

- future sales of our common stock or other securities, including shares issuable upon the exercise of outstanding warrants or otherwise issued pursuant to certain contractual rights;
- period-to-period fluctuations in our financial results; and
- low or high trading volume of our common stock due to many factors, including the terms of our financing arrangements.

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be significant impact on the market price of our common stock. Additionally, as we approach the announcement of anticipated significant information and as we announce such information, we expect the price of our common stock to be volatile and negative results would have a substantial negative impact on the price of our common stock.

In some cases, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

The Class A Warrants may not have value.

The Class A Warrants being offered by us in this offering have an exercise price of $7.00 per share and will expire five years from the date of issuance. In the event that our common stock does not exceed the exercise price of the Class A Warrants during the period when such warrants are exercisable, such Class A Warrants may not have any value.

Holders of our warrants will have no rights as shareholders until they acquire shares of our common stock, if ever.

If you acquire the warrants to purchase shares of our common stock in this offering, you will have no rights with respect to our common stock until you acquire shares of such common stock upon exercise of your warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a holder of common stock only as to matters for which the record date occurs after the exercise date.

There is no public market for either of the warrants being offered by us in this offering and an active trading market for the same is not expected to develop.

There is no established public trading market for either of the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for any listing of either of the warrants offered hereby on the Nasdaq Capital Market or any other securities exchange or nationally recognized trading system. Without an active market, the liquidity of the warrants will be severely limited.

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.

If you purchase Preferred Stock in lieu of common stock in this offering, as a holder of Preferred Stock, you will have no rights as a common stockholder with respect to the shares of common stock underlying the Preferred Stock until you acquire our common stock.

If you purchase Preferred Stock in lieu of common stock in this offering, until you acquire our common stock upon conversion of your Preferred Stock, you will have no rights with respect to the common stock underlying the Preferred Stock. Upon conversion of your Preferred Stock, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date for actions to be taken by our common stockholders occurs after the date you convert your Preferred Stock.

Our Preferred Stock will rank junior to all our liabilities to third party creditors, and to any class or series of our capital stock created after this offering specifically ranking by its terms senior to the Preferred Stock, in the event of a bankruptcy, liquidation or winding up of our assets.

In the event of bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Preferred Stock only after all our liabilities have been paid. Our Preferred Stock will effectively rank junior to all existing and future liabilities held by third party creditors. The terms of our Preferred Stock do not restrict our ability to raise additional capital in the future through the issuance of debt. Our Preferred Stock will also rank junior to any class or series of our capital stock created after this offering specifically ranking by its terms senior to the Preferred Stock. In the event of bankruptcy, liquidation or winding up, there may not be sufficient assets remaining, after paying our liabilities, to pay amounts due on any or all of our Preferred Stock then outstanding.

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 will enter into lock-up agreements pursuant to which, subject to certain exceptions, such persons will not sell 9,812,735 shares of our common stock (including common stock underlying options and warrants) that they own for six months after the date of this prospectus, as further described in "*Underwriting*." Notwithstanding the foregoing, the lock-up provisions in these agreements may be waived, at any time and without notice by the representative.

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 of 1933, as amended, or 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.

The determination of the offering price for the shares is more arbitrary compared with the pricing of securities for an established operating company.

There is no direct relationship between the offering price and our assets, book value, net worth, or any other economic or financial criteria. Rather, the price of the shares was derived through negotiations with the underwriters after considering various factors including prevailing market conditions, our future prospects and our capital structure. Although these factors were considered, the determination of the offering price is more arbitrary than the pricing of securities for an established operating company. This price does not necessarily accurately reflect the actual value of the shares or the price that may be realized upon disposition of the 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) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (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.

As a result of becoming a public company, we will 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 will be 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 second annual report we file with the SEC. 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 will incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. 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 will incur 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 will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

All statements other than statements of historical fact or relating to present facts or current conditions included in this prospectus are forward-looking statements. Forward-looking statements include, but are not limited to, statements regarding expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These statements may include words such as “anticipate,” “estimate,” “expect,” “project,” “plan,” “intend,” “believe,” “may,” “should,” “can have,” “likely” and other words and terms of similar meaning, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this prospectus are based on our current expectations and beliefs concerning future developments and their potential effects on us. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “*Risk Factors*.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, 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 we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. 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. Except as required by the federal securities laws, we are under no duty to update any of these forward-looking statements after the date of this prospectus or to conform these statements to actual results or revised expectations.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of our securities in this offering will be approximately $18.88 million (or $21.86 million if the underwriters exercise the over-allotment option in full), after deducting the underwriting discounts and estimated offering expenses payable by us. We will not receive any proceeds from the exercise of the Class A Warrants or the Class B Warrants unless such warrants are exercised for cash. We intend to use the net proceeds from the offering as follows:

- approximately $6.5 million to obtain our initial 510(k) regulatory approval in the United States for our sepsis product candidate, including completing any product development required to meet regulatory requirements and establishing relationships with manufacturing facilities with sufficient capacity for clinical evaluation and commercial scale production of the biosensor architecture;
- approximately $3.5 million to market the Sepsis test and Symphony system and establish a distribution network across the United States; and
- the remainder for working capital and general corporate purposes.

We expect the net proceeds to be sufficient to enable us to obtain regulatory approvals, including completing the related product development and establishing the related manufacturing facilities, as well as to market the Sepsis Test for Symphony and establish a distribution network.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and prevailing business conditions, which could change in the future as our plans and prevailing business conditions evolve. Predicting the cost necessary to develop medical devices can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical evaluations, any collaborations that we may enter into with third parties and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending the use of the net proceeds of this offering, we intend to invest the net proceeds in short-term investment-grade, interest-bearing securities.

We believe that the net proceeds from this offering will allow us to operate for at least the next 12 months. In addition, available resources may be consumed more rapidly than currently anticipated, and there can be no assurance that we will be successful in developing our planned products and generating sufficient revenue in the timeframe set forth above, or at all. We may be unable to meet our targets for regulatory approval and market launch, or we may be unable to generate anticipated amounts of revenue from sales of the system. We may also need additional funding for developing new products and services and for additional sales, marketing and promotional activities. Should this occur, we may need to seek additional capital earlier than anticipated. In the event we require additional capital, there can be no assurances that we will be able to raise such capital on acceptable terms, or at all. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations*."

DIVIDEND POLICY

Since our inception, we have not paid any dividends on our common stock, and we currently expect that, for the foreseeable future, all earnings (if any) will be retained for the development of our business and no dividends will be declared or paid. In the future, our Board of Directors may decide, at their discretion, whether dividends may be declared and paid, taking into consideration, among other things, our earnings (if any), operating results, financial condition and capital requirements, general business conditions and other pertinent facts, including restrictions imposed by foreign jurisdictions on paying dividends or making other payments to us.

DILUTION

The difference between the public offering price per share of our common stock and our pro forma as adjusted net tangible book value per share after this offering constitutes the dilution to investors in this offering. Net tangible book value per share is determined by dividing our net tangible book value, which is our total tangible assets less total liabilities, by the number of outstanding shares of common stock.

At June 30, 2021, our historical net tangible book deficit was approximately $400,000, or approximately $0.04 per share. Our historical net tangible book deficit represents our total tangible assets (total assets less deferred offering costs) less total liabilities and convertible preferred stock, and our historical net tangible book deficit per share is that number divided by the number of shares of common stock outstanding as of June 30, 2021.

At June 30, 2021, our pro forma net tangible book value was approximately $3.6 million, or approximately $0.34 per share after giving effect to the issuance on August 4, 2021 of an additional $1.5 million convertible debentures, after deducting the origination fees and estimated offering expenses payable by us, and the mandatory conversion of the debentures into Series D convertible preferred stock in connection with this offering.

After giving further effect to the sale of all 2,160,000 units (and the shares of common stock thereunder), and after deducting the underwriting discounts and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at June 30, 2021 would have been approximately $22.5 million or $1.78 per share, representing an immediate increase in net tangible book value of $1.44 per share to our existing stockholders and an immediate dilution of $8.22 per share to new investors.

The following table illustrates the dilution to the new investors on a per-share basis:

Public offering price per share		$ 10.00
Historical net tangible book deficit per share before offering	$ (0.04)	
Increase per share attributable to the pro forma adjustments described above	$ 0.38	
Pro forma net tangible book value per share before offering	$ 0.34	
Increase in net tangible book value per share attributable to shares offered hereby	$ 1.44	
Pro forma as adjusted net tangible book value per share after offering		$ 1.78
Dilution in pro forma net tangible book value per share to investors in offering		$ 8.22

If the representative exercises the option to purchase additional shares to cover over-allotments in full, the pro forma as adjusted net tangible book value per share of our common stock after giving effect to this offering would be approximately $1.96 per share, and the dilution in pro forma as adjusted net tangible book value per share to investors in this offering would be approximately $8.04 per share of common stock.

The following table summarizes, as of June 30, 2021, and assuming the sale of all the shares offered hereby, the differences between the number of shares of our common stock purchased from us, the total cash consideration paid, and the average price per share paid by our existing stockholders prior to this offering and by our new investors purchasing shares in this offering, before deducting the underwriting discounts and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing Stockholders	10,477,880	82.9%	$ 4,598,410	17.6%	$ 0.44
New Investors	2,160,000	17.1%	$ 21,600,000	82.4%	$ 10.00
Total	12,637,880	**100.00%**	$ 26,198,410	**100.00%**	

The number of shares of common stock outstanding is based on 10,477,880 shares of common stock issued and outstanding as of June 30, 2021 and excludes the following:

- 4,500,000 shares of common stock issuable upon the conversion of our Series D Convertible Preferred Stock;
- 1,172,120 shares of common stock issuable upon the exercise of our outstanding warrants to purchase common stock at a weighted average price of $1.02 per share;
- 555,826 shares of common stock issuable upon the exercise of our outstanding options to purchase common stock at a weighted average price of $2.59 per share;
- 1,960,000 shares of common stock that will become available for future issuance under our 2021 Stock Plan;
- 2,160,000 shares of common stock issuable upon the exercise of Class A warrants to be issued in this offering;
- 2,160,000 shares of common stock issuable upon the exercise (including the cashless exercise) of Class B warrants to be issued in this offering; and
- 108,000 shares of common stock issuable upon the exercise of warrants to be issued to the underwriters upon the closing of this offering.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2021:

- on an actual basis;
- on a pro forma basis, after giving effect to the issuance on August 4, 2021 of an additional $1.5 million in principal amount of convertible debentures, after deducting the origination fees and estimated offering expenses payable by us, and the mandatory conversion of the debentures into Series D convertible preferred stock;
- on a pro forma as adjusted basis, after giving further effect to the sale of Units of our securities in this offering, and after deducting the underwriting discounts and estimated offering expenses payable by us.

You should read this table together with the section of this prospectus entitled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2021		
	Actual	**Pro Forma**	**Pro Forma As Adjusted**
Cash and cash equivalents	$ 2,400,457	$ 3,765,457	$ 22,649,457
Convertible Debentures[(1)]	$ 2,501,904	$ —	$ —
Stockholders' equity (deficit):			
Series D convertible preferred stock, $0.0001 par value: 4,500 shares authorized; 0 shares issued and outstanding actual, 4,500 shares issued and outstanding pro forma and pro forma as adjusted	—	3,811,298	3,811,298
Series E convertible preferred stock, $0.0001 par value: 0 shares authorized, actual, 0 shares authorized and pro forma and pro forma as adjusted; 0 shares issued and outstanding actual and pro forma and pro forma as adjusted	—	—	—
Common stock, $0.0001 par value; 30,000,000 shares authorized, actual pro forma and pro forma as adjusted; 10,477,880 shares issued and outstanding actual, and pro forma and 12,637,880 shares issued and outstanding pro forma as adjusted	1,048	1,048	1,264
Additional paid-in capital	4,916,376	5,083,193	23,699,086
Accumulated deficit	(5,040,909)	(5,040,909)	(5,040,909)
Total stockholders' equity (deficit)	(123,485)	3,854,630	22,470,739
Total capitalization	$ 2,378,419	$ 3,854,630	$ 22,470,739

(1) Net of discount and issuance costs of $539,052, and amortization thereof of $40,956.

The number of shares of common stock outstanding is based on 10,477,880 shares of common stock issued and outstanding as of June 30, 2021 and excludes the following:

- 4,500,000 shares of common stock issuable upon the conversion of our Series D Convertible Preferred Stock;
- 1,172,120 shares of common stock issuable upon the exercise of our outstanding warrants to purchase common stock at a weighted average price of $1.02 per share;
- 555,826 shares of common stock issuable upon the exercise of our outstanding options to purchase common stock at a weighted average price of $2.59 per share;
- 1,960,000 shares of common stock that will become available for future issuance under our 2021 Stock Plan;
- 2,160,000 shares of common stock issuable upon the exercise of Class A warrants to be issued in this offering;
- 2,160,000 shares of common stock issuable upon the exercise (including the cashless exercise) of Class B warrants to be issued in this offering; and
- 108,000 shares of common stock issuable upon the exercise of warrants to be issued to the underwriters upon the closing of this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

Prospective investors should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements." You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

All common stock share and per share amounts reported in the following analysis reflect the stock dividend of 2.15 share of common stock for each outstanding share of common stock, effected June 7, 2021 unless indicated otherwise.

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 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 a 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 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. Our losses attributable to operations for the fiscal year ended December 31, 2020 and December 31, 2019 were approximately $1.2 million and $0.8 million, respectively. As of June 30, 2021, we had an accumulated deficit of approximately $5 million.

Going Concern

Our financial statements are prepared based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging growth companies regarding product development and commercialization, limited working capital, recurring losses and negative cash flow from operations, future profitability, our ability to obtain future capital, our protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory environment, recruiting and retaining key personnel, our dependence on licensing agreements and our lack of sales and marketing activities. These factors raise substantial doubt about our ability to continue as a going concern.

We have relied exclusively on private placements to finance our business and operations. We do not have any credit facilities as a source of future funds. If we are not successful in securing additional outside financing, there are no assurances that investors will continue to fund us to an adequate level of financing needed for the long-term development and commercialization of our products.

There is substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of these uncertainties described above. Our management and board of directors believe that the net proceeds from this offering, our current cash balance and cash expected to be generated from commercial sales activity, will enable us to fund our operations for at least 12 months.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table sets forth our results of operations for the years ended December 31, 2020 and 2019:

	Years Ended December 31,	
	2020	**2019**
Revenues	$ —	$ —
Operating costs and expenses		
Research and development	527,253	454,610
General and administrative	596,116	883,999
Marketing and business development	73,022	292,804
Total operating expenses	1,196,391	1,631,413
Operating loss	(1,196,391)	(1,631,413)
Other income (expenses)		
Gain on transfer of equipment at fair value	—	741,590
Gain on forgiveness of note payable, Paycheck Protection Program	102,000	—
Derivative warrant liability (loss) gain	(42,434)	9,842
Interest income (expense), net of amortization of premium	(26,997)	52,284
Other income	5,537	7,855
Net loss	$ (1,158,285)	$ (819,842)

Research and Development

Research and development expenses increased approximately $73,000, or 16%, for the year ended December 31, 2020, as compared to the same period of 2019. The increase was due to fees paid and accrued to Toray of approximately $240,000 in connection with our license agreements offset by decreases in payroll and other expenses due to funding shortages in 2020 as compared to 2019.

General and Administrative

General and administrative expenses decreased approximately $288,000, or 33%, for the year ended December 31, 2020, as compared to the same period of 2019. The decrease was primarily attributable to reduced general and administrative expenses related to funding shortages, including salary reductions and reduced spending.

Marketing and Business Development

Marketing and business development expenses decreased approximately $220,000, or 75%, for the year ended December 31, 2020, as compared to the same period of 2019 The decrease was primarily attributable to reduced sales and marketing expenses due to funding shortages, including reduction of expenses and headcount.

Gain on transfer of equipment at fair value

Gain on transfer of equipment at fair value decreased by $742,000 or 100%, for the year ended December 31, 2020 as compared to the same period of 2019, due to recognition of a gain relating to equipment transferred to us as in 2019 part of a licensing deal with Hitachi. As part of this agreement Hitachi transferred approximately $742,000 of equipment for use in the manufacture products licensed and related to the licensed technology. Such equipment was measured at fair value upon transfer to the Company.

Gain on forgiveness of note payable, Paycheck Protection Program

The gain on forgiveness of note payable, Paycheck Protection Program was due to a loan the Company received under the Paycheck Protection Program ("PPP") totaling $116,000 of which $102,000 was forgiven in 2020 as the Company met the requirements as to usage of the funds.

Derivative Warrant Liability Gain (Loss)

Derivative warrant liability loss increased by approximately $52,000 or 531% in the year ended December 31, 2020 as compared to the same period of 2019, primarily because of a revaluation of the derivative warrant liability that is required each reporting period.

Interest Expense, Net of Amortization of Premium

Interest expense increased by approximately $79,000 or 152% in the year ended December 31, 2020 as compared to the same period of 2019. The increase was primarily related to the notes issued in October 2020 which were issued at a discount, the amortization of which increased non-cash interest expense by approximately $65,000, which was offset by the amortization of premium on the notes payable issued in 2017.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table sets forth our results of operations for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,	
	2021	**2020**
Revenues	$ —	$ —
Operating costs and expenses		
Research and development	250,175	105,469
General and administrative	529,741	321,752
Marketing and business development	119,354	39,222
Total operating expenses	899,270	466,443
Operating loss	(899,270)	(466,443)
Other income (expenses)		
Derivative warrant liability (loss) gain	9,676	(49,667)
Interest income (expense), net of amortization of premium	(32,116)	24,610
Grant income	75,000	—
Other income	12,289	5,228
Net loss	$ (834,421)	$ (486,272)

Research and Development

Research and development expenses increased approximately $145,000, or 137%, for the six months ended June 30, 2021, as compared to the same period of 2020. The increase was primarily due to fees paid to Sanyoseiko of approximately $140,000 in connection with developing procedures, necessary components and machines, and trainings needed to manufacture the Symphony analyzers in Sanyoseiko's factories.

