May 1, 2023

FORM C-AR: Annual Report

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ANNUAL REPORT FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022

This Form C-AR (including the cover page and all exhibits attached hereto, the "Form C-AR") is being furnished by 20/20 GeneSystems, Inc., a Delaware corporation ("we," "us," "our" or "our company") for the sole purpose of providing certain information about the convertible promissory notes offered and sold by our company pursuant to Regulation Crowdfunding under the Securities Act of 1933, as amended (the "Securities Act"), for the fiscal year ended December 31, 2022. A copy of this report may be found on the company's website at www.2020gene.com.

As of December 31, 2022, we have issued convertible promissory notes in the aggregate principal amount of $213,010 for total gross proceeds of $213,010 and net proceeds of approximately $189,217. This offering was terminated on December 15, 2022.

No federal or state securities commission or regulatory authority has passed upon the accuracy or adequacy of this document. No federal or state securities commission or regulatory authority has recommended or approved the securities. The U.S. Securities and Exchange Commission ("SEC") does not pass upon the accuracy or completeness of any disclosure document or literature. We are filing this Form C-AR pursuant to Regulation CF (§ 227.100 et seq.) which requires that we must file a report with the SEC annually and post the report on our website no later than 120 days after the end of each fiscal year covered by the report. We may terminate our reporting obligations in the future in accordance with Rule 202(b) of Regulation CF (§ 227.202(b)) by (1) being required to file reports under Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended, (2) filing at least one annual report pursuant to Regulation CF and having fewer than 300 holders of record, (3) filing annual reports for three years pursuant to Regulation CF and having assets equal to or less than $10,000,000, (4) the repurchase of all the securities sold in the offering by us or another party, or (5) the liquidation or dissolution of our company.

THIS FORM C-AR DOES NOT CONSTITUTE AN OFFER TO PURCHASE OR SELL SECURITIES.

Forward Looking Statement Disclosure

This Form C-AR and any documents incorporated by reference herein or therein contain forward-looking statements and are subject to risks and uncertainties. All statements other than statements of historical fact or relating to present facts or current conditions included in this Form C-AR are forward-looking statements. Forward-looking statements give our current reasonable expectations and projections relating to our financial condition, results of operations, plans, objectives, future performance and business. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. 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 in connection with any discussion of the timing or nature of future operating or financial performance or other events.

The forward-looking statements contained in this Form C-AR and any documents incorporated by reference herein or therein are based on reasonable assumptions we have made in light of our industry experience, perceptions of historical trends,

current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this Form C-AR, you should understand that these statements are not guarantees of performance or results. They involve risks, uncertainties (many of which are beyond our control) and assumptions. Although we believe that these forward-looking statements are based on reasonable assumptions, you should be aware that many factors could affect its actual operating and financial performance and cause our performance to differ materially from the performance anticipated in the forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of these assumptions prove incorrect or change, our actual operating and financial performance may vary in material respects from the performance projected in these forward-looking statements.

Any forward-looking statement made by us in this Form C-AR or any documents incorporated by reference herein or therein speaks only as of the date of this Form C-AR. Factors or events that could cause our actual operating and financial performance to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

About this Form C-AR

You should rely only on the information contained in this Form C-AR. We have not authorized anyone to provide you with information different from that contained in this Form C-AR. We have sold securities only in jurisdictions where offers and sales are permitted. You should assume that the information contained in this Form C-AR is accurate only as of the date of this Form C-AR, regardless of the time of delivery of this Form C-AR. Our business, financial condition, results of operations, and prospects may have changed since that date.

Statements contained herein as to the content of any agreements or other document are summaries and, therefore, are necessarily selective and incomplete and are qualified in their entirety by the actual agreements or other documents.

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BUSINESS DESCRIPTION

Overview

We are a commercial stage diagnostics company with the core mission of developing and commercializing clinical laboratory tests for early disease detection and prevention and associated software that is powered by machine learning and real-world data to improve diagnostic accuracy and clinical utility.

Our lead tests currently assist in early cancer detection. Of the ten deadliest cancers in the U.S., only three—breast, colon, and prostate—have widely adopted screening modalities. This is despite growing evidence that early detection saves or extends lives for cancers of the lung, liver, pancreas, esophagus, and ovaries which are not yet the subject of widespread asymptomatic screening. To address this deficiency, we are offering what we believe to be one of the first multi-cancer early detection, or MCED, blood tests to enter the American market. Known as OneTest, ours may be the first and only MCED test to enter the U.S. market based on the levels of tumor antigens rather than circulating tumor DNA, or ctDNA. Tumor antigen measurement is a proven technology and each of the antigens detected in the OneTest panel uses an existing *in vitro* diagnostic test that has been cleared by the U.S. Food and Drug Administration, or the FDA, and approved for other indications. This approach permits significantly lower costs and easier access with no demonstrable loss in test accuracy, especially for early-stage detection of the major cancers for which there is no widespread screening.