General and Administrative

General and administrative expenses increased approximately $208,000, or 65%, for the six months ended June 30, 2021, as compared to the same period of 2020. The increase was primarily attributable to increased accounting, legal, and professional fees of approximately $219,000 related to our preparation to perform an initial public offering of common stock that do not qualify as offering costs, as well as expense for expiring inventory of approximately $85,000, offset by reduced payroll expenses of approximately $114,000 related to headcount reductions in June 2020 due to funding shortages.

Marketing and Business Development

Marketing and business development expenses increased approximately $80,000, or 204%, for the six months ended June 30, 2021, as compared to the same period of 2020. The increase was primarily attributable to increased sales and business development expenses of approximately $90,000 paid to consultants to expand the development and commercialization of our Symphony platform.

Derivative Warrant Liability Gain (Loss)

Derivative warrant liability gain increased by approximately $59,000 or 119% in the six months ended June 30, 2021, as compared to the same period of 2020, primarily because of a revaluation of the derivative warrant liability that is required each reporting period.

Interest Income (Expense), Net of Amortization of Premium

Interest expense increased by approximately $57,000 or 230% in the six months ended June 30, 2021, as compared to the same period of 2020. The increase was primarily related to the amortization of discount and accrued interest on the notes issued in June 2021 of approximately $41,000 and $15,000, respectively, offset by the amortization of premium on the notes payable issued in 2017.

Grant Income

Grant income increased by $75,000 in the six months ended June 30, 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

We have funded our operations to date primarily with net proceeds from sales of our preferred stock and issuance of convertible notes. On June 30, 2021, we had cash of approximately $2.4 million and we had a working capital deficit of approximately $516,000.

In 2017, we issued 106 units, at a purchase price of $20,000 per unit, with each unit consisted of 100 shares of Series A redeemable, convertible preferred stock (“Series A”) at a purchase price of $100 per share and $10,000 in notes payable (the “Notes”). Gross proceeds from the financing were $2,120,000, less $183,194 in issuance costs. All Series A and related notes were converted to common stock and retired on June 1, 2021.

On April 5, 2019, we issued 4,455 shares of Series B redeemable, preferred stock (“Series B”) at a purchase price of $361.50 per share. Gross proceeds from the Series B financing were approximately $1.61 million. We also issued 622 Series B warrants in connection with the Series B financing. Through the rest of 2019 we issued an additional 277 shares of Series B and 41 Series B warrants for gross proceeds of $100,000. In 2020, we issued 456 additional shares of Series B and 68 Series B warrants for gross proceeds of $50,000. The 731 warrants convertible into Series B were adjusted and restated to convert into 36,600 shares of common stock and following the split were convertible into 115,190 shares of common stock.

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. All warrants were adjusted and restated to be convertible to common stock on June 1, 2021. On June 7, 2021 all notes were converted to common stock pursuant to related warrants or repaid (see below).

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. All shares were converted to common stock in June 2021.

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.

On June 1, 2021, our Series A with a stated value of approximately $1.1 million was converted into 530,000 (prior to the stock dividend) shares of common stock, our Series B preferred stock with a stated value of approximately $1.8 million was converted into 259,350 (prior to the stock dividend) shares of common stock, and our Series C preferred stock with a stated value of approximately $1.0 million was converted into 31,800 (prior to the stock dividend) shares of common stock. In addition, holders of our 2017 secured notes amended and restated their agreement such that the notes would automatically convert into 184,292 (prior to the stock dividend) shares of common stock upon the occurrence of a qualified financing (as defined in the notes) and certain warrants issued in connection with the issue of Series B preferred stock were amended and restated to be exercisable into common stock.

On June 7, 2021, certain holders of approximately $132,000 in principal of our convertible subordinated notes elected to convert their debt, inclusive of accrued interest, into 1,323,830 (prior to the stock dividend) shares of common stock and we repaid the remaining principal and interest of approximately $28,000 on the remaining notes.

Also on June 7, 2021, we:

- declared a stock dividend which increased the number of shares of common stock outstanding from 3,329,272 to 10,477,880;
- adjusted the number of shares of common stock issuable upon exercise of the restated Series B warrants from 36,600 to 115,190;
- adjusted the number of shares of common stock issuable upon exercise of the remaining warrants issued with subordinated notes from 216,170 to 680,331;
- adjusted the number of shares issuable upon exercise of outstanding options under our 2018 equity incentive plan from 119,416 to 375,826 and the number of shares reserved for issue under future grants from 80,584 to 253,614; and
- approved an amendment to our certificate of incorporation to increase the number of authorized shares of common and preferred stock to 30 million and 5 million shares, respectively.

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. The Debentures are convertible, at Sabby’s option, into our Series D Preferred Stock at a conversion price of $1,000 per share.

On August 4, 2021 we issued and additional $1.5 million in principal amount of the Debentures to Sabby.

Upon completion of this offering, we expect our existing cash and the net proceeds of this offering to support our operations for at least 12 months. In order to finance 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 through the issuance of common stock, preferred stock, and convertible or non-convertible 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, 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.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to continue to operate without the threat of liquidation for the foreseeable future unless we raise additional capital.

Summary Statement of Cash Flows for the Years Ended December 31, 2020 and 2019

The following table summarizes our cash flows for the periods indicated:

	Years Ended December 31,	
	2020	**2019**
Net cash provided by (used in):		
Operating activities	$ (508,710)	$ (1,690,118)
Investing activities	—	(6,021)
Financing activities	1,325,060	1,511,801
Net increase (decrease) in cash and cash equivalents	$ 816,350	$ (184,338)

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately $509,000 for the year ended December 31, 2020. We had a net loss of approximately $1.2 million offset by non-cash loss on revaluation of our derivative warrant liability of approximately $42,000, and an increase in operating liabilities of approximately $538,000 and a decrease in operating assets of approximately $58,000. The change in operating assets and liabilities was due to our efforts to conserve cash in the period prior to closing our Series C financing which occurred in November 2020 and most invoices were paid in January 2021.

Net cash used in operating activities was approximately $1.7 million for the year ended December 31, 2019. We incurred a net loss of approximately $820,000, a non-cash gain of $742,000 on the transfer of equipment used in the manufacture of the licensed technology from Hitachi as part of an agreement and a decrease in working capital of approximately $178,000. We anticipate our research and development efforts and on-going general and administrative costs will generate negative cash flows from operating activities for the foreseeable future.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately $1.3 million for the year ended December 31, 2020. The proceeds were primarily the result of receipt of approximately $60,000 related to our Series B financing, approximately $995,000 related to our Series C financing, approximately $154,000 related to our 2020 subordinated promissory notes, and approximately $116,000 related to our PPP loan.

Net cash provided by financing activities was approximately $1.5 million for the year ended December 31, 2019. The proceeds were primarily attributable to $1.7 million related to our Series B financing offset by $265,000 in principal payments on notes payable.

Summary Statement of Cash Flows for the Six Months Ended June 30, 2021 and 2020

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2021	**2020**
Net cash provided by (used in):		
Operating activities	$ (732,669)	$ (264,829)
Investing activities	1,934	—
Financing activities	2,218,831	223,926
Net increase (decrease) in cash and cash equivalents	$ 1,488,096	$ (40,903)

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately $733,000 for the six months ended June 30, 2021. We had a net loss of approximately $834,000 offset by non-cash depreciation expense of approximately $64,000, and an increase in working capital of approximately $50,000. The change in working capital was primarily due to expiring inventory we wrote down of approximately $85,000 and an increase in accrued expenses of approximately $77,000 offset by a decrease in payables of approximately $108,000.

Net cash used in operating activities was approximately $265,000 for the six months ended June 30, 2020. We incurred a net loss of approximately $486,000, offset by an increase in payables and accrued expenses of approximately $221,000.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately $2.2 million for the six months ended June 30, 2021. The proceeds were primarily the result of receipt of $3 million from the issuance of convertible debentures in June 2021, offset by issuance costs of $395,000, deferred offering costs of approximately $88,000, and payments of our outstanding notes payable of approximately $290,000.

Net cash provided by financing activities was approximately $224,000 for the six months ended June 30, 2020. The proceeds were primarily attributable to $116,000 from our PPP loan and approximately $108,000 we received from issuance of Series B redeemable, convertible preferred stock, net of issuance costs.

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 financial statements.

We have analyzed all other recent accounting pronouncements and determined that no others would have a material impact on the Company.

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 financial statements may not be comparable to those of companies that comply with public company effective dates.

Derivative Instruments

We issued warrants to purchase preferred stock as part of our Series B Preferred Stock issuance in 2020 and 2019 that do not meet the requirements for classification as equity and 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 operation 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.

Long-Lived Assets

Purchased property and equipment are carried at cost. Transferred property and equipment are carried at the estimated fair value as of the date of transfer. Depreciation expense is provided over the estimated useful lives of the assets using the straight-line method. Equipment was transferred to us as part of a licensing deal with Hitachi in

2019. The agreement provides us with an exclusive, non-transferable license to licensed technology information and patents to make, use, sell, market export or otherwise distribute the product and specifies that Hitachi is responsible for transferring all equipment and machinery necessary to manufacture the product from Japan to our US facilities. Hitachi was also responsible for providing training on the operation, maintenance, and use of the machinery and manufacturing know-how of the product. In exchange for those concessions, we released Hitachi from all charges, claims, obligations, and costs arising out of our prior agreement. There was no other consideration exchanged as part of this agreement. We determined the fair value of the equipment transferred was approximately $742,000 at the time of transfer based on an outside third-party valuation.

Long-lived tangible assets, including property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We regularly evaluate whether events or circumstances have occurred that indicate possible impairment and rely on a number of factors, including expected future operating results, business plans, economic projections, and anticipated future cash flows. We use an estimate of the future undiscounted net cash flows and comparisons to like-kind assets, as appropriate, of the related asset over the remaining life in measuring whether the assets are recoverable. Measurement of the amount of impairment, if any, is based upon the difference between the asset's carrying value and estimated fair value. Fair value is determined through various valuation techniques, including cost-based, market and income approaches as considered necessary. We depreciate intangible assets on a straight-line basis over their estimated useful lives.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC. We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for any other contractually narrow or limited purpose.

Emerging Growth Company and Smaller Reporting Company Status

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

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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 a 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 as a Research Use Only ("RUO") product in Japan by selected clinical institutions for measurement of IL-6 in rheumatoid arthritis to monitor disease progression. Based in part on this extensive development, we believe we are positioned now to complete the last stages of development needed to move to 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) is able to 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 Interleukin-6 ("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. It is a biomarker that appears early on 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 detection of IL-6 early on might allow physicians to make better therapeutic and treatment decisions. Due to the clinical significance of IL-6 testing, 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 heightened in patients with COVID-19-associated systemic inflammation and hypoxic respiratory failure. In addition, certain of the institutions that we are working with on our clinical studies have Clinical Laboratory Improvement Amendments ("CLIA") certified labs. These CLIA certified laboratories, might adopt Symphony IL-6 tests for their clinical testing as laboratory developed tests.

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 cleared products and our 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 this offering 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 was 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 increases, 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 X1. 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.

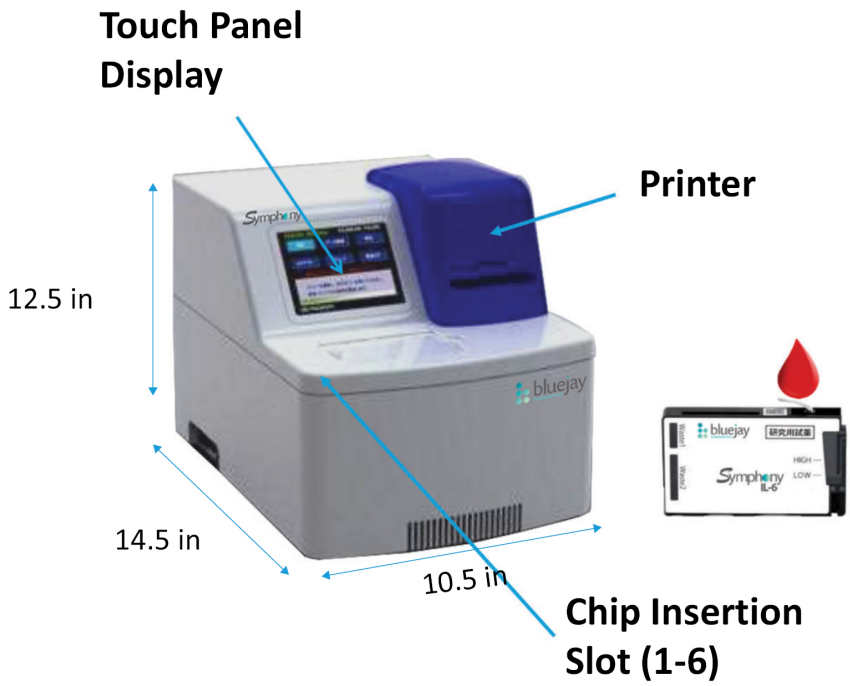

Figure X1. Photograph of the Symphony Fluorescence Immuno-analyzer and a Symphony IL-6 Cartridge. Barcode reader (not pictured) is included to streamline clinical workflow.

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 X2. 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.

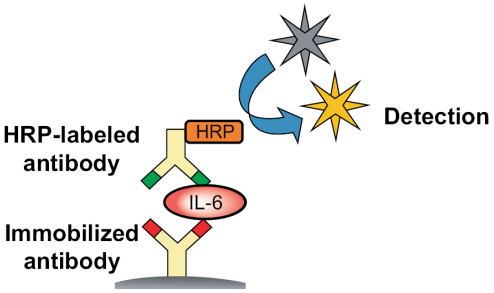

Figure X2. Overview of the Symphony IL-6 test principle.

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 X3. 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 X3. 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 as a RUO product 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 RUO product in the U.S. Certain laboratories may choose to utilize the RUO Symphony in an 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. In order to expedite the submission of our 510(k), we may seek to obtain data from laboratories using the RUO Symphony in LDTs.

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; Parkland Clinic; William P. Clements Jr. University Hospital (CUH); and Zale Lipshy Pavilion 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. Data from previous studies with other IL-6 measurement systems suggest a prevalence of intubation in this population of roughly 25% and a test sensitivity of roughly 85% and specificity of roughly 65% at the estimated optimal cutoff value. 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 for these tests to be completed in October 2021.

In December 2021, 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.

In January 2022, we plan to submit 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. We believe our planned study design will also qualify us to apply for EUA for 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. We have not completed any testing of our Symphony IL-6 product candidate related to COVID-19. 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 through distribution as an RUO followed by seeking 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 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 an initial payment of $120,000 and are required to make an additional $120,000 prior to October 2021. 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 components 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 adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and subject to FDA enforcement action. 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. 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, 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 I and II 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 for Class III devices include the EUA, 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 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 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 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.

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 inspects 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.

Adverse Event Reporting and 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 FDCA but has for the most part exercised enforcement discretion and has not required clearance, authorization, or approval of LDTs prior to marketing. Laboratories certified as "high complexity" under CLIA may develop, manufacture, validate and run LDTs.

In August 2020, the Department of Health and Human Services ("HHS") announced that FDA will not require premarket review of LDTs absent notice-and-comment rulemaking, and rescinded FDA guidance documents and other informal statements concerning premarket review of LDTs. The HHS announcement did not define the term LDT. In an accompanying FAQ document, HHS stated that, while LDTs are not subject to premarket review, FDA may still regulate LDTs under the Public Health Service Act. As of November 2020, HHS instructed the FDA to review voluntary EUA submissions of LDTs for COVID-19 in order to extend certain statutory immunities to liability for those laboratories under the federal Public Readiness and Emergency Preparedness Act ("PREP Act"). Failure to obtain an EUA for a COVID-19 LDT can impair such immunity and could make payor reimbursement for COVID-19 LDTs under the Family First Coronavirus Act unavailable.

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 products 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 products 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 June 30, 2021, we have five full-time employees and one part-time employee located in Acton, Massachusetts. We also contract for hire with two outside consultants and contractors.

Facilities

We use approximately 3,700 square feet of office space at our headquarters in Acton, Massachusetts pursuant to an expense sharing agreement we have with Lana Management and Business Research International, LLC (“LMBRI”), an entity owned and controlled by Mr. Dey and Ms. Dey. Pursuant to our agreement, we reimburse LMBRI monthly for certain shared expenses, including insurance, rent, salaries, telephone, and other miscellaneous expenses. We are billed $4,000 monthly for these expenses. We believe that we will need additional office and laboratory space subsequent to the capital raise to facilitate our planned expansion.

Legal Proceedings

We are currently not a party to any pending legal proceeding, nor is our property the subject of a pending legal proceeding, that we believe is not ordinary routine litigation incidental to our business or otherwise material to the financial condition of our business.

Allereye

In June 2021, we entered into a Contribution and Assumption Agreement with a newly created and wholly owned subsidiary, Bluejay Spinco, LLC (“Spinco”), to contribute the assets related to its Allereye product to Spinco, including specifically related assets and intellectual property. We have no current plans to commercialize these assets and we do not intend to utilize any proceeds from this offering in connection with these assets.

Periodic Reporting and Audited Financial Statements

We are registering the securities offered by this prospectus under the Securities Exchange Act of 1934, as amended, and will have reporting obligations, including the requirement to file annual and quarterly reports with the SEC, following this offering. In accordance with the requirements of the Securities Exchange Act of 1934, our annual reports will contain financial statements audited and reported on by an independent registered public accounting firm.

MANAGEMENT

Executive Officers and Directors

Set forth below is a list of the names, ages as of June 30, 2021 and positions and a brief account of the business experience of the individuals who serve as our executive officers and directors as of the date of this prospectus.