MCEDs gained significant attention in 2022 as the White House included MCEDs as a core component of its "Cancer Moonshot" program and bi-partisan legislation has been introduced in Congress to make it easier for these types of screening tests to achieve reimbursement by government payers. This focus on MCEDs has been further bolstered by the activities of high-profile companies offering or developing ctDNA based tests following technological advances in next-generation DNA sequencing. While ctDNA-based tests are newer and seeing growing use by scientists, they are generally more expensive, are lacking in the level and number of analytical and clinical validation studies to support them and generally have not performed any better than protein-based technologies in terms of sensitivities for early-stage cancers in asymptomatic populations.

As discussed below, we believe that there are considerable advantages of our unique, patented technical approach to the development of MCED tests via application of sophisticated machine learning algorithms to analyze tumor antigen data collected from large cohorts of asymptomatic real-world populations. Our use of this technical approach has been demonstrated to substantially improve the accuracy of using tumor antigen-based tests for screening and risk-assessment. We have directly demonstrated this advantage in real-world population studies performed in collaboration with researchers in East Asia, where tumor antigens are currently used to test millions of individuals without the added value of our AI-enhanced methods (see "Improving Multi-Tumor Biomarker Health Check-up Tests with Machine Learning Algorithms" *Cancers* 2020 Jun 1;12(6):1442).

We are also planning to bring to market a blood test specifically for the early detection of lung cancer in smokers and former smokers. That test was developed by a team at The University of Texas MD Anderson Cancer Center, or MD Anderson, with over $50 million in funding from federal and state agencies as well as various philanthropies. Validated using blood specimens from diverse, blinded cohorts comprising thousands of pre-symptomatic individuals, the lung cancer test analyzes several of the same tumor antigens that are part of OneTest, along with a novel biomarker (ProSurfactant B) discovered by members of that team. The test will be used primarily to screen individuals with a history of tobacco use to improve both the compliance and effectiveness of low-dose CT, or LDCT, scans which are now part of U.S. screening guidelines.

Large scale clinical trials have proven that screening of those with a history of tobacco use using LDCT can reduce the death rate from lung cancer by 20% (see "Reduced lung-cancer mortality with low-dose computed tomographic screening" *N Engl J Med* 2011;365:395-409). Unfortunately, despite heavy promotion by the American Lung Association and others, according to the National Cancer Institute, fewer than 6% of Americans who meet the current guidelines for yearly scans (based on smoking history) comply with these recommended screening guidelines. Our collaborators at MD Anderson have preliminary evidence that their test not only detects cancers early but can improve mortality. They believe that their test will substantially boost LDCT compliance and could potentially result in over 5,000 more lives saved per year over current screening paradigms.

To increase our menu of innovative tests faster and at a lower cost and risk than through internal development, in 2021 we established our Clinical Laboratory Innovation Accelerator, or CLIAx, which permits diagnostics start-up companies from around the world to launch their laboratory developed tests in our CLIA (Clinical Laboratory Improvement Amendments) licensed laboratory using shared equipment and laboratory personnel. To date, we have enrolled one company in our CLIAx, Minomics of Australia, and helped them validate and launch their blood test to help determine whether prostate specific antigen, or PSA, levels should be followed up with a biopsy. Our CLIAx, which we believe to be the first such shared CLIA

laboratory facility in the U.S., reduces the costs and expense for start-up companies to launch their novel tests in the American market while providing us with sales and marketing rights to additional products. In 2022, it earned an "Honorable Mention" in *Fast Company* magazine's list of "World Changing Ideas."

In response to the novel coronavirus pandemic that began in early 2020, we expanded our business and offered several COVID-19 testing solutions, both rapid kits and laboratory-based tests. In the third quarter of 2020, in response to substantial and urgent demand for expanded viral testing in Maryland, we also began to provide COVID-19 viral testing using polymerase chain reaction (PCR) analytical equipment in our clinical laboratory. This pandemic associated testing resulted in several years of profitability and forged business alliances that are being leveraged to support our core business.

Our legacy business also includes a pioneering field test kit for screening suspicious powders for bioterror agents known as BioCheck that is used regularly by hundreds of first responder organizations worldwide. Our BioCheck kits for screening suspicious powders remains profitable, but with limited growth potential. We are also working with IDenta of Israel to develop and validate a disposable device for testing whether illicit drugs like cocaine contain trace amounts of fentanyl.

Key Products

OneTest for Cancer—A Multi-Cancer Early Detection Blood Test

The survival rate for the deadliest cancers is closely linked to stage at time of diagnosis. With lung cancer, for example, some studies show a five-year survival rate approaching 90% for screen detected Stage 1 cancers (see Henschke, et al. "Survival of patient with Stage 1 Lung Cancer Detected on CT Screening," *N. Engl. J. Med*. 355 (2006)). That survival plummets to under 5% for cancers first diagnosed in Stage 4. For these reasons in certain regions of the world, especially East Asia, an aggressive cancer screening posture is commonplace. Tens of millions of individuals in Japan, Korea, China and Taiwan undertake 3-5 hour "health checks" each year that usually include blood tests for an array of cancers. Typically, these blood tests measure the levels of between three to eight tumor antigens, which are proteins secreted by tumors that can be detected using antibodies. Large scale observational studies by our collaborators in Taiwan using data from cancer registries demonstrate that these tests are useful for detecting even early-stage cancers (see Y.-H. We et al., "Cancer screening through a multi-analyte serum biomarker panel during health check-up examinations: Results from a 12-year experience," *Clinica Chemica Acta* 450 (2015)). However, using our patented methodology, this screening approach can be rendered significantly more accurate using machine learning algorithms that integrate the outcomes of tens of thousands of tested individuals together with clinical factors (e.g., age, gender, smoking history, etc.) with the biomarker levels (see "Improving Multi-Tumor Biomarker Health Check-up Tests with Machine Learning Algorithms," *Cancers,* 2020 Jun 1;12(6):1442).