Name	Age	Position
Neil (Indranil) Dey	58	President, Chief Executive Officer and Director
Gordon Kinder	41	Chief Financial Officer
Dr. Jason Cook	39	Chief Technology Officer
Kevin Vance	64	Chief Commercial Officer
Douglas C. Wurth	56	Chairman of the Board
Svetlana Dey	49	Director
Donald R. Chase	74	Director
Fred S. Zeidman	74	Director
Gary Gemignani	56	Director Nominee

Neil Dey, President, Chief Executive Officer and Director

Mr. Dey co-founded Bluejay Diagnostics in 2015. In 2008, Mr. Dey co-founded Lana Management and Business Research International, LLC (“LMBRI”), and served as Chief Operating Officer of LMBRI from 2008 through 2015. LMBRI is a management consulting company focused on product launch and marketing in the medical field in the U.S., Japan and EU. During his tenure with LMBRI, he spent approximately 8 years consulting with Toray Industries, Hitachi Chemicals (now Showa denko Materials Co. Ltd.), Fujifilm (Fuji Chemicals), Merck & Co., SRI International, among others. From 2005 to 2007, Mr. Dey served as Vice President of Business Development and Market for Definines, AG. From 2001 to 2005, Mr. Dey served as Head of Business Development, Western U.S. for IMPATH, Inc., where he was responsible for three business units and the introduction of Her2neu diagnostics for breast cancer treatment with Herceptin. Earlier positions include Chief Business Officer for Genmethrax, Inc.; Manager, Technology Licensing, Thomas Jefferson Medical University; Manager, Technology Licensing, Ciba Geigy (Novartis). Mr. Dey earned both Bachelor of Science and Master of Science degrees in Biochemistry from Visva-Bharati University in India and a Ph.D. in Lipid Membrane Biochemistry from Biological Research Center in Hungary. He also earned a Master’s in Business Administration (Fulbright Scholarship) from the University of Cambridge. We believe Mr. Dey’s history with our company, coupled with his extensive business development experience in the medical device industry, provide him with the qualifications to serve as a director.

Gordon Kinder, Chief Financial Officer

Mr. Kinder joined us in 2021. Mr. Kinder founded Capella Financial Services, an accounting and financial services firm in 2008. In connection with the services provided by Capella Financial Services, Mr. Kinder served as part-time chief financial officer of Passport Systems, Inc., which filed a petition in the United States Bankruptcy Court for the District of Massachusetts in November 2020 under Chapter 7 of the U.S. Bankruptcy Code. From 2013 to 2017, Mr. Kinder was Senior Director, Treasurer and Controller for Blue Sky Biotech through its acquisition by LakePharma, Inc. From 2012 to 2013, Mr. Kinder was Director of Finance and Controller for Building Engines, Inc. and from 2010 to 2011 he was Senior Financial Analyst for Vantage Travel Services. Mr. Kinder started his career at Ernst & Young, LLP where he was employed from 2005 to 2008. Mr. Kinder earned a Bachelor of Arts in History from Kenyon College and Master of Business Administration and Master of Science in Accounting degrees from Northeastern University.

Dr. Jason Cook, Chief Technology Officer

Dr. Cook joined us in 2021. From 2014 to 2021, Dr. Cook served as the chief executive officer of NanoHybrids, Inc., a nanotechnology company specializing in the development and manufacture of theranostic nanoparticle platform technologies. He was also a director and served as chairman of its board from 2020 to 2021, and from 2014 to 2017, he served as senior scientist developing many of the core technologies of the company. Dr. Cook earned a Ph.D.

in Biomedical Engineering from University of Texas at Austin focusing on medical diagnostic system design and development. His postdoctoral work focused on the improvement of bioconjugation strategies of nanoparticles for molecular targeting. Dr. Cook also serves as an ad-hoc reviewer for numerous panels at the National Institute of Health and peer reviewed scientific journals.

Kevin Vance, Chief Commercial Officer

Mr. Vance joined us in 2021. Prior to that, Mr. Vance served as Chief Business Development Executive for Vibra Healthcare from 2016 to 2018, an operator of 46 long term acute care hospitals. From 2013 to 2016, Mr. Vance was Director of Business Development for the Commercial Division at Lifebridge Health Systems, which was converting multiple hospital and entities into an Accountable Care Organization (ACO) system. He was responsible for joint ventures and the expansion of commercial services, including Urgent Care, Outpatient Surgery, Out Patient Physical Therapy, Sleep Centers, Homecare and Retail Pharmacy among others. Prior to Lifebridge Health he was Senior Executive Director of Business Development and Marketing for UMass Memorial Healthcare, a seven hospital system, from 2005 to 2011. Mr. Vance earned a Masters of Business Administration degree in Finance from Western New England College and a Bachelor of Science degree in Industrial Engineering and Operations Research from the University of Massachusetts.

Douglas C. Wurth, Chairman of the Board

Mr. Wurth has served as Chairman of the Board of Bluejay Diagnostics since 2017. Since 2016, Mr. Wurth has been a private investor. Mr. Wurth has served as Chief Executive Officer and a Director of Good Works II Acquisition Corp. since February 2021, and Co- Chairman of Good Works Acquisition Corp. since October 2020. Mr. Wurth led major businesses within J.P. Morgan Asset Management during his nearly 20 years at J.P Morgan from 1997 to 2016. Mr. Wurth was the Chief Executive Officer of Alternative Investments in Asset Management, and Chief Executive Officer of J.P. Morgan's International Private Bank, where he led the expansion of the franchise in Asia, Latin America and Europe while based in New York, Hong Kong, and London. Since leaving J.P. Morgan Mr. Wurth has invested in and helped lead several private companies, of which he is Chairman of the Board of Standard Power and Vestrata, and a board member of Triax Technologies. Before joining J.P. Morgan, Mr. Wurth practiced law at the New York firm Skadden, Arps, Slate, Meagher & Flom from 1992 to 1995, and served as General Counsel to former U.S. Senator Robert Dole's 1996 presidential campaign. Mr. Wurth earned a Bachelor of Arts degree from the University of Notre Dame and a J.D. from the University of Virginia School of Law. We believe that Mr. Wurth is well qualified to serve on our board of directors due to his overall leadership experience, his experience in the private equity and alternative investments industry and his legal experience.

Donald R. Chase, Director

Mr. Chase has served as on our Board of Directors since 2017. Mr. Chase has been a member of Board of Directors of Merchants Bank and Merchants Bancshares, Inc., in South Burlington. VT, from 2015 through 2017. Mr. Chase was Chairman of the Board of NUVO Bank and Trust Company of Springfield, Massachusetts since its inception in 2008 through 2015. Mr. Chase served as President and Chief Executive Officer, Vice Chairman, and a Director of Westbank Corporation and its wholly-owned subsidiary, Westbank from 1988 to 2007. Mr. Chase is active in a number of commercial real estate, farming and ranching activities and serves in a number of civic roles. He is Chairman of the Board of Trustees for the Eastern States Exposition in West Springfield, MA and a Trustee of the Big E Trust. Mr. Chase is also a commissioner of the Board of Public Safety for the City of West Springfield, MA and is a member to the Massachusetts Board of Agriculture. Mr. Chase is a veteran of the United States Army during which he served in combat in Vietnam from 1967 through 1969. Mr. Chase graduated with honors from Western New England University with a Bachelor of Science degree in Accounting. We believe that Mr. Chase is well qualified to serve on our board of directors due to his executive experience and his financial experience.

Fred S. Zeidman, Director

Mr. Zeidman has served on our Board of Directors since May 2021. Mr. Zeidman is Chairman of WoodRock & Co., an investment banking service business and serves as Chairman and CEO of Good Works Acquisition Corp. and Chairman of Good Works II Acquisition Corp, both publicly held SPACs and Mr. Zeidman served as Chairman of Gordian Group LLC, a U.S. investment bank specializing in board level advice in complex,

distressed or “story” financial matters. Mr. Zeidman, Chairman Emeritus of the United States Holocaust Memorial Council was appointed by President George W. Bush in March 2002 and served in that position from 2002-2010. A prominent Houston based business and civic leader; Mr. Zeidman also is Chairman Emeritus of the University of Texas Health Science System Houston. He is formerly National Chairman of the Development Corp of Israel Campaign (Israel Bonds) and served on the Board of the National World War II Museum. Mr. Zeidman was the former CEO, President and Chairman of Seitel, Inc., a Houston-based onshore seismic data provider where he was instrumental in the successful turnaround of the Company. He served as lead Director of Straight Path Communications, Inc. until its sale to Verizon in 2018. He was also Director of REMA a division of NRG Corp. and he further serves on the board of Prosperity Bank and was formerly Restructuring Officer of TransMeridian Exploration Inc. and Chief Bankruptcy Trustee of AremisSoft Corp. He held the post of Chairman of the Board and CEO of Unibar Corporation, the largest domestic independent drilling fluids company, until its sale to Anchor Drilling Fluids in 1992. Mr. Zeidman holds a Bachelor’s degree from Washington University in St. Louis and a Master’s in Business Administration from New York University. We believe that Mr. Zeidman is well qualified to serve on our board of directors due to his extensive leadership and corporate finance experience, as well has his extensive relationships in the investing and investment banking businesses.

Svetlana Dey, Director

Ms. Svetlana Dey has been member of Bluejay’s Board of Directors since 2015. Ms. Dey co-founded Bluejay Diagnostics in 2015. She also co-founded LMBRI in 2008, a management consulting company focused on product launch and marketing in the medical field in the U.S., Japan and India. Ms. Dey has served as LMBRI’s President and CEO since 2008. Ms. Dey is a Board Member of Laminar Pharma, Inc. Prior to LMBRI, Ms. Dey spent more than 15 years in healthcare consulting businesses. In these roles, she has been involved in management and operations of healthcare and life sciences products development, sales & marketing operations and general management for more than 12 years. Ms. Dey earned a Master’s Degree in Mathematics from the State University of Mari El Republic, Russia. We believe Ms. Dey’s history with our company, coupled with her extensive experience in the healthcare industry, provide her with the qualifications to serve as a director.

Gary Gemignani, Director Nominee

Mr. Gemignani will join our Bluejay’s Board of Directors upon the closing of this offering. Mr. Gemignani has served as EVP, Chief Financial Officer of Acacia Pharma Group plc, a hospital pharmaceutical company since January 2020. Prior to Acacia Pharma, Mr. Gemignani served as CFO of Synergy Pharmaceuticals Inc. from 2017 to 2019 where he successfully led the sale of this Nasdaq-listed company’s assets to Bausch Health. Synergy Pharmaceuticals Inc. filed a petition in the United States Bankruptcy Court for the Southern District of New York in December 2018 under Chapter 11 of the U.S. Bankruptcy Code. Previously, Mr. Gemignani served as CEO and CFO of Biodel Inc., overseeing business and strategic planning, operations and financing activities of the company. Prior to this, Mr. Gemignani served in senior and executive financial and operational roles with multiple public and private companies including, Prudential Financial, Gentium, Novartis and Wyeth. Mr. Gemignani started his career at Arthur Andersen & Co. We believe that Mr. Gemignani is well qualified to serve on our board of directors due to his extensive public company experience, as well as his accounting and financial experience.

Family Relationships

Ms. Svetlana Dey is married to Mr. Neil Dey.

Director Independence

Our Board of Directors has determined that Messrs. Wurth, Chase, Zeidman, and Gemignani would each be considered an “independent director” under the Nasdaq listing rules, which is defined generally as a person other than an executive officer or employee of ours who does not have a relationship that, in the opinion of our Board of Directors, would interfere with the director’s exercise of independent judgment in carrying out the responsibilities of a director. Our independent directors together constitute a majority of our full Board of Directors. Our independent directors will have regularly scheduled meetings at which only independent directors are present.

Board Leadership Structure and Role in Risk Oversight

Our Board of Directors recognizes that one of its key responsibilities is to evaluate and determine its optimal leadership structure so as to provide effective oversight of management.

Although management is responsible for the day-to-day management of the risks we face, our Board of Directors and its committees will take an active role in overseeing management of our risks and have the ultimate responsibility for the oversight of risk management. The Board of Directors will regularly review information regarding our operational, financial, legal and strategic risks. Specifically, senior management will attend periodic meetings of the Board of Directors, provide presentations on operations including significant risks, and will be available to address any questions or concerns raised by our Board of Directors.

In addition, we expect that committees will assist the Board of Directors in fulfilling its oversight responsibilities regarding risks. The Audit Committee will coordinate the Board of Directors' oversight of our internal control over financial reporting, disclosure controls and procedures, related party transactions and code of conduct and corporate governance guidelines and management will regularly report to the Audit Committee on these areas. The Compensation Committee will assist the Board in fulfilling its oversight responsibilities with respect to the management of risks arising from our compensation policies and programs. When any of the committees receives a report related to material risk oversight, the chairperson of the relevant committee will report on the discussion to the full Board of Directors.

Board Committees

Our Board of Directors has three standing committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee has a written charter, which will be available on our corporate website.

Audit Committee

We have established an Audit Committee of the Board of Directors, which consists of Messrs. Wurth and Chase. Mr. Chase is the current chairperson of the Audit Committee. Upon the closing of this offering, Mr. Gemignani will join the Audit Committee and serve as chairperson of the Audit Committee. Each of Messrs. Wurth, Chase and Gemignani are independent directors under the Nasdaq listing standards applicable to audit committees. Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. The Audit Committee consists exclusively of directors who are financially literate. In addition, Mr. Gemignani is considered an "audit committee financial expert" as defined by the SEC's rules and regulations.

The Audit Committee's duties, which are specified in the Audit Committee charter, include, but are not limited to:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the Board of Directors whether the audited financial statements should be included in our Form 10-K;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- reviewing and approving all related-party transactions;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;

- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies.

Compensation Committee

We have established a Compensation Committee of the Board of Directors which consists Messrs. Wurth, Chase and Gemignani, each of whom is an independent director under the NASDAQ Stock Market listing standards applicable to compensation committees. Mr. Chase serves as chairperson of the Compensation Committee. The Compensation Committee's duties, which are specified in our Compensation Committee charter, include, but are not limited to:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to our principal executive officer's compensation, evaluating our principal executive officer's performance in light of such goals and objectives and determining and approving the remuneration (if any) of our principal executive officer based on such evaluation;
- reviewing and approving the compensation of all of our other executive officers;
- reviewing our executive compensation policies and plans;
- implementing and administering our incentive compensation equity-based remuneration plans;
- assisting management in complying with our proxy statement and annual report disclosure requirements;
- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our executive officers and employees;
- if required, producing a report on executive compensation to be included in our annual proxy statement; and
- reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors.

The charter will also provide that the Compensation Committee may, in its sole discretion, retain or obtain the advice of a compensation consultant, legal counsel or other adviser and will be directly responsible for the appointment, compensation and oversight of the work of any such adviser. However, before engaging or receiving advice from a compensation consultant, external legal counsel or any other adviser, the Compensation Committee will consider the independence of each such adviser, including the factors required by the NASDAQ Stock Market and the SEC.

Nominating and Corporate Governance Committee

We have established a Nominating and Corporate Governance Committee of the Board of Directors, which consist of Messrs. Wurth, Chase and Zeidman, each of whom is an independent director under the NASDAQ Stock Market listing standards applicable to nominating committees. Mr. Wurth is the chairperson of the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee is responsible for overseeing the selection of persons to be nominated to serve on our Board of Directors. The Nominating and Corporate Governance Committee considers persons identified by its members, management, stockholders, investment bankers and others.

Code of Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our code of business conduct and ethics will be posted on our corporate website and is filed as an exhibit to this registration statement. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, on our corporate website or in filings under the Exchange Act.

Limitation of Directors Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our amended and restated certificate of incorporation will limit the liability of our directors to the fullest extent permitted by Delaware law.

We propose to purchase director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act. Our amended and restated certificate of incorporation and by-laws also will provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. Our amended and restated by-laws will further provide that we will indemnify any other person whom we have the power to indemnify under Delaware law. In addition, we intend to enter into customary indemnification agreements with each of our officers and directors.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceedings that may result in a claim for such indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Director Compensation

During the year ended December 31, 2020, none of our non-employee directors were paid any amounts as compensation for serving on our Board of Directors, other than Mr. Wurth who has received health insurance in the amount of $19,881.

Upon the closing of this offering, our Board of Directors has approved a new compensation plan for our non-employee directors, pursuant to which such directors will be entitled to annual cash fees of $40,000 plus $10,000 for the Chairman of the Board. Each member of the Audit Committee and Compensation Committee will receive an annual fee of $5,000, with the chairperson receiving $10,000. Each member of the Nominating and Governance Committee will receive an annual fee of $2,500, with the chairperson receiving $5,000. In addition, our non-employee directors will receive an annual stock option grant of a number of shares equal to $50,000 divided by the market price on the date of grant subject to a one-year vesting period.

Upon his appointment, Mr. Zeidman was issued an option to purchase 10,000 shares of our common stock at an exercise price of $3.50 per share. In addition, Mr. Zeidman also began receiving the cash compensation set forth in the preceding paragraph effective upon his appointment.

EXECUTIVE COMPENSATION

The following table shows the compensation awarded to or earned in the last two fiscal years by our chief executive officer. We did not have any officers that received more than $100,000 in compensation during 2020.

Summary Compensation Table - 2020

Name and Principal Position	Year	Salary ($)	Total ($)
Neil Dey, Chief Executive Officer and President	2020	20,833	20,833

Employment Agreements

Neil Dey, Chief Executive Officer and President

In July 2021, we entered into an employment agreement with Neil Dey pursuant to which Mr. Dey agreed to serve as our Chief Executive Officer and President. The agreement provides for an initial annual salary of $250,000, which shall increase to $350,000 upon the closing of this offering. Mr. Dey may receive an annual bonus, provided that the final determination on the amount of the annual bonus, if any, will be made by the Compensation Committee of the Board of Directors, based on criteria established by the Compensation Committee. The targeted annual bonus for 2021 is 50% of Mr. Dey's base salary, and is payable in a combination of cash and options to purchase our common stock, as determined in the sole discretion of the Compensation Committee. If Mr. Dey's employment is terminated at our election without "cause" (as defined in the agreement), Mr. Dey shall be entitled to receive severance payments equal to twelve months of Mr. Dey's base salary and he shall also receive a pro rata portion of the target annual bonus for such year.

Gordon Kinder, Chief Financial Officer

In July 2021, we entered into an employment agreement with Gordon Kinder pursuant to which Mr. Kinder agreed to serve as our Chief Financial Officer and Vice President. The agreement provides for an initial annual salary of $232,000, which shall increase to $250,000 upon the closing of this offering. Mr. Kinder may receive an annual bonus, provided that the final determination on the amount of the annual bonus, if any, will be made by the Compensation Committee of the Board of Directors, based on criteria established by the Compensation Committee. The targeted annual bonus for 2021 is 40% of Mr. Kinder's base salary, and is payable in a combination of cash and options to purchase our common stock, as determined in the sole discretion of the Compensation Committee. Pursuant to the agreement, Mr. Kinder was granted a ten-year option to purchase 40,000 shares of common stock at an exercise price of $3.50 per share. The option vests in four installments of 6,667 shares on December 31, 2021; 6,666 shares on July 7, 2022; 13,333 shares on July 7, 2023; and 13,334 shares on July 7, 2024, provided Mr. Kinder is employed on such vesting date. If Mr. Kinder's employment is terminated at our election without "cause" (as defined in the agreement), Mr. Kinder shall be entitled to receive severance payments equal to three months (increasing to six months if such termination occurs after one year) of Mr. Kinder's base salary and he shall also receive a pro rata portion of the target annual bonus for such year.

Jason Cook, Chief Technology Officer

In July 2021, we entered into an employment agreement with Jason Cook pursuant to which Dr. Cook agreed to serve as our Chief Technology Officer. The agreement provides for an initial annual salary of $200,000. Dr. Cook may receive an annual bonus, provided that the final determination on the amount of the annual bonus, if any, will be made by the Compensation Committee of the Board of Directors, based on criteria established by the Compensation Committee. The targeted annual bonus for 2021 is 30% of Dr. Cook's base salary, and is payable in a combination of cash and options to purchase our common stock, as determined in the sole discretion of the Compensation Committee. Dr. Cook is also entitled to receive a $30,000 relocation allowance if he relocates to the Acton town area within 18 months. Pursuant to the agreement, Dr. Cook was granted a ten-year option to purchase 75,000 shares of common stock at an exercise price of $3.50 per share. 41,668 shares underlying the option vested immediately and the remainder of the option vests in four equal installments based on the achievement of various milestones set forth in the agreement, provided Dr. Cook is employed on each such vesting date. If Dr. Cook's employment is terminated at our election without "cause" (as defined in the agreement), Dr. Cook shall be entitled to receive severance payments equal to three months (increasing to six months if such termination occurs after one year) of Dr. Cook's base salary and he shall also receive a pro rata portion of the target annual bonus for such year.

Kevin Vance, Chief Commercial Officer

In July 2021, we entered into an employment agreement with Kevin Vance pursuant to which Mr. Vance agreed to serve as our Chief Commercial Officer. The agreement provides for an initial annual salary of $200,000. Mr. Vance may receive an annual bonus, provided that the final determination on the amount of the annual bonus, if any, will be made by the Compensation Committee of the Board of Directors, based on criteria established by the Compensation Committee. The targeted annual bonus for 2021 is 30% of Mr. Vance's base salary, and is payable in a combination of cash and options to purchase our common stock, as determined in the sole discretion of the Compensation Committee. Mr. Vance is also entitled to receive a $600 per month automobile allowance. Pursuant to the agreement, Mr. Vance was granted a ten-year option to purchase 55,000 shares of common stock at an exercise price of $3.50 per share vesting as follow: (i) 5,000 shares vested immediately; (ii) 30,000 shares shall vest upon the successful closing of this offering; (iii) 10,000 shares shall vest if and when Mr. Vance acquires a customer for us and the customer completes a LDT; and (iv) 10,000 shares shall vest if Mr. Vance procures customer orders for sales in the aggregate of $1.5 million; provided Mr. Vance is employed on each such vesting date. If Mr. Vance's employment is terminated at our election without "cause" (as defined in the agreement), Mr. Vance shall be entitled to receive severance payments equal to three months (increasing to six months if such termination occurs after one year) of Mr. Vance's base salary and he shall also receive a pro rata portion of the target annual bonus for such year. In addition to the amounts payable to Mr. Vance pursuant to the agreement, we intend to enter into a sales commission agreement with Mr. Vance pursuant to which Mr. Vance will be entitled to receive additional compensation based on our sales.

2021 Stock Plan

In July 2021, we adopted the Bluejay Diagnostics, Inc. 2021 Stock Plan, or 2021 Plan. The 2021 Plan is a stock-based compensation plan that provides for discretionary grants of stock options, stock awards, stock unit awards and stock appreciation rights to key employees, non-employee directors and consultants. The following is a summary of the material features of the 2021 Plan.

Administration. The 2021 Plan is administered by either the Compensation Committee of our Board of Directors or our entire Board of Directors for the period prior to the establishment of our Compensation Committee (we refer to the body administering the 2021 Plan as the "Committee"). The Committee has full authority to select the individuals who will receive awards under the 2021 Plan, determine the form and amount of each of the awards to be granted and establish the terms and conditions of awards.

Limit on Non-Employee Director Compensation. Under the 2021 Plan, the aggregate value of all compensation granted or paid to any individual for service as a non-employee director with respect to any calendar year, including awards granted under the 2021 Plan and cash fees paid to such non-employee director, will not exceed $300,000 in total value. For purposes of this limitation, the value of awards is calculated based on the grant date fair value of such awards for financial reporting purposes.

Number of Shares of Common Stock. The number of shares of the common stock that may be issued under the 2021 Plan is 1,960,000.

Shares issuable under the 2021 Plan may be authorized but unissued shares or treasury shares. If there is a lapse, forfeiture, expiration, termination or cancellation of any award made under the 2021 Plan for any reason, the shares subject to the award will again be available for issuance. Any shares subject to an award that are delivered to us by a participant, or withheld by us on behalf of a participant, as payment for an award or payment of withholding taxes due in connection with an award will not again be available for issuance, and all such shares will count toward the number of shares issued under the 2021 Plan. Shares purchased by us with the proceeds received from a stock option exercise will not be available again for issuance. The number of shares of common stock issuable under the 2021 Plan is subject to adjustment, in the event of any reorganization, recapitalization, stock split, stock distribution, merger, consolidation, split-up, spin-off, combination, subdivision, consolidation or exchange of shares, any change in the capital structure of the company or any similar corporate transaction. In each case, the Committee has the discretion to make adjustments it deems necessary to preserve the intended benefits under the 2021 Plan. No award granted under the 2021 Plan may be transferred, except by will, the laws of descent and distribution.

Of the shares available for issuance: (i) the maximum number issuable as stock options or stock appreciation rights to any employee in any calendar year is 250,000, and (ii) the maximum number of shares issuable as stock awards or such units granted to any employee in any calendar year is 250,000.

Eligibility. All employees designated as key employees for purposes of the 2021 Plan, all non-employee directors and consultants are eligible to receive awards under the 2021 Plan.

Awards to Participants. The 2021 Plan provides for discretionary awards of stock options, stock awards, stock unit awards and stock appreciation rights to participants. Each award made under the 2021 Plan will be evidenced by a written award agreement specifying the terms and conditions of the award as determined by the Committee in its sole discretion, consistent with the terms of the 2021 Plan.

Stock Options. The Committee has the discretion to grant non-qualified stock options or incentive stock options to participants and to set the terms and conditions applicable to the options, including the type of option, the number of shares subject to the option and the vesting schedule; provided that, commencing as of the initial public offering of our common stock, the exercise price of each stock option will be the closing price of the common stock on the date on which the option is granted ("fair market value"), each option will expire ten years from the date of grant and no dividends or dividend equivalents may be paid with respect to stock options.

In addition, an incentive stock option granted to a key employee is subject to the following rules: (i) the aggregate fair market value (determined at the time the option is granted) of the shares of common stock with respect to which incentive stock options are exercisable for the first time by a key employee during any calendar year (under all incentive stock option plans of the company and its subsidiaries) cannot exceed $100,000, and if this limitation is exceeded, that portion of the incentive stock option that does not exceed the applicable dollar limit will be an incentive stock option and the remainder will be a non-qualified stock option; (ii) if an incentive stock option is granted to a key employee who owns stock possessing more than 10% of the total combined voting power of all classes of stock of the company, the exercise price of the incentive stock option will be 110% of the closing price of the common stock on the date of grant and the incentive stock option will expire no later than five years from the date of grant; and (iii) no incentive stock option can be granted after ten years from the earlier of the date the 2021 Plan was adopted or approved by stockholders.

Stock Appreciation Rights. The Committee has the discretion to grant stock appreciation rights to participants. The Committee determines the exercise price for a stock appreciation right, which cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant in common stock or in cash, at our discretion, an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the exercise price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. The Committee has the discretion to set the terms and conditions applicable to the award, including the number of shares subject to the stock appreciation right and the vesting schedule, provided that each stock appreciation right will expire not more than ten years from the date of grant and no dividends or dividend equivalents shall be paid with respect to any stock appreciation right prior to the exercise of the stock appreciation right.

Stock Awards. The Committee has the discretion to grant stock awards to participants. Stock awards will consist of shares of common stock granted without any consideration from the participant or shares sold to the participant for appropriate consideration as determined by the Board. The number of shares awarded to each participant, and the restrictions, terms and conditions of the award, will be at the discretion of the Committee. Subject to the restrictions, a participant will be a shareholder with respect to the shares awarded to him or her and will have the rights of a shareholder with respect to the shares, including the right to vote the shares and receive dividends on the shares; provided that dividends otherwise payable on any stock award subject to restrictions will be held by us and will be paid to the holder of the stock award only to the extent the restrictions on such stock award lapse.

Stock Units. The Committee has the discretion to grant stock unit awards to participants. Each stock unit entitles the participant to receive, on a specified date or event set forth in the award agreement, one share of common stock or cash equal to the fair market value of one share on such date or event, as provided in the award agreement. The number of stock units awarded to each participant, and the terms and conditions of the award, will be at the discretion of the Committee. Unless otherwise specified in the award agreement, a participant will not be a shareholder with respect to the stock units awarded to him prior to the date they are settled in shares of common stock. The award agreement may provide that until the restrictions on the stock units lapse, the participant will be paid an amount equal to the dividends that would have been paid had the stock units been actual shares; provided that such dividend equivalents will be held by us and paid only to the extent the restrictions lapse.

Payment for Stock Options and Withholding Taxes. The Committee may make one or more of the following methods available for payment of any award, including the exercise price of a stock option, and for payment of the tax obligation associated with an award: (i) cash; (ii) cash received from a broker dealer to whom the holder has submitted an exercise notice together with irrevocable instructions to deliver promptly to us the amount of sales proceeds from the sale of the shares subject to the award to pay the exercise price or withholding tax; (iii) by directing us to withhold shares of common stock otherwise issuable in connection with the award having a fair market value equal to the minimum amount required to be withheld; and (iv) by delivery of previously acquired shares of common stock that are acceptable to the Committee and that have an aggregate fair market value on the date of exercise equal to the exercise price or withholding tax, or certification of ownership by attestation of such previously acquired shares.

Provisions Relating to a "Change in Control" of the Company. Notwithstanding any other provision of the 2021 Plan or any award agreement, in the event of a "Change in Control" of the Company, the Board has the discretion to provide that all outstanding awards will become fully exercisable, all restrictions applicable to all awards will terminate or lapse, and performance goals applicable to any stock awards will be deemed satisfied at the highest level. In addition, upon such Change in Control, the Committee has sole discretion to provide for the purchase of any outstanding stock option for cash equal to the difference between the exercise price and the then fair market value of the common stock subject to the option had the option been currently exercisable, make such adjustment to any award then outstanding as the Committee deems appropriate to reflect such Change in Control and cause any such award then outstanding to be assumed by the acquiring or surviving corporation after such Change in Control.

Amendment of Award Agreements; Amendment and Termination of the 2021 Plan; Term of the 2021 Plan. The Committee may amend any award agreement at any time, provided that no amendment may adversely affect the right of any participant under any agreement in any material way without the written consent of the participant, unless such amendment is required by applicable law, regulation or stock exchange rule.

The Board may terminate, suspend or amend the 2021 Plan, in whole or in part, from time to time, without the approval of the stockholders, unless such approval is required by applicable law, regulation or stock exchange rule, and provided that no amendment may adversely affect the right of any participant under any outstanding award in any material way without the written consent of the participant, unless such amendment is required by applicable law, regulation or rule of any stock exchange on which the shares are listed.

Notwithstanding the foregoing, neither the 2021 Plan nor any outstanding award agreement can be amended in a way that results in the repricing of a stock option. Repricing is broadly defined to include reducing the exercise price of a stock option or stock appreciation right or cancelling a stock option or stock appreciation right in exchange for cash, other stock options or stock appreciation rights with a lower exercise price or other stock awards. (This prohibition on repricing without stockholder approval does not apply in case of an equitable adjustment to the awards to reflect changes in the capital structure of the company or similar events.

No awards may be granted under the 2021 Plan on or after the tenth anniversary of the initial effective date of the 2021 Plan.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of the date of this prospectus by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock;
- each of our named executive officers, directors and director nominees; and
- all our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Except as otherwise indicated, each person or entity named in the table has sole voting and investment power with respect to all shares of our capital shown as beneficially owned, subject to applicable community property laws.

In computing the number and percentage of shares beneficially owned by a person, shares that may be acquired by such person within 60 days of the date of this prospectus are counted as outstanding, although such shares are not counted as outstanding for computing the percentage ownership of any other person. The percentage of shares beneficially owned before the offering is computed on the basis of 10,534,265 shares of our common stock outstanding immediately prior to the date of this prospectus. The percentage of shares beneficially owned after the offering assumes the representative does not exercise the option to purchase additional shares to cover over-allotments. Unless otherwise indicated, the address of each person listed below is c/o Bluejay Diagnostics, Inc., 360 Massachusetts Avenue, Suite 203, Acton, MA 01720.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Common Stock Beneficially Owned Prior to Offering	Percent of Common Stock Beneficially Owned After Offering
Executive officers and directors:			
Neil (Indranil) Dey	4,540,148[1]	43.1%	35.8%
Gordon Kinder	—	—	—
Dr. Jason Cook	41,668[2]	*	*
Kevin Vance	35,000[2]	*	*
Svetlana Dey	4,091,356[1]	38.8%	32.2%
Douglas C. Wurth	3,463,450[3]	32.4%	26.9%
Donald R. Chase	839,312[4]	7.9%	6.6%
Fred S. Zeidman	—	—	—
Gary Gemignani	—	—	—
All Executive Officers and Directors as a group (9 persons)	8,919,578	82.2%	68.5%
5% or greater shareholders			
Kathleen A. Jalbert	582,248[5]	5.5%	4.6%
Mirza Mehdi	719,013[6]	6.8%	5.7%

* Less than 1%.

(1) Of the amounts set forth in the table, 4,091,356 shares are held by Lana Management & Business Research International, LLC, an entity owned by Mr. Dey and Ms. Dey. Ms. Dey has voting and dispositive power over the shares held by such entity.

(2) Consists of shares underlying options at an exercise price of $3.50 per share.

(3) Includes (i) 39,340 shares underlying options at an exercise price of $0.16 per share and 59,010 shares at an exercise price of $0.95, and (ii) 62,000 shares underlying warrants at an exercise price of $2.30 per share and 7,868 shares underlying warrants at an exercise price of $0.95 per share.

(4) Includes (i) 39,340 shares underlying options at an exercise price of $0.16 per share and 11,802 shares at an exercise price of $0.95 per share, and (ii) 22,818 shares underlying warrants at an exercise price of $2.30 per share.

(5) Includes 13,061 shares underlying warrants at an exercise price of $2.30 per share.

(6) Includes (i) 11,802 shares underlying options at an exercise price of $0.95 per share and (ii) 16,366 shares underlying warrants at an exercise price of $2.30 per share.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We are a party to an expense sharing agreement with LMBRI, an entity owned and controlled by Mr. Dey and Ms. Dey, pursuant to which we reimburse LMBRI monthly for certain shared expenses, including insurance, rent, salaries, telephone, and other miscellaneous expenses. We are billed up to $4,000 monthly for these expenses. During each of the years ended December 31, 2020 and 2019, we paid or accrued to LMBRI $48,000 for these shared expenses.

Since our inception, LMBRI has advanced funds on our behalf for operational purposes and for FDA pre-submission funding purposes. As of December 31, 2020 and 2019, the amounts payable to LMBRI were $125,102 and $86,005, respectively. The outstanding balance due to LMBRI is payable upon demand.

Related Party Transactions — Policies

Related party transactions are defined under SEC rules as transactions in which (1) the aggregate amount involved will or may be expected to exceed the lesser of $120,000 or one percent of the average of our total assets for the last two completed fiscal years, (2) we or any of our subsidiaries is a participant, and (3) any (a) executive officer, director or nominee for election as a director, (b) greater than 5% beneficial owner of our shares of common stock, or (c) immediate family member, of the persons referred to in clauses (a) and (b), has or will have a direct or indirect material interest (other than solely as a result of being a director or a less than 10% beneficial owner of another entity). A conflict of interest situation can arise when a person takes actions or has interests that may make it difficult to perform his or her work objectively and effectively. Conflicts of interest may also arise if a person, or a member of his or her family, receives improper personal benefits as a result of his or her position.

All future and ongoing related party transactions (as defined under SEC rules) will require prior review and approval by the Audit Committee, which will have access, at our expense, to our attorneys or independent legal counsel. We will not enter into any such transaction without the approval of the Audit Committee. The Audit Committee will consider all relevant factors when determining whether to approve a related party transaction, including whether the related party transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related party's interest in the transaction.

No director may participate in the approval of any transaction in which he is a related party, but that director is required to provide the other members of the board with all material information concerning the transaction. Additionally, we require each of our directors and executive officers to complete a directors' and officers' questionnaire that elicits information about related party transactions.