OneTest is our MCED test and algorithm to screen for multiple cancer types from a single blood sample. OneTest is powered by our patented machine learning algorithms developed in the manner described above. Studies by our collaborators at the MD Anderson have found very little variability in the levels of these biomarkers across ethnicities and geographies. The algorithm combines the levels of protein biomarkers such as carcinoembryonic antigen, or CEA, alpha-fetoprotein, or AFP, PSA, and others, with patient information (e.g., age, gender, smoking history, etc.). We report the values of the biomarkers along with a proprietary score indicating the likelihood of being diagnosed with cancer within a year of the test date. The goal is to encourage those with the highest likelihood of having cancer to obtain follow-up imaging (ultrasound, CT, MRI, etc.) with the objective of finding early tumors that can be surgically removed or otherwise successfully treated before becoming fatal. Among the cancers for which OneTest screens, accuracies are strongest for those of the lung, liver, pancreas, and prostate. The foundation of this product is the measurement of a panel to tumor antigens—CEA, cancer antigen 125, Cyfra, AFP, cancer antigen 19.9, cancer antigen 15.3, and PSA.

In Asia, several hundred million individuals receive yearly blood tests for many of the tumor markers that are part of OneTest. These tests are typically private pay (i.e., not covered by health insurance) averaging about $100 per test, depending on the number of biomarkers measured. Our list price is currently $189 with discounts for volume and special offers. According to 2020 US Census Data, there are about 115 million Americans between the ages 45-75, the optimal ages for cancer screening. Thus, we estimate that OneTest addresses a market of over $15 billion in the U.S. alone based on our current list price.

In the U.S., our CLIA licensed clinical laboratory utilizes immunoassay detection kits and analyzers from Roche Diagnostics. For overseas customers, our algorithms have been optimized to accommodate data from the following kits and analyzers: Roche Diagnostics, Abbott Diagnostics, Siemens Healthcare and Beckman Coulter.

The OneTest Machine Learning Algorithm—A Unique and Patented Technical Approach

OneTest is built around the installed base of existing FDA approved tumor marker detection kits which run on automated instruments available from companies like Roche Diagnostics, Abbott Diagnostics, Siemens Diagnostics, and others. In the

U.S., approval for most of these kits, except PSA, is for monitoring of disease recurrence, not screening. These tests and instruments are used in thousands of clinical testing labs worldwide, thereby permitting us to obtain data from around the world. Throughout East Asia in particular millions of individuals have their tumor antigen levels tested each year at physical examination or health checkup centers. This has permitted us to develop machine learning algorithms based on historical outcome data from cancer registries that would otherwise require long and expensive prospective clinical trials if novel biomarkers are incorporated.

Evidence of our approach was first published in a respected oncology journal in May 2020 co-authored by several of our scientists ("Improving Multi-Tumor Biomarker Health Check-up Tests with Machine Learning Algorithms," *Cancers* 2020, *12*, 1442). Incorporation of changes to the levels of these biomarkers over time (a/k/a/ biomarker "trends" or "velocity") has also been shown in numerous studies to improve diagnostic accuracy and usefulness. An updated machine learning algorithm that we developed was published in March 2022 in "Long short-term memory model – A deep learning approach for medical data with irregularity in cancer predication with tumor markers" *Computers in Biology and Medicine* 144 (2022) 105362. This research was also presented as a poster at the 2021 Annual Meeting of the American Association for Clinical Chemistry where it won the First-Place award for industry submissions.

In short, our unique technical approach involves the following three elements: (i) obtain "real-world" data from tens of thousands of apparently healthy individuals (i.e. no apparent signs of symptoms of cancer when tested) who are screened for cancer using blood tests that are routine in certain parts of the world (e.g. East Asia), (ii) use this data to build machine learning algorithms that improve the accuracy of those tests by integrating cancer outcomes and clinical factors (age, gender, etc.), and (iii) introduce those tests and algorithms worldwide even in parts of the world where this testing approach is less common (e.g. North America) while examining variability across patient populations.

We have also successfully applied this unique methodology to develop machine learning algorithms that improve clinical lab tests for cardiovascular disease. To that end, on April 12, 2022, we entered a license agreement with IBM Watson Health to obtain lab test data from large numbers of Americans who had either a heart attack, cardiac arrest, or a stroke.

Artificial intelligence (AI) and machine learning are expected to transform healthcare by helping physicians diagnose and treat patients with greater accuracy and precision. As we continue to collect reliable outcome data (i.e., whether cancer was diagnosed) from individuals tested with the OneTest biomarkers (either from our customers or from research collaborators), our ability to leverage the latest and most powerful forms of machine learning will increase.

On April 4, 2023, U.S. Patent No. 11,621,080 titled "Methods and Machine Learning Systems for Predicting the Likelihood or Risk of Having Cancer" was issued to us. We believe that this patent is the first of several that will be issued in the U.S. and overseas that are directed to our novel approach of developing and using machine learning and prospective outcome data from thousands of previously tested persons to predict a newly tested individual's likelihood of having cancer.

MCED Research, Development and Product Improvements

Our plans are to introduce a "premium" version of OneTest, at a higher price point, together with the "basic" version that we are now providing. To that end, in August 2022, we executed a technology license and access agreement with Korean-based BioInfra Life Science, Inc., or BioInfra. BioInfra commercializes an MCED in Korea primarily based on the levels of tumor antigens, such as CEA, CA-125, etc. However, their panel also includes a number of inflammatory markers such as C-reactive protein, Transthyretin, Beta-2-Microglobulin, etc. that BioInfra has demonstrated to result in improved accuracy (see "Diagnostic value of combining tumor and inflammatory biomarkers in detecting common cancers in Korea," *Clinica Chimica Acta* 516 (2021) 169–178). In the first quarter of 2023, BioInfra conducted a real-world analysis of their test performance based on data from Korean governmental cancer registries. The test performance was excellent compared to standard screening modalities.

Under the terms of our agreement with BioInfra, we have the exclusive right to commercialize BioInfra's test panel and algorithm in the United States after paying the requisite fees and concluding bridging studies to validate those algorithms on a Western population. Our current plan is to introduce this OneTest Premium version in the second quarter of 2023.

Another promising source for improvements to our MCED may be our collaborators at MD Anderson. While our current option agreement with MD Anderson is directed to their stand-alone lung cancer panel, we have held informal discussions with them about future improvement to our MCED. The biomarkers, methodology and intellectual property associated with their lung cancer test panel overlaps with that of our MCED, but the MD Anderson team has access to one million blood specimens from individuals collected before any cancer diagnoses. This unique and extraordinary resource, coupled with the scientific and clinical acumen of MD Anderson's team, is expected to yield several important and novel biomarkers in the months and years to come that may function to improve the performance of the biomarkers measured in our current OneTest.

Our scientific and laboratory personnel are actively seeking to compare and validate test performance using capillary blood with that of venous blood. The requirement of engaging with a phlebotomist adds cost and burden to many of our consumers, especially those who purchase OneTest online. Since our test requires only a fraction of the blood typically collected through venipuncture, we believe the test can function comparatively with capillary blood collected from fingerstick or the upper arm. Fortunately, several new devices are entering the market to improve capillary collection. Obviating the need for phlebotomist should permit our test to be more easily accessed at pharmacy counters and even at home thereby increasing uptake and adoption.

In terms of establishing clinical utility (i.e., demonstrating a mortality benefit), the U.S. National Cancer Institute is planning to sponsor randomized clinical trials of various MCEDs as part of the White House "Cancer Moonshot" program. We have formally notified the U.S. National Cancer Institute of our willingness to participate in those trials which will likely span at least seven years.

Blood Test for the Early Detection of Lung Cancer

Lung cancer is the third most common cancer and the leading cause of cancer deaths among both men and women, according to the American Cancer Society. In January 2023, we executed an option agreement with MD Anderson for a lung cancer blood test developed by one of the world's leading experts in early cancer detection. This option can convert to an exclusive license if we meet certain mutually agreed milestones, including financing initiatives. The MD Anderson team led by Sam Hanash, MD, Ph.D. has received over $50 million in funding from federal and state governments as well as philanthropies in support of developing this test. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments*" for more information regarding this option agreement.

Validated using blood specimens from diverse, blinded cohorts comprising thousands of pre-symptomatic individuals, the blood test analyzes several of the same tumor antigens that are part of OneTest (CEA, CA-125, Cyfra) along with a novel biomarker (ProSurfactant B) discovered by members of that team. The main purpose of the test is to screen individuals with a history of tobacco use for their increased lung cancer risk.

Large scale clinical trials have proven that screening of those with a history of tobacco use using LDCT scans can reduce the death rate from lung cancer by 20% (see *N Engl. J Med* 2014; 371:1793-1802). Unfortunately, despite heavy promotion by the American Lung Association and others, fewer than 6% of Americans who meet the current guidelines for yearly scans (based on smoking history) comply and get a yearly scan, according to the National Cancer Institute. Our collaborators at MD Anderson believe that a blood test used to direct those with the highest risk to LDCT will substantially boost compliance and result in over 5,000 more lives saved per year over current screening paradigms.

The lung cancer test will be positioned both before and after LDCT screening. The pre-CT applications include screening of smokers and former smokers while post-CT the test will be used to help resolve ambiguous pulmonary nodules. The later will likely require a distribution agreement with a channel partner that employs a dedicated sales team calling on pulmonary medicine specialists as well as participation in trade shows such as the American Thoracic Society annual meeting.