These procedures are intended to determine whether any such related party transaction impairs the independence of a director or presents a conflict of interest on the part of a director, employee or officer.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material United States federal income tax considerations applicable to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other United States federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-United States tax laws are not discussed. This discussion is based on the United States Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the United States Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS will not take, or that a court will not sustain, a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all United States federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income or the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- United States expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid United States federal income tax;
- partnerships or other entities or arrangements treated as partnerships for United States federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons who own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below); and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into account in an applicable financial statement.

If an entity treated as a partnership for United States federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships (or other entities treated as a partnership for United States federal income tax purposes) holding our common stock and the partners in such partnerships or other entities should consult their tax advisors regarding the United States federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE UNITED STATES FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE UNITED STATES FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-UNITED STATES TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for United States federal income tax purposes.

A U.S. person is any person that, for United States federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation, or an entity treated as a corporation, created or organized in the United States or under the laws of the United States, any state thereof, or the District of Columbia, or other entity treated as such for United States federal income tax purposes;
- an estate, the income of which is subject to United States federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a United States court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for United States federal income tax purposes.

Distributions

As described in the section entitled "Dividend policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, amounts not treated as dividends for United States federal income tax purposes will constitute a return of capital and will first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in our common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "*— Sales or Other Taxable Dispositions of Common Stock*."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, dividends paid to a Non-U.S. Holder of our common stock will be subject to United States federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder timely furnishes a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate of United States withholding tax, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the United States federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must timely furnish to the applicable withholding agent a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to United States federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sales or Other Taxable Dispositions of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to United States federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a non-resident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a United States real property interest, or USRPI, by reason of our status as a United States real property holding corporation, or USRPHC, for United States federal income tax purposes.

Gain described in the first bullet point above generally will be subject to United States federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to United States federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale or other disposition, which may be offset by United States source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed United States federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Generally, a corporation is a UUSRPHC only if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-United States real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become a USRPHC in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to United States federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

NON-U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING POTENTIALLY APPLICABLE INCOME TAX TREATIES THAT MAY PROVIDE FOR DIFFERENT RULES.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-United States status, such as by furnishing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld.

In addition, proceeds on the sale or other taxable disposition of our common stock within the United States, or conducted through certain United States-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-United States office of a non-United States broker generally will not be subject to backup withholding or information reporting. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's United States federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-United States financial institutions and certain other non-United States entities. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the United States Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock, and subject to the recently released proposed Treasury

Regulations described below, will apply to payments of gross proceeds from the sale or other disposition of such stock on or after January 1, 2019. The Treasury Department recently released proposed Treasury Regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed Treasury Regulations, the Treasury Department stated that taxpayers may generally rely on the proposed Treasury Regulations until final Treasury Regulations are issued.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE POTENTIAL APPLICATION OF WITHHOLDING UNDER FATCA TO THEIR INVESTMENT IN OUR COMMON STOCK.

DESCRIPTION OF OUR SECURITIES

The following summary is a description of the material terms of our securities and is not complete. You should also refer to our certificate of incorporation and bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part.

Authorized Capital Stock

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. Upon the closing of this offering, we will have 12,694,265 shares of common stock outstanding immediately after the closing of this offering.

Units Offered Hereby

We are offering 2,160,000 Units at an offering price of $10.00 per Unit. Each Unit consists of (a) one share of our common stock, (b) one Class A warrant (the "Class A Warrants") 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, and (c) one Class B warrant (the "Class B Warrants," and together with the Class A Warrants, the "Warrants") to purchase one share of our common stock at an exercise price equal to $10.00 per share (or 100% of the unit offering price), exercisable until the fifth anniversary of the issuance date and subject to certain adjustment and cashless exercise provisions as described herein. The shares of our common stock and the Warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

We are also offering to those purchasers, if any, whose purchase of our common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to substitute Series E Convertible Preferred Stock, referred to as "Preferred Stock" for the shares of common stock included in the Units purchased by that investor. Each share of Preferred Stock is being sold together with the same Warrants described above being sold with each share of common stock. For each share of Preferred Stock purchased in this offering in lieu of common stock, we will reduce the number of shares of common stock being sold in the offering on a one-for-one basis. Pursuant to this prospectus, we are also offering the shares of common stock issuable upon conversion of the Preferred Stock. The shares of Preferred Stock will otherwise have the preferences, rights and limitations described under "Description of Capital Stock — Series E Convertible Preferred Stock Being Issued in this Offering" below.

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.

Series D Convertible Preferred Stock

Prior to this offering, we will have 4,500 shares of our Series D convertible preferred stock outstanding. Each of our Series D convertible preferred stock will convert into 1,000 shares of our common stock; provided that the holder will not be permitted to convert the preferred stock to the extent that the holder or any of its affiliates would beneficially own in excess of 4.99% of our common stock after such conversion. The shares of Series D convertible preferred stock have no voting rights, except that the holders of shares of a majority of the Series D convertible preferred stock will be required to effect or validate any amendment, alteration or repeal of any of the provisions of the Certificate of Designation that materially adversely affects the powers, preferences or special rights of such series of preferred stock, with certain limited exceptions.

The holder of the Series D convertible preferred stock shall be entitled to receive cumulative dividends at the rate per share (as a percentage of the stated value per share of $1,000) of 7.5% per annum increasing to 15% per annum after November 23, 2021, payable quarterly on January 1, April 1, July 1 and October 1, 2021 and on each conversion date (with respect only to preferred stock being converted) in cash; provided, however, following the completion of our IPO no dividend shall accrue on the preferred stock thereafter. With respect to the distribution of assets upon liquidation or dissolution or winding up of the company, the Series D convertible preferred stock shall rank senior to the common stock. No sinking fund has been established for the retirement or redemption of the Series D convertible preferred stock.

Series E Convertible Preferred Stock

The following summary of certain terms and provisions of the Series E Preferred Stock offered in this offering is subject to, and qualified in its entirety by reference to, the terms and provisions set forth in our certificate of designation of preferences, rights and limitations of the Series E Preferred Stock, which has been filed as an exhibit to the registration statement of which this prospectus is a part. You should review a copy of the certificate of designation of the Series E Preferred Stock for a complete description of the terms and conditions of the Series E Preferred Stock.

Each share of Series E Preferred Stock is convertible at any time at the holder’s option into one share of common stock (subject to the beneficial ownership limitations as provided in the related certificate of designation of preferences), subject to adjustment as provided in the certificate of designation, provided that the holder will be prohibited from converting Series E Preferred Stock into shares of our common stock if, as a result of such conversion,

the holder, together with its affiliates, would own more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until the 61st day after such notice to us.

In the event of our liquidation, dissolution, or winding up, holders of our Series E Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series E Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Series E Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.

Shares of Series E Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. However, holders of our Series E Preferred Stock are entitled to receive dividends on shares of Series E Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by our board of directors, except for stock dividends or distributions payable in shares of common stock on shares of common stock or any other common stock equivalents for which the conversion price will be adjusted. We are not obligated to redeem or repurchase any shares of Series E Preferred Stock. Shares of Series E Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

The holders of the Series E Preferred Stock have no voting rights, except as required by law. We may not disproportionally alter or change adversely the powers, preferences and rights of the Series E Preferred Stock or amend the certificate of designation or amend our articles of incorporation or bylaws in any manner that disproportionally adversely affect any right of the holders of the Series E Preferred Stock without the affirmative vote of the holders of a majority of the shares of Series E Preferred Stock then outstanding.

Warrant Agent

The Class A Warrants and Class B Warrants will be issued 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 will be filed as an exhibit to the Registration Statement on Form S-1, of which this prospectus forms a part. 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 Offered Hereby

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.

The price of the Class A Warrants has been arbitrarily established by us and the underwriter after giving consideration to numerous factors, including but not limited to, the pricing of the Units in this offering. No particular weighting was given to any one aspect of those factors considered. We have not performed any method of valuation of the 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 (or 100% of the unit offering price), 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.

The price of the Class B Warrants has been arbitrarily established by us and the underwriter after giving consideration to numerous factors, including but not limited to, the pricing of the Units in this offering. No particular weighting was given to any one aspect of those factors considered. We have not performed any method of valuation of the warrants.

Warrants

We have the following warrants outstanding as of the date of this prospectus:

- 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 680,331 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.

In addition, upon the closing of this offering, we will issue to the underwriters warrants to purchase 5.0% of the shares of our common stock issued in this offering. See “*Underwriting*.”

Registration Rights

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”) 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. The Debentures will convert into Series D preferred stock at a conversion price of $1,000 per share in connection with the closing of this offering. Pursuant to the issuance of the Debentures, we agreed to register the resale of the shares of our common stock underlying the Series D preferred stock.

In March 2021, we issued a financial consultant a warrant to purchase 226,599 shares of our common stock having an exercise price per share equal to $3.18. The warrant agreement provides for “piggy-back” registration rights with respect to the shares of common stock underlying the warrant.

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 will 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 will specify certain requirements regarding the form and content of a stockholder's notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our meetings of stockholders.

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

Stockholders will not be permitted to cumulate their votes for the election of directors. In addition, stockholders will not be able to take action by written consent, and will only be able to take action at annual or special meetings of our stockholders. Furthermore, special meetings of our stockholders may be called only by 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 will require, to the fullest extent permitted by law, subject to limited exceptions, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel in any action brought to enforce the exclusive forum provision. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our amended and restated certificate of incorporation.

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

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

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."

SHARES ELIGIBLE FOR FUTURE SALE

Before this offering, there has not been a public market for shares of our common stock. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding warrants, in the public market after this offering, or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

Upon the closing of this offering, we will have:

- 12,694,265 shares of common stock outstanding;
- 4,500,000 shares of common stock issuable upon the conversion of our Series D Convertible Preferred Stock;
- 1,255,775 shares of common stock issuable upon the exercise of our outstanding warrants to purchase common stock at a weighted average price of $1.03 per share;
- 500,786 shares of common stock issuable upon the exercise of our outstanding options to purchase common stock at a weighted average price of $2.98 per share;
- 1,770,000 shares of common stock that are available for future issuance under our 2021 Stock Plan;
- 2,160,000 shares of common stock issuable upon the exercise of Class A warrants to be issued in this offering;
- 2,160,000 shares of common stock issuable upon the exercise (including the cashless exercise) of Class B warrants to be issued in this offering; and
- 108,000 shares of common stock issuable upon exercise of warrants to be issued to the underwriters in connection with this offering.

All of the shares sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by one of our affiliates as that term is defined in Rule 144 under the Securities Act, which generally includes directors, officers or 10% stockholders.

All of the foregoing shares that will be outstanding after this offering, other than the shares sold in this offering, are or will be upon issuance “restricted securities” as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 under the Securities Act, which are summarized below.

Rule 144

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, upon the expiration of the lock-up agreements described below, 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.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon the expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, or
- the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Lock-Up Agreements

We and each of our officers, directors, affiliates and certain existing stockholders aggregating at least 9,812,735 of our outstanding shares have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock for a period of six months after this offering is completed without the prior written consent of the representative of the underwriters.

The representative of the underwriters may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the representative will consider, among other factors, the security holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

Registration Statement on Form S-8

We intend to file a registration statement on Form S-8 under the Securities Act to register shares that may be issued pursuant to the 2021 Plan. The registration statement on Form S-8 is expected to become effective immediately upon filing, and shares covered by the registration statement will then become eligible for sale in the public market upon issuance, subject to the Rule 144 limitations applicable to affiliates, vesting restrictions and any applicable lock-up agreements.

Selling Stockholder Resale Prospectus

As described in the Explanatory Note to the registration statement of which this prospectus forms a part, the registration statement also contains the Resale Prospectus to be used in connection with the potential resale by certain selling stockholders of our common stock. These shares of common stock have been registered to permit public resale of such shares, and the selling stockholders may offer the shares for resale from time to time pursuant to the Resale Prospectus. The selling stockholders may also sell, transfer or otherwise dispose of all or a portion of their shares in transactions exempt from the registration requirements of the Securities Act or pursuant to another effective registration statement covering those shares. Any shares sold by the selling stockholders until our common stock is listed or quoted on an established public trading market will take place at $10.00, which is the public offering price of the shares of common stock we are selling in our initial public offering. Thereafter, any sales will occur at prevailing market prices or in privately negotiated prices.

UNDERWRITING

Dawson James Securities, Inc. ("Dawson James" or the "Representative") is acting as the lead managing underwriter and as representative of the underwriters. Subject to the terms and conditions of an underwriting agreement, dated, November 10, 2021, between us and the Representative, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of units listed next to its name in the following table:

Name of Underwriter	Number of Units
Dawson James Securities, Inc.	1,236,000
I-Bankers Direct, LLC	774,000
I-Bankers Securities	50,000
Viewtrade Securities	100,000
Total	2,160,000

The underwriters are committed to purchase all of the units offered by this prospectus if they purchase any units. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased, or the offering may be terminated. The underwriters are not obligated to purchase the shares of common stock and warrants covered by the underwriters' option to purchase additional shares of common stock and warrants described below. The underwriters are offering the units, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have granted the representative of the underwriters an option exercisable for up to 45 days after the date of the underwriting agreement, to purchase up to 324,000 shares of common stock, and/or Class A Warrants, and/or Class B Warrants at the public offering price listed on the cover page of this prospectus, less underwriting discounts. The underwriters may exercise this option solely to cover over-allotments, if any, made in connection with this offering. To the extent the option is exercised, and the conditions of the underwriting agreement are satisfied, we will be obligated to sell to the underwriters, and the underwriters will be obligated to purchase, these additional shares of common stock and/or warrants.

Discounts and Commissions

We have agreed to pay the underwriters a cash fee equal to 8.0% of the aggregate gross proceeds. Upon the closing of this offering, we will issue to Dawson James, as representative of the underwriters, warrants entitling the representative to purchase 5.0% of the aggregate number of shares issued in this offering (including the number of shares issuable upon conversion of any shares of Series E Convertible Preferred Stock). The warrants shall be exercisable for a period of five years following the date of the commencement of sales in this offering at an exercise price of 125% of the public price per unit issued in the offering. Pursuant to FINRA Rule 5110(e), the Representative warrants and any shares of common stock issued upon exercise of the Representative warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of reorganization of the issuer; (ii) to any FINRA member firm participating in the offering and the officers, partners, registered persons or affiliates thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the Representative or related persons does not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period; (vi) if we meet the registration requirements of Forms S-3, F-3 or F-10; or (vii) back to us in a transaction exempt from registration with the SEC.

The Representative has advised us that the underwriters propose to offer the shares directly to the public at the public offering price set forth on the cover of this prospectus. In addition, the Representative may offer some of the shares to other securities dealers at such price less a concession of up to $0.40 per share. After the offering to the public, the offering price and other selling terms may be changed by the Representative without changing the Company's proceeds from the underwriters' purchase of the units.

The following table shows the public offering price, underwriting discounts and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option. The underwriting discounts are equal to the public offering price per share less the amount per share the underwriters pay us for the shares.

		Total	
	Per Unit	Without Over-Allotment Option	With Over-Allotment Option
Public offering price	$ 10.00	$ 21,600,000	$ 24,840,000
Underwriting discounts	$ 0.80	$ 1,728,000	$ 1,987,200
Proceeds, before expenses, to us	$ 9.20	$ 19,872,000	$ 22,852,800

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts, will be approximately $988,000, all of which are payable by us. This figure includes an expense allowance of $125,000 for accountable expenses and up to $12,500 for the actual roadshow expenses of the Representative that we have agreed to pay the Representative for reimbursement of its expenses related to this offering.

Determination of Offering Price

Before this offering, there has been no public market for our common stock. Accordingly, the public offering price will be negotiated between us and the representative. Among the factors to be considered in these negotiations are:

- the prospects for our company and the industry in which we operate;
- our past and present financial and operating performance;
- financial and operating information and market valuations of publicly traded companies engaged in activities similar to ours;
- the prevailing conditions of United States securities markets at the time of this offering; and
- other factors deemed relevant.

Lock-Up Agreements

We and each of our officers, directors, and 5% of greater stockholders have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock for a period of six months after this offering is completed without the prior written consent of the Representative.

The Representative may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the representative will consider, among other factors, the security holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

Right of First Refusal

According to the terms of the underwriting agreement, the Representative shall have the right of first refusal for a period of twelve months after the closing of this offering to act as sole book-running manager for all future public equity offerings by us, or any successor to or subsidiary of our company, during such period.

Indemnification

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on a website maintained by the Representative and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the Representative to underwriters that may make Internet distributions on the same basis as other allocations. In connection with the offering, the underwriters or syndicate members may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

The underwriters have informed us that they do not expect to confirm sales of shares offered by this prospectus to accounts over which they exercise discretionary authority.

Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Price Stabilization, Short Positions and Penalty Bids

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more shares than are set forth on the cover page of this prospectus. This creates a short position in our common stock for its own account. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares common stock over-allotted by the underwriters is not greater than the number of shares of common stock that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock involved is greater than the number of shares common stock in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our common stock or reduce any short position by bidding for, and purchasing, common stock in the open market.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing a security in this offering because the underwriter repurchases that security in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, shares of our common stock in market making transactions, including "passive" market making transactions as described below.

These activities may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in our common stock immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act.

Certain Relationships

Certain of the underwriters and their affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates for which they may in the future receive customary fees, however, except for the right of first refusal disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Schiff Hardin LLP, Washington, DC. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel to the underwriters in this offering.

EXPERTS

Our financial statements appearing elsewhere in this prospectus have been included herein in reliance upon the report of Wolf and Company, P.C., an independent registered public accounting firm, as stated in their report appearing elsewhere herein, and upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the completion of this offering, we will be required to file periodic reports, proxy statements, and other information with the SEC pursuant to the Exchange Act. You may read and copy this information at the SEC's Public Reference Room, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, including us, that file electronically with the SEC. The address of this site is *www.sec.gov*.

Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Bluejay Diagnostics, Inc. (the "Company") as of December 31, 2020 and 2019, the related statements of operations, changes in redeemable preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes to the financial statements (collectively referred to as 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of a Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and its total liabilities exceed its total assets. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Wolf & Company, P.C.

Boston, Massachusetts
June 30, 2021

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

Bluejay Diagnostics, Inc.
Balance Sheets

	December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 912,361	$ 96,011
Accounts receivable	—	645
Inventory	84,762	123,508
Prepaid expenses	7,965	10,262
Other current assets	53,106	69,915
Total current assets	1,058,194	300,341
Property and equipment, net	459,138	616,177
Total assets	$ 1,517,332	$ 916,518
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 374,928	$ 29,125
Due to related party	125,102	86,005
Accrued expenses	133,820	—
Notes payable, current portion	1,041,186	265,000
Note payable, Paycheck Protection Program	14,725	—
Deposit for future stock subscriptions	—	100,000
Derivative warrant liability	155,629	96,408
Total current liabilities	1,845,390	576,538
Notes payable, long-term	—	804,288
Total liabilities	1,845,390	1,380,826
Series A redeemable, convertible preferred stock, $0.0001 par value; 10,600 shares authorized, issued and outstanding (preference in liquidation of $1,219,513 at December 31, 2020)	1,077,303	892,809
Series B redeemable, convertible preferred stock, $0.0001 par value; 5,918 shares authorized; 5,187 shares issued and outstanding (preference in liquidation of $1,950,105 at December 31, 2020)	1,800,347	1,575,321
Series C redeemable, convertible preferred stock, $0.0001 par value; 636 shares authorized, issued and outstanding (preference in liquidation of $1,008,227 at December 31, 2020)	1,000,465	—
Stockholders' deficit:		
Common stock, $0.0001 par value; 9,000,000 shares authorized; 3,147,200 shares issued and outstanding	315	315
Additional paid-in capital	—	—
Accumulated deficit	(4,206,488)	(2,932,753)
Total stockholders' deficit	(4,206,173)	(2,932,438)
Total liabilities, redeemable preferred stock and stockholders' deficit	$ 1,517,332	$ 916,518

See report of independent registered public accounting firm and notes to the financial statements.
Reflects a 1-for-3.15 stock dividend effective June 7, 2021.

Bluejay Diagnostics, Inc.
Statements of Operations

	Year Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 527,253	$ 454,610
General and administrative	596,116	883,999
Marketing and business development	73,022	292,804
Total operating expenses	1,196,391	1,631,413
Operating loss	(1,196,391)	(1,631,413)
Other income (expense):		
Gain on transfer of equipment at fair value	—	741,590
Gain on forgiveness of note payable, Paycheck Protection Program	102,000	—
Derivative warrant liability gain (loss)	(42,434)	9,842
Interest income (expense), net of amortization of premium	(26,997)	52,284
Other income	5,537	7,855
Total other income, net	38,106	811,571
Net loss	$ (1,158,285)	$ (819,842)
Loss per share:		
Basic and diluted loss per share	$ (0.37)	$ (0.26)
Weighted average common shares:		
Basic and diluted	3,147,200	3,147,200

See report of independent registered public accounting firm and notes to the 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' Deficit

	Redeemable, Convertible Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	10,600	$ 708,315	—	$ —	—	$ —	3,147,200	$ 315	$ —	$ (1,938,462)	$ (1,938,147)
Issuance of Series B redeemable, convertible preferred stock, net of issuance costs of $33,682	—	—	4,732	1,676,801	—	—	—	—	—	—	—
Reclassification of derivative warrant liability	—	—	—	(106,250)	—	—	—	—	—	—	—
Accretion of Series B redeemable, convertible preferred stock to redemption value	—	—	—	4,770	—	—	—	—	(4,770)	—	(4,770)
Accretion of Series A redeemable, convertible preferred stock to redemption value	—	184,494	—	—	—	—	—	—	(10,045)	(174,449)	(184,494)
Stock-based compensation expense	—	—	—	—	—	—	—	—	14,815	—	14,815
Net loss	—	—	—	—	—	—	—	—	—	(819,842)	(819,842)
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 warrant	—	—	—	—	—	—	—	—	148,892	—	148,892
Stock-based compensation expense	—	—	—	—	—	—	—	—	7,370	—	7,370
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)

See report of independent registered public accounting firm and notes to the financial statements.
Reflects a 1-for-3.15 stock dividend effective June 7, 2021.

Bluejay Diagnostics, Inc.
Statements of Cash Flows

	Year Ended December 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,158,285)	$ (819,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	157,039	142,975
Stock-based compensation expense	7,370	14,815
Non-cash interest expense	(51,530)	(98,351)
Gain on forgiveness of note payable, Paycheck Protection Program	(102,000)	—
Gain on transfer of equipment at fair value	—	(741,591)
Loss (gain) on revaluation of derivative warrant liability	42,434	(9,842)
Changes in operating assets and liabilities:		
Accounts receivable	645	(645)
Inventory	38,746	(103,877)
Prepaid expenses	2,297	3,547
Other current assets	16,809	(59,946)
Accounts payable	345,803	(25,213)
Due to related party	39,097	12,000
Accrued expenses	152,865	(4,148)
Net cash used in operating activities	(508,710)	(1,690,118)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	—	(6,021)
Net cash used in investing activities	—	(6,021)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of principal on notes payable	—	(265,000)
Proceeds from issuance of Series B redeemable, convertible preferred stock, net of issuance costs	60,228	1,676,801
Proceeds from issuance of Series C redeemable, convertible preferred stock, net of issuance costs	994,832	—
Proceeds from issuance of notes payable	154,000	—
Proceeds from note payable, Paycheck Protection Program	116,000	—
Deposit for future stock subscriptions	—	100,000
Net cash provided by financing activities	1,325,060	1,511,801
Increase (decrease) in cash and cash equivalents	816,350	(184,338)
Cash and cash equivalents, beginning of year	96,011	280,349
Cash and cash equivalents, end of year	$ 912,361	$ 96,011
SUPPLEMENTAL DISCLOSURES		
Interest paid	$ 53,240	$ 46,067
Accretion of Series A redeemable, convertible preferred stock dividend	$ 42,400	$ 42,400
Accretion of Series A redeemable, convertible preferred stock issuance costs and fair value adjustment	$ 142,094	$ 142,094
Accretion of Series B redeemable, convertible preferred stock dividend	$ 75,018	$ —
Accretion of Series B redeemable, convertible preferred stock issuance costs	$ 6,567	$ 4,770
Accretion of Series C redeemable, convertible preferred stock dividend	$ 4,619	$ —
Accretion of Series C redeemable, convertible preferred stock issuance costs	$ 1,014	$ —
Fair value of warrants issued for Series B redeemable, convertible preferred stock	$ 16,787	$ 106,250
Relative fair value of warrants for common stock issued in connection with notes payable	$ 148,892	$ —

See report of independent registered public accounting firm and notes to the financial statements.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Bluejay Diagnostics, Inc. (the "Company") commenced its activities on March 20, 2015 incorporated under the laws of the State of Delaware. The Company is a mission-driven in-vitro diagnostic company that aims to develop and market minimally-invasive Point-of-Care ("POC") diagnostics tests and devices that provide patients and providers with access to affordable and timely healthcare. The Company's focus is on the infectious disease, inflammation, and oncology markets.

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.

The Company pursuing biomarker detection of Sepsis, Cancer and other diseases, 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 Cardiac Ishcemia and Congestive Heart Failure.

Since its inception, the Company has devoted substantially all of its efforts to business planning, sales and marketing, research and development, and raising capital.

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 pharmaceutical and 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.

To date, the Company has experienced significant changes in the business as a result of the COVID-19 pandemic. The impact has delayed the Company's ability to generate revenue as result of the diversification of potential customer budgets towards the COVID-19 pandemic. 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.

Stock Split

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 ("Stock Split"). This stock dividend was deemed a large stock dividend and was treated as a 1-for-3.15 stock split. The common stock shares and per share amounts (other than authorized shares) in these financial statements and related notes have been retroactively restated to reflect the stock dividend for all periods presented.

Going concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern. The Company has experienced recurring losses from operations, and has a stockholders' deficit and negative working capital of $4,206,173 and $787,196, respectively, as of December 31, 2020. The Company has relied on raising capital to finance its operations.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION (cont.)

The Company plans to raise capital through equity and/or debt financings and expects to generate revenue from sales to customers in the second half of 2021. There is no assurance, however, that the Company will be able to raise sufficient capital to fund its operations on terms that are acceptable, if at all, or generate profitable operations.

There is substantial doubt about the Company's ability to continue as a going concern within a year after the date that the financial statements are issued. These financial statements do not include any adjustments relating to the recoverability of recorded asset amounts that might be necessary as a result of the above uncertainty.

2. SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the accompanying financial statements follows:

Use of estimates

The preparation of the Company's financial statements and related disclosures in conformity with U.S. Generally Accepted Accounting Principles ("US GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

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.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined using standard cost on a first-in, first-out basis, reduced for excess and obsolete inventory, if necessary. Costs to ship inventory to storage facilities are included in inventory. There was no excess and/or obsolete inventory at December 31, 2020 or 2019. Net realizable value is calculated as the estimated selling price in the ordinary course of business, less selling costs Total inventory at December 31, 2020 and 2019 consists entirely of finished goods.

Property and equipment

Property and equipment are carried at cost (see Note 3). Depreciation expense is provided over the estimated useful lives of the assets using the straight-line method. A summary of the estimated useful lives is as follows:

Classification	Estimated Useful Life in Years
Office furniture, fixtures, and equipment	5
Website	5
Lab equipment	5

Maintenance and repairs are charged to expense as incurred, while any additions or improvements are capitalized.

Research and development expenses

Costs incurred for research and development are expensed as incurred. Research and development expenses primarily consist of salaries and related expenses for personnel, outside consulting services and sponsored research and the costs of materials and supplies used.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

2. SIGNIFICANT ACCOUNTING POLICIES (cont.)

Concentrations of credit risk

Cash and cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. The Company may maintain deposits in financial institutions in excess of government insured limits. The Company believes that it is not exposed to significant credit risk as its deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses on these deposits. As of December 31, 2020, the Company's cash and cash equivalents are held with one financial institution.

Income taxes

The Company is primarily subject to U.S. federal and Massachusetts state income tax.

For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities, net operating loss carryforwards and research and development tax credits. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, the Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are realizable.

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 authority. Tax positions not deemed to meet a more-likely-than-not threshold are recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure in the financial statements as of December 31, 2020 and 2019. The Company's policy is to recognize interest and penalties related to income tax, if any, in income tax expense. As of December 31, 2020 and 2019, the Company has no accruals for interest or penalties related to income tax matters. Generally, the Company is no longer subject to federal and state tax examinations by tax authorities for the years subsequent to 2016. There are currently no pending income tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period.

Fair Value of Financial instruments

The fair value of Company's financial instruments, consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, convertible promissory notes and notes payable approximates their recorded amounts due to their relatively short settlement terms.

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.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

2. SIGNIFICANT ACCOUNTING POLICIES (cont.)

Redeemable Convertible Preferred Stock

The Company has classified redeemable, convertible preferred stock ("Preferred Stock") as temporary equity in the accompanying balance sheets due to terms that allow for redemption of the shares upon certain events that are outside of the Company's control.

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 period of the award.

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.

During 2020 and 2019, the Company calculated fair value of share-based awards using the Black-Scholes model with the following assumptions:

	2020	2019
Risk-free interest rate	0.27% – 0.28%	2.47% – 3.00%
Expected dividend yield	0.00%	0.00%
Volatility factor	88.60%	48.10%
Expected life of option (in years)	5.00	5.75 – 6.25

Derivative instruments

The Company generally 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.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

2. SIGNIFICANT ACCOUNTING POLICIES (cont.)

The fair value of the outstanding Series B redeemable preferred stock warrants (see Note 9) at December 31, 2020 and 2019 was based on the assumptions as follows:

	2020	2019
Risk-free interest rate	0.17% – 0.36%	1.69%
Dividend rate	0.00%	0.00%
Volatility	88.60%	48.10%
Expected life (in years)	3.23 – 4.64	4.25

Advertising costs

The Company expenses advertising costs as incurred. For the years ended December 31, 2020 and 2019, the Company incurred $16,000 and $12,000 in advertising expenses, respectively.

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, 2020 and 2019, all of the Company's assets were located in the United States.

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 if their effect is antidilutive. 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, 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.

The following potential common shares were not included in the computation of diluted net loss per share since such inclusion would have been anti-dilutive:

	Years ended	
	2020	2019
Redeemable, convertible preferred stock	2,584,323	949,195
Options to purchase common stock	375,826	472,080
Warrants for common stock	4,846,688	—
Warrants for Series B redeemable, convertible preferred stock	115,030	104,330

Recently Issued Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* ("ASU 2016-02") which establishes new accounting and disclosure requirements for leases. ASU No. 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company will adopt the provisions of ASU 2016-02 in the quarter beginning January 1, 2022.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

2. SIGNIFICANT ACCOUNTING POLICIES (cont.)

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. The Company is currently evaluating the impact of this ASU on the financial statements.

3. BUSINESS AGREEMENTS

License and Distribution Agreement with Hitachi

On October 1, 2015, the Company entered into a licensing and distribution agreement with Hitachi Chemical Co., Ltd ("Hitachi") for the manufacturing and supply of the ALLEREYE product (the "Product"). The agreement also specifies that at the Company's request, Hitachi shall grant exclusive rights to manufacture the Product or have the Product manufactured by a third party contract manufacturer using all or part of the Licensed Technology. Licensed Technology includes Hitachi's patents, patent applications, and know-how that is required to manufacture the Product.

On September 26, 2018, the Company entered into a technology and patent licensing agreement (the "Restructured Agreement") with Hitachi and its majority owned subsidiary, Kyowa Medex Co., Ltd ("KMX"), which terminated the October 1, 2015 licensing and distribution agreement. The Restructured Agreement specifies that KMX will grant to the Company an exclusive, non-transferable license to licensed technology information and patents to make, use, sell, market, export, or otherwise distribute the ALLEREYE product. The Restructured Agreement also specifies that Hitachi is responsible for transferring all equipment and machinery necessary to manufacture the product from Japan to the Company's designated facilities in the United States, and Hitachi will provide training on the operation, maintenance, and use of the machinery and manufacturing know-how of the product. In exchange for such concessions, the Company released Hitachi from all charges, claims, obligations, and costs arising out of the October 1, 2015 agreement. There was no other consideration exchanged as part of this agreement. The fair value of equipment transferred in 2019 was determined to be approximately $742,000. The fair value was recorded as equipment and a corresponding gain in 2019.

License and Development Agreement with Naval Medical Research Center

On March 7, 2019, the Company entered into a cooperative research and development agreement ("CRAD Agreement") with Naval Medical Research Center ("NMRC"). The objective of the agreement is for the development of lateral flow rapid test for sensitive and accurate diagnosis of various tick-borne diseases including Lyme disease. The CRAD Agreement grants the Company a non-exclusive, royalty-free, non-commercial research use license to any innovation made by NMRC occurring under the CRAD Agreement in performance of the objective. During the years ended December 31, 2020 and 2019, the Company paid $0 and $75,000, respectively, to NMRC in connection with the CRAD Agreement. The remaining commitment under the CRAD Agreement is $76,350 as of December 31, 2020 and 2019, and is included in accounts payable on the balance sheet.

License and Supply Agreement with Toray

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 milestone payments of $120,000 each. The first milestone payment was made in January 2021, and the second milestone payment is due one year from the date in which the Toray Agreement was executed. Both milestone payments totaling $240,000 were accrued for as of December 31, 2020, and are included in current liabilities on the balance sheet. 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

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

3. BUSINESS AGREEMENTS (cont.)

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 year ended December 31, 2020.

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2020 and 2019:

	December 31,	
	2020	**2019**
Furniture, fixtures, and equipment	$ 16,046	$ 16,046
Website	4,619	4,619
Lab equipment	741,591	741,591
	762,256	762,256
Less: accumulated depreciation	(303,118)	(146,079)
Property and equipment, net	$ 459,138	$ 616,177

5. INCOME TAXES

For the years ended December 31, 2020 and 2019, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company and a valuation allowance on its deferred tax assets.

The effective income tax rate differed from the statutory federal income tax rate due to the following:

	Year ended December 31,	
	2020	**2019**
Federal income taxes	21.00%	21.00%
State income taxes, net of federal benefit and tax credits	6.80%	7.80%
Permanent differences	0.72%	(1.54)%
Change in valuation allowance	(28.48)%	(27.28)%
Effective income tax rate	0.00%	0.00%

Significant components of the Company's net deferred tax assets and liabilities as of December 31, 2020 and 2019 are as follows:

	Year ended December 31,	
	2020	**2019**
Deferred tax assets		
Net operating losses	$ 958,000	$ 654,000
Tax credits	31,000	28,000
Intangibles assets	74,000	10,000
Other	7,000	5,000
Gross deferred tax asset	1,070,000	697,000
Valuation allowance	(997,000)	(662,000)
	$ 73,000	$ 35,000
Deferred tax liabilities		
Note premium amortization	(47,000)	(33,000)
Fixed assets	(26,000)	(2,000)
	$ (73,000)	$ (35,000)

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

5. INCOME TAXES (cont.)

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, 2020 and 2019, 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 $335,000 and $242,000 during 2020 and 2019, respectively, related mainly to a full valuation allowance recorded against additional net operating losses and tax credits generated in the year.

As of December 31, 2020, the Company had federal net operating losses of $3,585,000, which may be available to offset future federal income tax liabilities. The Company's federal net operating losses incurred prior to 2018 of $713,000 expire through 2037, while its federal net operating losses incurred in 2018 and onwards, $2,872,000, can be carried forward indefinitely.

As of December 31, 2019, the Company had federal net operating losses of $2,487,000, which may be available to offset future federal income tax liabilities.