The far larger lung cancer screening market will rely on many of the same sales and marketing strategies employed with OneTest, including large, self-insured employers and direct-to-consumer advertising. Prior to that, we are targeting large, self-insured employers in occupations like transportation, construction and manufacturing with large numbers of tobacco users in their workforce.

The MD Anderson developed test will expand the pool of those eligible to receive LDCT from 20 pack year smokers (i.e., those who smoked an average of a pack a day for 20 years) to 10 pack-year smokers. Eventually it may be utilized by never-smokers for which incidents of lung cancer have been on the rise.

We estimate that the market for the lung cancer test alone to be over $600 million by the year 2030. That projection is based on the following assumptions:

- According to data from the U.S. Department of Health & Human Services, Substance Abuse and Mental Health Services Administration, about 27 million Americans have smoked an average of one pack of cigarettes per day for 10 or more years (before becoming smoke free for 15 years) and would benefit from the MD Anderson developed blood test on a yearly basis.

- Based on an estimated annual uptake of PSA blood tests of 40%, we estimate that 20% of those 27 million eligible Americans will undertake yearly blood testing for lung cancer by 2030, or 5.4 million tests per year.

- At an average selling price of $119 per test per year, this creates an over $640 million annual revenue opportunity over the next 7 years.

Currently, no marketed tests are known to be addressing this market in a meaningful way. Accordingly, we have an opportunity for a first mover advantage.

Other Lab Tests for Early Disease Detection

We intend to introduce other lab tests to aid in the early detection or prevention of chronic diseases such as cardiovascular and neurological disorders. Our clinical lab can now run most of the routine tests (those ordered as part of a yearly check-up) and we are able to attract and acquire innovative tests through our CLIAx facility. Our strategy is to upsell additional wellness and screening tests to our OneTest customers, since only 20% of the quantity of blood we receive is required for the MCED tumor markers alone. The residual blood can be used to screen for other diseases.

Occupational health practices provide an especially attractive opportunity in this regard as they typically conduct thousands of blood draws per year. Since the amount of blood collected and shipped to our lab is more than five times the amount needed to run OneTest, the residual blood is more than ample to run dozens of other routine analytes such as lipid profiles, vitamins, glucose, metabolic panels, etc. Providing ancillary testing to our MCED and lung cancer test customers saves them time and helps us improve the economics of our operations. In short, we obtain more revenue for each dollar spent on marketing, selling, and shipping.

To make us an attractive choice for routine cardiovascular testing, we have developed a machine learning algorithm to predict the risk of cardiac arrest based on cholesterol values and other common cardiac markers. This OneTestforCardio is built with data from over 50,000 patient records procured from IBM Watson Health. We are also in discussions with other CLIA labs that specialize in heart disease related diagnostics.

The aforementioned CLIAx is expected to serve as a magnet for new test developers from around the world interested in launching their tests in the American market. This will help us increase our tests menu faster and with less expense than organic research and development.

COVID-19 Tests

In the third quarter of 2020, in response to substantial and urgent demand for expanded pandemic related testing in Maryland, we began to provide COVID-19 viral testing using polymerase chain reaction (PCR) analytical equipment in our clinical laboratory. Initially, most of our customers were nursing/assisted living facilities. In the first quarter of 2021, we began receiving and testing specimens under contract with and collected by the Montgomery Department of Health and Human Services. In August of 2021, we were one of five CLIA certified laboratories to be awarded a contract with the Maryland Department of Health to perform coronavirus screening at K-12 schools. Since then, we have collected and run PCR lab tests on over 138,000 specimens from over 80 public and private schools throughout the State of Maryland.

Profits from COVID-19 testing are being deployed to grow our core cancer diagnostics business. Additionally, some of the commercial partnerships we entered for COVID-19 testing are being extended for non-pandemic related testing.

Field Tests for Screening Suspicious Powders

We have a longstanding business that makes and sells a proprietary test kit for screening suspicious powders called BioCheck. These kits are widely used by fire departments and other emergency responders to quickly screen unknown suspicious powders for compounds such as ricin, anthrax, and other bioweapon agents and to identify false alarms in minutes at the site of a suspected bioterror threat. The powder screening kit works by quickly identifying the presence or absence of protein, a biomolecule found in all living materials. It therefore provides a rapid screen for the possible presence of multiple bioterrorism agents while ruling out most of the ordinary substances that citizens have frequently feared to be possible bio-agents of terror. Such ordinary substances include, for example, talc, ceiling tile dust, powdered sugar, etc., none of which are expected to contain detectable levels of protein.

We also have a North American distribution agreement with an Israeli based company called Identa that makes kits to screen for fentanyl and other illegal narcotics. That company is currently conducting studies to demonstrate the advantages of their kits over standard fentanyl test strips for which there is growing demand in response to the crisis of fentanyl overdoses.