As of December 31, 2020, the Company had post-apportioned Massachusetts net operating losses of $3,244,000 that can generally be carried forward 20 years. As of December 31, 2019, the Company had post-apportioned state net operating losses of $2,142,000 that can generally be carried forward 20 years.

As of December 31, 2020, the Company had $4,000 and $35,000 of federal and state research and development credits, respectively, which will expire at various dates through 2040. As of December 31, 2019, the Company had $4,000 and $31,000 of federal and state research and development credits, respectively, which will expire at various dates through 2039.

6. FAIR VALUE MEASUREMENTS

Liabilities measured at fair value on a recurring basis are summarized as follows:

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

	December 31, 2019			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Derivative warrant liability	$ —	$ —	$ 96,408	$ —
	$ —	$ —	$ 96,408	$ —

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

6. FAIR VALUE MEASUREMENTS (cont.)

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

	Warrant Liability
Balance at December 31, 2018	$ —
Issuance of Series B warrants	106,250
Unrealized gain	(9,842)
Balance at December 31, 2019	96,408
Issuance of Series B warrants	16,787
Unrealized loss	42,434
Balance at December 31, 2020	$ 155,629

Unrealized gain (loss) on revaluation of derivative warrant liability is included in derivative warrant liability gain (loss) in the Statements of Operations.

There are no assets measured at fair value on a recurring basis, nor are there assets or liabilities measured at fair value on a non-recurring basis, other than the fair value of equipment transferred from Hitachi in 2019 (see Note 3) and the fair value of Common Stock Warrants (see Note 7).

7. 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. 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).

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 was added to the principal balance of the Notes and not paid out to investors. For the years ended December 31, 2020 and 2019, interest expense on the Notes was $59,274 and $45,792, respectively, all of which was paid 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. For the year ended December 31, 2019, principal payments made to investors were $265,000. The Notes, plus any related accrued interest, 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).

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. The Company recognized $116,670 credit to non-cash interest expense due to the amortization of the premium and $18,319 of non-cash interest expense due to the amortization of the issuance costs, recorded as a discount on the Notes in both 2020 and 2019. The remaining premium and discount on the Notes of $145,837 and $22,900, respectively, are included in the outstanding notes payable on the balance sheet as of December 31, 2020. The remaining premium and discount on the Notes of $262,507 and $41,219, respectively, are included in the outstanding notes payable on the balance sheet as of December 31, 2019.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

7. NOTES PAYABLE (cont.)

2020 Subordinated Promissory 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 have a maturity date of March 31, 2021. The Company defaulted on the Subordinated Notes on March 31, 2021 and these notes started to accrue 15% penalty interest starting on the date of default.

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 ("Common Stock Warrants") totaling 4,846,688 Common Stock Warrants, of which 944,160 were issued to LMBRI (see Note 10). The Common Stock Warrants have an exercise price of $0.03 per share, and are exercisable starting at the issuance date and have 5 year term. The Common Stock Warrants may be exercised for cash or through cancellation of the Subordinated Notes. The Common Stock Warrants were accounted for as equity. The fair value of the Common Stock Warrant was estimated to be $4,488,570 using a Black-Scholes option pricing model.

The following assumptions were used to estimate the fair value of the Common Stock Warrants using the Black-Scholes option pricing model:

Risk-free interest rate	0.38%
Dividend rate	0%
Volatility	88.60%
Expected life (in years)	5

The Company does not have a history of market prices of its common stock, and as such, volatility of the Company's common stock is estimated using historical volatilities of similar public entities. The expected life is the remaining contractual term of the warrant instrument. The risk-free interest rate assumption is based on observed interest rates appropriate for the remaining contractual term. The dividend yield assumption is based on history and expectation of paying no dividends.

The proceeds from the issuance of the Subordinated Notes were allocated between the Subordinated Notes and the Common Stock 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 Common Stock Warrants were recorded in additional paid-in capital on the accompanying balance sheet as of December 31, 2020. The allocation of the proceeds to the Common Stock Warrants resulted in a discount to the Subordinated Notes of $148,891. The Company is amortizing this discount using the effective interest method, of which $65,140 was amortized during the year ended December 31, 2020 and included in interest income (expense), net of amortization of premium in the Statement of Operations.

8. STOCKHOLDERS' EQUITY

Preferred Stock

The Company's Certificate of Incorporation, as amended, provides for issuance of Series A redeemable, convertible preferred stock ("Series A"), Series B redeemable, convertible preferred stock ("Series B"), and Series C redeemable, convertible preferred stock ("Series C"), collectively referred to as "Preferred Stock".

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

8. STOCKHOLDERS' EQUITY (cont.)

In connection with the Financing (see Note 7), 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 and resulted in the Series A being recorded at $476,651, net of $91,597 of issuance costs. The Series A are 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 $184,494 for the year ended December 31, 2020 and 2019.

On April 5, 2019, the Company entered into Subscription Agreements for the issuance of Series B (the "Series B Financing"). In connection with the Series B Financing, the Company issued 4,455 shares of Series B at a purchase price of $361.50 per share. Gross proceeds from the Series B Financing were approximately $1,610,000. The Subscription Agreements also specify 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 622 Series B Warrants were issued in 2019 in connection with the Series B Financing.

In connection with the Series B Financing, in 2019 the Company entered into an Amended Subscription Agreement with an investor to issue additional Series B and warrants for committed proceeds up to $150,000, available to be drawn on within one year of the date of the closing of the offering. During 2019, the Company drew $100,000 of the committed amount and issued 277 shares of Series B and 41 Series B Warrants. Series B Warrants issued in 2019 expire between April 2024 and December 2024.

The remaining $50,000 commitment was drawn on 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 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 Warrants issued in 2020 expire between January and December 2025.

The Series B are accreted 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 $81,585 and $4,770 for the years ended December 2020 and 2019, respectively.

The Series B Warrants are accounted for as a derivative liability under ASC 480 – *Distinguishing Liabilities from Equity*. The fair value of Series B Warrants at the issuance date in 2020 and 2019 was determined to be $16,787 and $106,250, 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 per share of $1,578.50. Proceeds from the Series C Financing, net of issuance costs were $994,832.

The Series C are 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 $5,633 for the year ended December 2020.

The Series A ranks senior to Series B and Series C. Series B is pari passu with the Series C. Significant terms of the Series A, Series B and Series C (collectively, "Preferred Stock") are as follows:

Voting

The holder of each share of 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 Preferred Stock and Common Stock shall vote together as a single class.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

8. STOCKHOLDERS' EQUITY (cont.)

Dividends

The holders of 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 through December 31, 2020.

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 Series A, Series B and Series C 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.

2018 Stock Incentive Plan

In 2018, the Company adopted the 2018 Stock Incentive Plan (the "2018 Plan"). 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 to employees, consultants, and directors of the Company. The maximum number of shares reserved for issuance under the 2018 Plan is 629,440. At December 31, 2020, there were 253,614 shares available for grants under the 2018 Plan.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

8. STOCKHOLDERS' EQUITY (cont.)

The following is a summary of stock option activity for the year ended December 31, 2020:

	Number of Stock Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2019	472,080	$ 0.50		
Granted	13,898	0.95		
Cancelled/forfeited	(110,152)	0.16		
Outstanding at December 31, 2020	375,826	$ 0.59	8.0	$ 245,619
Exercisable at December 31, 2020	265,675	$ 0.46	7.9	$ 207,544

There were no options exercised in the years ended December 31, 2020 and 2019. The intrinsic value at December 31, 2020 was estimated based on the fair value of common stock of $1.24 per the most recent common stock valuation as of December 31, 2020.

For the years ended December 31, 2020 and 2019, the Company recorded stock-based compensation expense of $7,370 and $14,815, respectively, in connection with share-based payment awards, which are recorded in general and administrative expenses in the statements of operations.

At December 31, 2020, there was approximately $800 of unrecognized compensation expense related to non-vested stock option awards that are expected to be recognized over a weighted-average period of 1.3. The weighted-average fair value of stock options granted for each of the years ended December 31, 2020 and 2019, under Black Scholes option pricing model, were $0.65 per share and $0.04 per share, respectively.

9. WARRANTS

The following table summarizes information with regard to warrants outstanding at December 31, 2020.

	Shares	Exercisable for	Exercise Price	Weighted Average Remaining Life
Series B Warrants	731	Series B	$ 361.50	3.3
Common Stock Warrants	4,846,688	Common Stock	$ 0.03	4.8

10. RELATED PARTY TRANSACTIONS

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. Amounts payable to LMBRI from the Company at December 31, 2020 and 2019 were $125,102 and $86,005, respectively, and are included in due to related party on the balance sheets. 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. The Company incurred and paid LMBRI $48,000 for these shared expenses in each of the years 2020 and 2019. Such amounts are included in general and administrative expenses on the accompanying statement of operations.

Bluejay Diagnostics, Inc.
Notes to Financial Statements
Years Ended December 31, 2020 and 2019

11. NOTE PAYABLE, PAYCHECK PROTECTION PROGRAM

In response to the COVID-19 pandemic, the Paycheck Protection Program ("PPP") was established under the Coronavirus Aid, Relief, and Economic Security ("CARES") Act and administered by the United States Small Business Administration ("SBA"). On April 7, 2020, the Company received a loan of $116,000 under the PPP through its bank. The loan bears interest at 1.0%, with principal and interest payments deferred for the first six months of the loan. After that, the loan and interest would be paid back over a period of eighteen months, if the loan is not forgiven under the terms of the PPP.

The Company received notice of forgiveness from the SBA in November 2020 for $102,000 of the PPP loan, and recognized a gain on forgiveness the loan of $102,000 in the statement of operations. In February 2021, the Company received a corrected notice of forgiveness for an additional $5,000 and repaid the remaining balance of $9,000. The PPP loan balance as of December 31, 2020 includes the accrued interest outstanding of $725. During 2020, the Company also received an advance of $5,000 from the COVID-19 Economic Injury Disaster Loan (EIDL) program that does not need to be repaid and was recognized in other income in the statement of operations.

12. SUBSEQUENT EVENTS

In February 2021, the Company repaid $268,000 in principal and $2,010 in accrued interest on the Notes, and $9,000 in PPP loan principal.

On March 15, 2021, pursuant to a financial services agreement with a financial advisor, the Company granted warrants to purchase 226,599 shares of common stock at an exercise price of $3.177 per share. The warrants are exercisable until March 15, 2026. The terms of the financial services agreement also provide for the incentive bonus of $200,000 payable upon closing of an IPO if such a closing occurs on or before January 31, 2022.

On June 1, 2021, the Company's Series A was converted into 1,668,016 shares of common stock, its Series B was converted into 816,226 shares of common stock, and its Series C was converted into 100,081 shares of common stock. In addition, the Company's remaining 2017 Notes were amended such that they would automatically convert into shares of common stock upon the occurrence of a qualified financing, as defined, and the Series B Warrants were amended to be exercisable into common stock. The Notes automatically converted on June 8, 2021 into 580,002 shares of common stock. The company is currently analyzing the accounting impact of the Notes and Series B Warrants modification.

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 (see Note 1). The Company transferred assets and liabilities in accordance with the Contribution and Assumption Agreement to the newly created subsidiary. 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.

On June 7, 2021, the holders of $132,383 in principal of the 2020 Subordinated Promissory Notes, as amended, 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 2020 Subordinated Promissory Notes was repaid in cash and the related warrants to purchase 680,331 shares of common stock at an exercise price of $0.03 per share remain outstanding.

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. Further, the Company approved an amendment to the Company's certificate of incorporation to increase the number of authorized shares of common and preferred stock to 30 million and 5 million shares, respectively. As noted in Note 1 to these financial statements, the common stock shares and per share amounts (other than authorized shares) in these financial statements and related notes reflect the stock dividend for all periods presented, including the amounts reported in subsequent events disclosed above.

On June 8, 2021, the Company entered into a definitive agreement to issue a total of $4.5 million of 7.5% Senior Secured Convertible Debentures (the "Debentures"), of which $3.0 million were issued on June 8, 2021. The agreement provides for the purchase by the holder of the Debentures of an additional $1.5 million Debentures after the Company files a registration statement in an Initial Public Offering. The Debentures are convertible, at the holder's option, into the Company's Series D Convertible Preferred Stock at $1,000 conversion price per share.

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,400,457	$ 912,361
Inventory	—	84,762
Prepaid expenses	6,390	7,965
Deferred offering costs	267,891	—
Other current assets	58,106	53,106
Total current assets	2,732,844	1,058,194
Property and equipment, net	392,700	459,138
Total assets	$ 3,125,544	$ 1,517,332
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 309,381	$ 374,928
Due to related party	115,102	125,102
Accrued expenses	211,431	133,820
Notes payable, current portion	—	1,041,186
Note payable, Paycheck Protection Program	—	14,725
Derivative warrant liability	—	155,629
Convertible debentures	2,501,904	—
Other current liabilities	111,211	—
Total liabilities	3,249,029	1,845,390
Commitments and Contingencies (See Note 6)		
Series A redeemable, convertible preferred stock, $0.0001 par value; 10,600 shares authorized; 0 and 10,600 shares issued and outstanding at June 30, 2021 and December 31, 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 June 30, 2021 and December 31, 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 June 30, 2021 and December 31, 2020, respectively	—	1,000,465
Stockholders' deficit:		
Common stock, $0.0001 par value; 30,000,000 shares authorized; 10,477,880 and 3,147,200 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	1,048	315
Additional paid-in capital	4,916,376	—
Accumulated deficit	(5,040,909)	(4,206,488)
Total stockholders' deficit	(123,485)	(4,206,173)
Total liabilities, redeemable, convertible preferred stocks and stockholders' deficit	$ 3,125,544	$ 1,517,332

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

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

	Six Months Ended June 30,	
	2021	**2020**
Operating expenses:		
Research and development	$ 250,175	$ 105,469
General and administrative	529,741	321,752
Marketing and business development	119,354	39,222
Total operating expenses	899,270	466,443
Operating loss	(899,270)	(466,443)
Other income (expense):		
Derivative warrant liability gain (loss)	9,676	(49,667)
Interest income (expense), net of amortization of premium	(32,116)	24,610
Grant income	75,000	—
Other income	12,289	5,228
Total other income (expense), net	64,849	(19,829)
Net loss	$ (834,421)	$ (486,272)
Net loss per share – Basic and diluted	$ (0.20)	$ (0.15)
Weighted average common shares outstanding:		
Basic and diluted	4,201,688	3,147,200

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

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

	Redeemable, Convertible Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
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)**
Accretion of redeemable, convertible preferred stock to redemption value	—	73,912	—	33,994	—	19,961	—	—	(127,867)	—	(127,867)
Stock-based compensation expense	—	—	—	—	—	—	—	—	319	—	319
Fair value of warrants issued for services	—	—	—	—	—	—	—	—	180,339	—	180,339
Exercise of common stock warrants	—	—	—	—	—	—	4,166,357	417	131,966	—	132,383
Conversion of redeemable, convertible preferred stock into common stock	(10,600)	(1,151,215)	(5,187)	(1,834,341)	(636)	(1,020,426)	2,584,323	258	4,005,724	—	4,005,982
Conversion of Amended 2017 Convertible Notes	—	—	—	—	—	—	580,000	58	579,942	—	580,000
Reclassification of Series B Warrants	—	—	—	—	—	—	—	—	145,953	—	145,953
Net loss	—	—	—	—	—	—	—	—	—	(834,421)	(834,421)
Balance at June 30, 2021	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**10,477,880**	**$ 1,048**	**$ 4,916,376**	**$ (5,040,909)**	**$ (123,485)**

	Redeemable, Convertible Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
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 $4,570	—	—	139	50,249	—	—	—	—	—	—	—
Reclassification of derivative warrant liability	—	—	—	(5,228)	—	—	—	—	—	—	—
Accretion of redeemable, convertible preferred stock to redemption value	—	92,247	—	40,793	—	—	—	—	—	(133,040)	(133,040)
Stock-based compensation benefit	—	—	—	—	—	—	—	—	—	(1,841)	(1,841)
Net loss	—	—	—	—	—	—	—	—	—	(486,272)	(486,272)
Balance at June 30, 2020	**10,600**	**$ 985,056**	**4,871**	**$ 1,661,135**	**—**	**$ —**	**3,147,200**	**$ 315**	**$ —**	**$ (3,553,906)**	**$ (3,553,591)**

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

Table of Contents

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

	Six Months Ended June 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (834,421)	$ (486,272)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	64,504	73,030
Stock-based compensation expense (benefit)	319	(1,841)
Gain on forgiveness of note payable, Paycheck Protection Program	(5,000)	—
Non-cash interest expense	1,770	(49,175)
Loss (gain) on revaluation of derivative warrant liability	(9,676)	49,667
Changes in operating assets and liabilities:		
Accounts receivable	—	645
Inventory	84,762	(84,762)
Prepaid expenses and other current assets	(3,425)	13,044
Accounts payable	(98,389)	197,738
Due to related party	(10,000)	23,097
Accrued expenses and other current liabilities	76,886	—
Net cash used in operating activities	**(732,669)**	**(264,829)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	1,934	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of principal on notes payable	(289,617)	—
Payments of convertible debenture issuance costs	(395,000)	
Payments of deferred offering costs	(87,552)	—
Proceeds from issuance of convertible debentures	3,000,000	—
Proceeds from issuance of Series B redeemable, convertible preferred stock, net of issuance costs	—	107,926
Proceeds (payments) on note payable, Paycheck Protection Program	(9,000)	116,000
Net cash provided by financing activities	**2,218,831**	**223,926**
Increase (decrease) in cash and cash equivalents	1,488,096	(40,903)
Cash and cash equivalents, beginning of period	912,361	96,011
Cash and cash equivalents, end of period	$ 2,400,457	$ 55,108
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH ACTIVITIES:		
Interest paid	$ 25,328	$ —
Accretion of Series A redeemable, convertible preferred stock dividend	$ 17,667	$ 21,200
Accretion of Series A redeemable, convertible preferred stock issuance costs and fair value adjustment	$ 56,245	$ 71,047
Accretion of Series B redeemable, convertible preferred stock dividend	$ 31,258	$ 37,509
Accretion of Series B redeemable, convertible preferred stock issuance costs	$ 2,736	$ 3,284
Accretion of Series C redeemable, convertible preferred stock dividend	$ 16,727	$ —
Accretion of Series C redeemable, convertible preferred stock issuance costs	$ 3,234	$ —
Exercise of warrants through debt principal conversion	$ 132,383	$ —
Conversion of preferred stock into common stock	$ 4,005,982	$ —
Conversion of amended 2017 convertible notes	$ 580,000	$ —
Reclassification of derivative warrant liability into additional paid-in capital	$ 145,953	$ —
Fair value of warrants for common stock issued for services	$ 180,339	$ —

See notes to unaudited condensed consolidated financial statements.