Lab Facility

We operate a high-complexity CLIA licensed clinical laboratory facility where our lab tests are performed at our Gaithersburg facility. This clinical lab became accredited by the College of American Pathologists, or CAP, in 2022. Our CLIA lab is currently equipped with immunodiagnostic, clinic chemistry, and molecular (PCR) analyzers, extractors, and liquid handling robots. CAP and CLIA regulations establish standards for proficiency testing, facility administration, general laboratory systems, preanalytic, analytic, and postanalytic systems, personnel qualifications and responsibilities, quality control, quality assessment, and specific cytology provisions for labs performing moderate to high complexity tests. Our laboratory is inspected biennially as part of its ongoing certification under the CLIA.

In connection with our lease agreement for a new, larger facility in Gaithersburg Maryland, we have established what we believe to be the country's first accelerator facility specifically for diagnostics innovators worldwide seeking to launch novel diagnostic tests in a CLIA laboratory. Our CLIAx is expected to help drive growth for us over the next few years. We signed up our first CLIAx tenant in 2022 August, Minomics of Australia, which we helped to launch a novel blood test and algorithm to help predict prostate cancer following an abnormal PSA test. We seek co-marketing rights to all tests run out of our CLIAx. Our CLIAx received an Honorable Mention by Fast Company magazine as part of their 2022 "World Changing Ideas" competition.

Sales and Marketing Strategy

To date, our largest market segments for our MCED are (i) self-insured employers, especially those whose workers are believed to have higher cancer than normal incidences (e.g., firefighters), (ii) medical providers specializing in wellness and disease prevention and (iii) consumers who purchase on-line. Based on our sales in the first quarter of 2023, we estimate that the percentage of our sales from each of these three market segments for this year will be approximately 70%, 20% and 10% respectively.

We believe that the most reliable near-term market for our cancer tests in the U.S. is occupational health, and more specifically, organizations that employ or care for individuals with perceived high risk for cancers. One such occupation is firefighters. Studies by several research groups, including the National Institutes of Occupational Safety & Health, have proven that firefighters have increased incidence and mortality for several types of cancers, including those of the digestive, respiratory, and urinary tracts. Importantly, for many of these high incidence cancers (e.g. lung cancer and mesothelioma), the biomarkers that we measure have been shown to be elevated in numerous published studies (see "Exposure–response relationships for select cancer and non-cancer health outcomes in a cohort of US firefighters from San Francisco, Chicago and Philadelphia (1950–2009)", *Occup Environ Med* 2015;72:699–706.) Thus, OneTest has become a popular tool for cancer screening of current and former firefighters.

Penetration of this exceptionally large occupational health market will require significant business to business sales and marketing campaigns as well as direct-to-consumer campaigns that must be coupled with convenient access to phlebotomy services and telemedicine practitioners to provide guidance on the test and its results. Retail (walk-in) clinics such as urgent care centers and pharmacy chains present the best opportunities to grow the direct-to-consumer market for OneTest.

We currently have engagements in place with over 600 retail clinics located throughout the U.S., mostly urgent care centers, to conduct blood draws for OneTest and include over 200 locations of AnyLabTestNow. These clinics, coupled with a dedicated telemedicine service, have made it practical for us to initiate a direct-to-consumer campaign.

The lung cancer test, in particular, presents compelling opportunities outside of the U.S. as it includes an important biomarker (ProsurfactantB) previously unavailable. At this time, we are exploring opportunities of the lung cancer test with our strategic shareholder Ping An, which currently provides diagnostic testing services to over 200 million Chinese individuals through its Ping An Good Doctor program.

Competition

Because of the substantial unmet medical need worldwide, many companies (and associated academic entities) are actively seeking to develop and commercialize tests of various types to detect cancers early, when it can be treated most effectively. Current approaches include *in-vivo* radiographic imaging as well as *in-vitro* tests using diverse bodily tissues and fluids including blood (serum or whole blood), urine, saliva, stool, sputum, and exhaled breath.

In the U.S., we know of no MCED blood tests that large numbers of Americans routinely utilize. Furthermore, there do not appear to currently be any companies in the U.S. that have adopted our approach of testing a panel of tumor antigens together with a machine learning algorithm. However, there is significant and growing competition in the MCED space with most

tests using next-generation sequencing to analyze ctDNA. Most notably, Grail Inc., which was acquired by Illumina for $8 billion in 2020, introduced their Galleri test in the second quarter of 2021 at a price of $949. Additionally, Thrive, Inc. was acquired by Exact Sciences for $2 billion, but it is unclear when they plan to launch their test CancerSeek MCED. These tests may present both competitive threats but also opportunities for OneTest. The fact that our test measures well known biomarkers creates several important competitive advantages. Our test with a list price of under $200 could be followed up with more expensive ctDNA tests for those individuals with high biomarkers levels or a high algorithm score.

In East Asia, where such biomarker tests are commonly offered as part of annual health check-ups, we are unaware of any widely used algorithms of the type we have developed, namely an algorithm built with real-world data from a large screening population with known cancer outcomes. However, there are many emerging companies seeking to use "liquid biopsy" and "next-gen sequencing" for pan-cancer testing. Furthermore, many companies are actively utilizing AI and machine learning to improve health outcomes, and at least some of those companies are likely seeking to use these techniques to improve cancer screening blood tests.

Competitive Strengths

We believe the following competitive strengths should enable us to compete effectively in and capitalize on the growing demand for novel screening, prevention, and wellness testing, especially in the fast-growing MCED market.

- ***Our MCED test and anticipated lung cancer tests and algorithms are supported by data from pre-symptomatic patient populations and therefore should translate well into real-world screening populations***. The reported diagnostic accuracy of our tests—typically quantified as a function of clinical sensitivity and specificity—are generally comparable to those reported by our competitors. However, most of our competitors derive their accuracy numbers mainly from retrospective studies of blood specimens from newly diagnosed individuals ("case-control" studies). Accuracy reports from retrospective studies tend to be artificially higher than what occurs when the test is administered for real-world screening purposes when blood is collected before presentation of signs or symptoms of cancer. Most competing products were developed in a laboratory setting involving blood samples from individuals after they were presented with symptoms of cancer when it has often advanced to a later stage. We believe that the accuracies of tests developed using this "case/control" model consistently fail to hold up in real-world screening practice.

- ***Our tests are designed to be compatible with widely installed lab systems***. Our tests are designed to be compatible with standard instrument systems manufactured and distributed by companies such as Roche Diagnostics, Abbott Diagnostics, and Siemens Healthcare. We believe that this dramatically lowers the barriers to adoption by hundreds of clinical diagnostics laboratories worldwide. Furthermore, it helps to pave the way for new sources of "big data" from individuals tested worldwide using standardized test kits and instruments.

- ***Our tests are far more affordable than DNA based liquid biopsies***. We project that the average selling price of the basic version of our MCED (blood test plus algorithm) at scale to range from $125 to $165 (with bulk discounts provided to companies). In contrast, the list price for Grail's Galleri test at the start of 2023 was $949. It simply costs far less to run tumor antigen tests on automated platforms than next-generation sequencing.

- ***Our tests require small quantities of blood making them adaptable to capillary collection at pharmacies and in homes***. At the start of 2023, we demonstrated with a small pilot program that the biomarkers in our MCED can likely be analyzed with capillary collected blood in a manner generally comparable to venous collection by a phlebotomist. Several novel devices are expected to receive FDA approval this year to enable the requisite quantities of capillary blood to be collected from the finger and upper arm. It is unlikely that ctDNA can be measured with those small quantities of blood. This gives us a competitive advantage by permitting our tests to be offered at pharmacies where phlebotomists are generally unavailable.

- ***Our test reports include the absolute levels of the biomarkers and relative changes from prior reports***. Numerous reports in the scientific and medical literature conclude that tumor antigens such as CEA, CA-125, AFP, and PSA tend to rise in the months before diagnosis of lung, pancreas, ovarian, liver, and prostate cancers respectively. Thus, an important feature of our test report—which differs from that of our competitors with ctDNA based tests—is to include the levels of each biomarker tested and the change from prior test reports. We have found this to be desired data for both individuals getting our tests and their physicians. In contrast, Grail's Galleri test report simply indicates whether the patient is positive or negative for various cancers.

Potential Limitations of our Approach

As stated, there are compelling advantages to protein-based screening instead of ctDNA sequencing. While this approach may yield greater sensitivity, especially for earlier stage cancers, it will likely result in less specificity, as it is harder to localize high biomarker levels or risk scores to particular organs. Therefore, we believe that OneTest and the lung cancer test we expect to introduce are best positioned as "top of funnel" first screens that can be followed up with imaging tests and/or ctDNA based blood tests.

Growth Strategies and Path to Profitability

We will strive to increase shareholder value by pursuing the following growth strategies:

- ***Facilitate access to our tests at retail clinics and pharmacy counters***. COVID-19 testing caused a paradigm shift in the way Americans seek access to testing. Previously, most testing was done at doctor's offices and at specialty patient service centers maintained by the large national lab chains. During the pandemic, testing was conducted at retail establishments and at home. OneTest currently requires a venipuncture blood collection. For those consumers without easy access to a phlebotomist, we currently make available over 600 locations throughout the U.S. where they can have their specimen collected. About 400 of these venues are urgent care facilities and the balance locations of the company Any Lab Test Now. We also have a telemedicine provider available to authorize the test and be available to consult with the patient in the event of a high-risk score. Going forward, our plan is to validate OneTest using a novel capillary collection device so that we can substantially expand the number of testing locations to venues that do not employ phlebotomists, especially to pharmacies nationwide. In the first quarter of 2023, we entered into an agreement to provide COVID-19 PCR testing with Giant Foods, a prominent grocery chain in the Washington, D.C. metropolitan area. Discussions are underway with several other large grocery store chains who have an interest in our cancer tests.

- ***Strategic partnerships and cooperative advertising***. To facilitate scale while mitigating expenses, we have initiated an ambitious plan of marketing alliances and partnerships with an array of other companies, large and small, including suppliers, other clinical labs, and organizations that offer wellness and screening tests. In many cases we seek to introduce the cooperative advertising model where marketing expenses are shared pro-rata based on revenue allotments.

- ***Targeting of employers, especially in high-risk occupations***. Certain professions, such as firefighters, have proven higher incidence and mortality rates for multiple cancer types and are therefore actively looking for new, affordable early detection solutions. We have found these communities to be accessible and early adopters for OneTest.