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Bluejay Diagnostics, Inc. (the "Company") commenced its activities on March 20, 2015 incorporated under the laws of the State of Delaware. The Company is a mission-driven in-vitro diagnostic company that aims to develop and market minimally-invasive Point-of-Care ("POC") diagnostics tests and devices that provide patients and providers with access to affordable and timely healthcare. The Company's focus is on the infectious disease, inflammation, and oncology markets.

The Company is pursuing biomarker detection of Sepsis, Cancer and other diseases, 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 Cardiac Ishcemia and Congestive 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.

Since its inception, the Company has devoted substantially all of its efforts to business planning, sales and marketing, research and development, and raising capital.

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 pharmaceutical and 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.

To date, the Company has experienced significant changes in the business as a result of the COVID-19 pandemic. The impact has delayed the Company's ability to generate revenue as result of the diversification of potential customer budgets towards the COVID-19 pandemic. 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.

Stock Split

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 ("Stock Split"). This stock dividend was deemed a large stock dividend and was treated as a 1-for-3.15 stock split. The common stock shares and per share amounts (other than authorized shares) in these condensed consolidated financial statements and related notes have been retroactively restated to reflect the stock dividend for all periods presented.

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION (cont.)

Going concern

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern. To date, the Company has experienced recurring losses from operations, and has a stockholders' deficit of $123,485 and negative working capital of $516,185 as of June 30, 2021. The Company has relied on raising capital and issuing debt to finance its operations.

The Company plans to raise capital through equity and/or debt financings and expects to generate revenue from sales to customers in the second half of 2021. There is no assurance, however, that the Company will be able to raise sufficient capital to fund its operations on terms that are acceptable, if at all, or generate profitable operations.

There is substantial doubt about the Company's ability to continue as a going concern within a year after the date that these condensed consolidated financial statements are issued. The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability of recorded asset amounts that might be necessary as a result of the above uncertainty.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in conformity with generally accepted accounting principles in the United States ("US GAAP") consistent with those applied in, and should be read in conjunction with, the Company's audited financial statements and related footnotes for the year ended December 31, 2020. The unaudited condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2021, and its results of operations and cash flows for the six months ended June 30, 2021 and 2020, in accordance with US GAAP. The unaudited condensed consolidated financial statements do not include all of the information and footnotes required by US GAAP for complete financial statements, as allowed by the relevant U.S. Securities and Exchange Commission ("SEC") rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading.

The results for the six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the full fiscal year ending December 31, 2021, or any other interim period with this fiscal year.

All intercompany balances and transactions have been eliminated in consolidation.

2. SIGNIFICANT ACCOUNTING POLICIES

During the six months ended June 30, 2021, there were no changes to the significant accounting policies as described in the 2020 Audited Financial Statements.

Use of estimates

The preparation of the Company's condensed consolidated financial statements and related disclosures in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

2. SIGNIFICANT ACCOUNTING POLICIES (cont.)

Derivative instruments

The Company generally 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.

On June 1, 2021, the Series B Warrants were amended to become exercisable into common stock. As a result, the Series B Warrants met the requirements for classification as equity, and were reclassified to additional paid-in capital (see Note 7). The Series B Warrants were remeasured at fair value immediately prior to the reclassification.

The fair value of the outstanding Series B redeemable preferred stock warrants (see Note 7) 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

Research and development expenses

Costs incurred for research and development are expensed as incurred. Research and development expenses primarily consist of salaries and related expenses for personnel, outside consulting services and sponsored research and the costs of materials and supplies used.

Redeemable Convertible Preferred Stock

The Company has classified redeemable, convertible preferred stock (“Preferred Stock”) as temporary equity in the accompanying condensed 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 June 30, 2021 and December 31, 2020, all of the Company’s assets were located in the United States.

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, and 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.

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

2. SIGNIFICANT ACCOUNTING POLICIES (cont.)

The following potential common shares were not considered in the computation of diluted net loss per share as their effect would have been anti-dilutive:

	June 30,	
	2021	2020
Redeemable, convertible preferred stock	—	2,434,359
Options to purchase common stock	375,826	361,928
Warrants for common stock	1,022,120	—
Warrants for Series B redeemable, convertible preferred stock	—	107,634
Convertible debentures	3,000,000	—

Grant Income

Grant income is recognized when the related work is performed and the qualifying research and development costs are incurred. Such costs are included as operating expenses in the Company's consolidated statement of operations. For the six-month period ended June 30, 2021, the Company recorded grant income of $75,000 received from a state agency, Massachusetts Growth Capital Corporation. No such grant was received in the six-months period ended June 30, 2020.

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.

Management does not expect any recently issued, but not yet effective, accounting standards to have a material effect on its results of operations or financial condition.

3. BUSINESS AGREEMENTS

License and Development Agreement with Naval Medical Research Center

On March 7, 2019, the Company entered into a cooperative research and development agreement ("CRAD Agreement") with Naval Medical Research Center ("NMRC"). The objective of the agreement is for the development of lateral flow rapid test for sensitive and accurate diagnosis of various tick-borne diseases including Lyme disease. The CRAD Agreement grants the Company a non-exclusive, royalty-free, non-commercial research use license to any innovation made by NMRC occurring under the CRADA Agreement in performance of the objective. No payments were made in connection with the CRADA Agreement during the six month periods ended June 30, 2021 and 2020. The remaining commitment under the CRADA Agreement is $76,350 as of June 30, 2021 and December 31, 2020, and is included in accounts payable on the condensed consolidated balance sheet.

License and Supply Agreement with Toray

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")

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

3. BUSINESS AGREEMENTS (cont.)

outside of Japan. In exchange for the license, the Company committed to make two milestone payments of $120,000 each. The first milestone payment was made in January 2021, and the second milestone payment is due one year from the date in which the Toray Agreement was executed. Milestone payments totaling $120,000 and $240,000 were accrued for as of June 30, 2021 and December 31, 2020, respectively, and are included in current liabilities on the condensed consolidated balance sheet. 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 year ended December 31, 2020 or the six month period ended June 30, 2021.

4. FAIR VALUE MEASUREMENTS

Liabilities measured at fair value on a recurring basis at December 31, 2020 are summarized in the table below. There were no liabilities measured at fair value at June 30, 2021.

	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, 2020	$ 155,629
Unrealized gain	(9,676)
Fair value of Series B warrants converted into warrants for common stock	(145,953)
Balance at June 30, 2021	$ —

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

There are no assets measured at fair value on a recurring basis, nor are there assets or liabilities measured at fair value on a non-recurring on June 30, 2021 and December 31, 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.

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 was added to

5. NOTES PAYABLE (cont.)

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. The Notes, plus any related accrued interest, 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 9).

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 six month period ended June 30, 2021. The Company recognized the amortization of the premium of $145,837 and $58,335 as a reduction to non-cash interest expense during the six months ended June 30, 2021 and 2020, respectively. The premium amortization was included in the interest income (expense) on the condensed 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 $9,160 as non-cash interest expense during the six months ended June 30, 2021 and 2020, respectively. The discount amortization was included in the interest income (expense) on the condensed consolidated statements of operations.

On February 17, 2021, the Company repaid in cash $268,000 in principal and $2,010 in accrued interest on the Notes and entered into an agreement to settle the remaining principal balance of $580,000 either through conversion into equity shares or in cash.

On May 26, 2021, the remaining Notes were amended and restated (the "Amended Notes"). The Amended Notes accrue no interest and are due in May 2023. The Amended Notes are automatically convertible into a number of 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), resulting in gross proceeds of at least $3,000,000. For the six months ended June 30, 2021 and 2020, the interest expense on the Notes was $6,360 and $24,565, respectively.

The Amended Notes principal automatically converted on June 8, 2021 into 580,000 shares of common stock upon the issuance of $3,000,000 in Convertible Debentures to Sabby as discussed in 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 condensed consolidated statement of operations for the six months ended June 30, 2021.

2020 Subordinated Promissory 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 six months ended June 30, 2021, interest expense on the Subordinated Notes was $7,443.

In conjunction with the issuance of the Subordinated Notes, the Company issued to each noteholder warrants to purchase shares of the Company's common stock ("Common Stock Warrants") totaling 4,846,688 Common Stock Warrants, of which 944,160 were issued to LMBRI. The Common Stock Warrants have an exercise price of $0.03 per

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

5. NOTES PAYABLE (cont.)

share, and are exercisable upon issuance date and have a 5-year term. The Common Stock Warrants may be exercised for cash or through cancellation of the Subordinated Notes. The fair value of the Common Stock Warrant at the issuance date was estimated to be $4,488,570 using a Black-Scholes option pricing model.

The Common Stock 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 Common Stock 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 Common Stock Warrants were recorded in additional paid-in capital on the accompanying balance sheet as of December 31, 2020.

The allocation of the proceeds to the Common Stock Warrants resulted in a discount to the Subordinated Notes of $148,892. The Company is amortizing this discount through non-cash interest expense using the effective interest method, of which $83,752 was amortized during the six months ended June 30, 2021 and included in the interest income (expense) in the condensed consolidated statement of operations.

On June 7, 2021, the holders of $132,383 in principal of the 2020 Subordinated Promissory 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 2020 Subordinated Promissory Notes was repaid in cash and the related warrants to purchase 680,331 shares of common stock remain outstanding at June 30, 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 initial public offering (“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. The Convertible Debentures are 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 is 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 will also automatically convert into Series D upon the effectiveness of an IPO. The Company is obligated to pay interest on the Convertible Debentures at the rate of 7.5% per annum, payable quarterly on January 1, April 1, July 1 and October 1, 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.

The Company incurred $539,052 in issuance costs related to the Convertible Debentures, which were netted against the outstanding Convertible Debentures on the condensed consolidated balance sheet at June 30, 2021. The resulting discount is amortized over the term of the Convertible Debentures using the effective interest method. The Company recognized $40,956 of amortization of the discount during the six months ended June 30, 2021, which was included in the interest income (expense) in the condensed consolidated statement of operations.

Under the terms of the service agreement, the placement agent was entitled to a warrant for the Company’s shares as a compensation for its services in relation to the Sabby Investment. The warrant was deemed to be issued in July 2021 and the Company established a liability to the placement agent of $111,211 at June 30, 2021, which is included in other current liabilities in the condensed consolidated balance sheet.

For the six months ended June 30, 2021, interest expense on the Convertible Debentures was $16,543.

Subsequent to period end, on August 4, 2021, the Company issued the remaining $1,500,000 of Convertible Debentures to Sabby (see note 10).

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

7. WARRANTS

In March 2021, the Company granted to a financial advisor warrants to purchase 226,599 shares of the Company's common stock as consideration for services in connection with the planned 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 is included in deferred offering costs at June 30, 2021.

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 will be recognized as offering costs upon the IPO.

The following assumptions were used in the Black-Scholes option pricing model to estimate the fair value of the Common Stock Warrants granted in the six months ended June 30, 2021:

Risk-free interest rate	0.26%
Dividend rate	0%
Volatility	106.00%
Expected life (in years)	5

The Series B Warrants issued in conjunction with the Series B (see Note 8) were accounted for as a derivative liability under ASC 480 — *Distinguishing Liabilities from Equity*. The fair value of Series B Warrants at the issuance date in 2020 and 2019 was determined to be $16,787 and $106,250, respectively.

On June 1, 2021, as a result of the conversion of Series B into common stock (see Note 8), the outstanding 731 Series B Warrants were amended to become exercisable into 115,190 shares of common stock at an exercise price of $7.23 per share ("Amended Series B Warrants"). The Amended Series B Warrants were accounted for as equity and reclassified from liabilities into additional paid-in capital at the fair value of $145,953 as of the amendment date.

The following table summarizes information with regard to warrants outstanding at June 30, 2021.

	Shares	Exercisable for	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
Common Stock Warrants	1,022,120	Common Stock	$ 1.54	4.2

8. STOCKHOLDERS' EQUITY

Preferred Stock

The Company's Certificate of Incorporation, as amended on June 7, 2021, provides 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.

Prior to June 1, 2021, the Company had outstanding Series A redeemable, convertible preferred stock ("Series A"), Series B redeemable, convertible preferred stock ("Series B"), Series C redeemable, convertible preferred stock ("Series C"), collectively referred to as "Preferred Stock".

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 $92,247 for the six months ended June 30, 2021 and 2020, respectively.

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

8. STOCKHOLDERS' EQUITY (cont.)

On April 5, 2019, the Company entered into Subscription Agreements for the issuance of Series B (the "Series B Financing"). In connection with the Series B Financing, the Company issued 4,455 shares of Series B at a purchase price of $361.50 per share. Gross proceeds from the Series B Financing were approximately $1,610,000. The Subscription Agreements also specify 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 622 Series B Warrants were issued in 2019 in connection with the Series B Financing.

In connection with the Series B Financing, in 2019 the Company entered into an Amended Subscription Agreement with an investor to issue additional Series B and warrants for committed proceeds up to $150,000, available to be drawn on within one year of the date of the closing of the offering. During 2019, the Company drew $100,000 of the committed amount and issued 277 shares of Series B and 41 Series B Warrants. Series B Warrants issued in 2019 expire between April 2024 and December 2024.

The remaining $50,000 commitment was drawn on 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 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 Warrants issued in 2020 expire between January and December 2025.

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 $40,793 for the six months ended June 30, 2021 and 2020, 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 six months ended June 30, 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 each of the Certificate 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 ranks senior to Series B and Series C. Series B is pari passu with the Series C. Significant terms of the Series A, Series B and Series C (collectively, "Preferred Stock") were as follows:

Voting

The holder of each share of 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 Preferred Stock and Common Stock shall vote together as a single class.

Dividends

The holders of 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 through June 30, 2021.

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

8. STOCKHOLDERS' EQUITY (cont.)

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 Series A, Series B and Series C 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.

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. There were no Series D issued or outstanding as of June 30, 2021. Significant terms of the Series D Preferred Stock are as follows:

Voting

The Series D shall have no voting rights.

Dividends

The holders shall be entitled to receive cumulative quarterly dividends at a rate of $7.5% per share per annum. The rate increases to 15% per share per annum after November 23, 2021. In the event of an IPO by the Company, no dividends shall accrue on the Preferred Stock following the IPO date.

Liquidation Preference

In the event of any liquidation, dissolution or winding up of the Company, the holders of Series D 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 Common Stock, in the amount equal to the Stated Value of $1,000 per share, plus all accrued but unpaid dividends thereon. If insufficient assets and funds are available to permit payment to the Series D holders, then all available assets and funds shall be distributed to the Series D holders on a pro rata basis.

Bluejay Diagnostics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

8. STOCKHOLDERS' EQUITY (cont.)

Conversion

Each share of Series D shall be convertible into 1,000 shares of Common Stock at $1.00 per share at any time by the holder following issuance.

2018 Stock Incentive Plan

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. At June 30, 2021, there were 253,614 shares available for grant under the 2018 Plan.

There were no options grants or exercises for the six months ended June 30, 2021. There were 375,826 outstanding option grants at June 30, 2021 with the weighted average exercise price per share of $0.59, the weighted average remaining contractual life of 7.5 years and the aggregate intrinsic value of $154,528. There were 277,476 options exercisable at June 30, 2021 with the weighted average exercise price per share of $0.47, the weighted average remaining contractual life of 7.4 years and the aggregate intrinsic value of $147,453.

For the six months ended June 30, 2021 and 2020, the Company recorded stock-based compensation expense (benefit) of $319 and $(1,841), respectively, in connection with share-based payment awards, which is included in the general and administrative expenses in the condensed consolidated statements of operations. The forfeitures occurring during the six months ended June 30, 2020 resulted in the total negative stock compensation expense.

At June 30, 2021, there was approximately $495 of unrecognized compensation expense related to non-vested stock option awards that are expected to be recognized over a weighted-average period of 1 year. The weighted-average fair value of stock options granted for the six months ended June 30, 2020 under Black Scholes option pricing model, was $0.65 per share.

9. RELATED PARTY TRANSACTIONS

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. Amounts payable to LMBRI from the Company at June 30, 2021 and December 31, 2020 were $115,102 and $125,102, respectively, and are included in due to related party on the condensed consolidated balance sheets. 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. The Company incurred and paid LMBRI $24,000 for these shared expenses during each of the six month periods ended June 30, 2021 and 2020. Such amounts are included in general and administrative expenses on the accompanying condensed consolidated statements of operations.

10. SUBSEQUENT EVENTS

On July 6, 2021, the Company's board of directors and stockholders approved and adopted the Bluejay Diagnostics, Inc. 2021 Stock 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 (see Note 8).

On August 4, 2021, the Company issued the remaining $1,500,000 of the Convertible Debentures to Sabby under the agreement entered into on June 7, 2021 (see Note 6). The agreement provided for the purchase of an additional $1,500,000 Debentures at the filing of a registration statement in an Initial Public Offering, which was filed on July 22, 2021. The Debentures are convertible, at the holder's option, into the Company's Series D Convertible Preferred Stock at $1,000 conversion price per share.

Bluejay Diagnostics, Inc.

2,160,000 Units consisting of:

Common Stock

Class A Warrants

Class B Warrants

Dawson James Securities, Inc. **I-Bankers Direct, LLC**

PROSPECTUS

Dated November 9, 2021

Through and including December 4, 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.