- ***Expanding test menu***. We plan to offer our MCED consumers different versions of that test (basic and premium) as well as add-ons that address other routine disease conditions. The volume of venous blood collected can easily facilitate multiple tests.

- ***Leverage algorithm access to foreign markets***. Our tests and algorithms measure the levels of biomarkers that can be assayed using kits and instruments widely available in thousands of clinical laboratories worldwide. The proprietary algorithms will be separate from the testing service so there is virtually no limit on scalability, both in volume and geography. Because the specimens can be tested in a local lab, costly shipping can be avoided so specimens do not need to be sent out using expensive overnight shipping services. In the future, we expect our tests to become available at pharmacy chains and walk-in clinics that have on-site blood sample collection capabilities and trained healthcare practitioners to educate consumers.

- ***Direct-to-consumer outreach***. We have had some success to date with direct-to-consumer advertising using both digital platforms and conventional media. This approach has proven cost-effective, especially when repeat (yearly) testing is factored in. In many cases, individuals refer us to their employers or medical providers which multiples the revenues derived from these advertisements. While consumers often initiate the test purchase process, in all cases we require a medical provider to order the test and be available to consult the patient in the event of an abnormal test result.

Facilities

On March 18, 2021, we entered into a lease agreement for a new office and laboratory space totaling 5,511 square feet in Gaithersburg, Maryland. The term of the lease commenced on December 8, 2021 and expires 88 months thereafter. The initial

monthly rent is $14,315 with annual increases to $17,308 for the final year of the lease. We will also pay our 7.75% pro rata portion of the property taxes, operating expenses and insurance costs and are also responsible to pay for the utilities used on the premises.

We believe that all our properties have been adequately maintained, are generally in good condition, and are suitable and adequate for our business.

Intellectual Property

As of the date of this report, we have 4 granted patents and 12 pending applications in the U.S. and various other jurisdictions including Canada, China and Japan in cancer diagnostics and field tests for bio-detection. The earliest patents granted and pending have a projected expiry of 2032, with other patents expiring up through 2041. No assurance is made that any pending patent applications within the portfolio will result in a granted patent.

Additionally, pursuant to our option agreement with MD Anderson, if this option is exercised, we would have an exclusive license to several pending patent applications.

To protect our intellectual property, we rely on a combination of laws and regulations, as well as contractual restrictions. We rely on Federal patent laws to protect our intellectual property, including our patented technology. We also rely on the protection of laws regarding unregistered copyrights for certain content we create and trade secret laws to protect our proprietary technology. To further protect our intellectual property, we enter into confidentiality agreements with our executive officers and directors.

Employees

As of December 31, 2022, we had a total of 30 employees of which 17 were full-time and 13 were part-time.

We believe that we maintain a satisfactory working relationship with our employees, and we have not experienced any significant labor disputes or any difficulty in recruiting staff for our operations. None of our employees are represented by a labor union.

Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

Government Regulation

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws and regulations have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change.

Both United States federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the federal government will continue to scrutinize, among other things, the marketing, labeling, promotion, manufacturing, and export of diagnostic healthcare products. The federal government also has increased funding in recent years to fight healthcare fraud, and various agencies, such as the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and state Medicaid fraud control units, are coordinating their enforcement efforts.

FDA and CLIA

Based on widespread industry practice and confirmatory advice of regulatory counsel, we believe that our products do not require pre-market approval from the FDA. In the U.S., our current products are Laboratory Developed Tests, or LDTs, regulated under the CLIA and the Maryland Department of Health. If in the future we elect to license or distribute software as a service those products would likely be deemed to be Clinical Decisions Support Software, or CDSS. As explained below,

products in both of those categories do not require FDA pre-market approval but could become subject to the FDA's policy of "enforcement discretion."

Laboratory Developed Tests. LDTs are tests run in the laboratory of the company that developed them. With very rare exceptions, LDTs are not regulated by the FDA but rather under a different regulatory regime called CLIA (Clinical Laboratory Improvement Amendments), state law and regulations, and organizations such as CAP. Our laboratory is fully certified and compliant with CLIA as a "High Complexity Lab." Furthermore, as of 2022 our lab has been accredited by CAP.

Under current law there is no requirement for CLIA regulated LDTs to obtain approval or clearance from the FDA prior to being marketed (outside the context of tests used in response to a declared pandemic emergency under which the FDA has been given special statutory authorities). In November 2016, the FDA issued a formal statement clarifying that LDTs can be marketed without pre-market approval, but that the agency maintains "enforcement discretion" to require their approval for those LDTs that are marketed in a way that is unsafe or could mislead or cause harm to patients. Since November 2016, such enforcement discretion has been exercised very rarely, and when it has been exercised, the tests were not ordered by independent medical professionals. To reduce the likelihood that our tests will face enforcement discretion by the FDA, we request that our tests be ordered by a physician who is independent of our company and that the physician aid the patient/consumer in interpreting the test results.

In March 2023, a senior FDA official announced at a lab industry meeting that the agency is advancing plans to regulate LDTs through the formal Notice and Comment rulemaking process. Most experts believe that such a rulemaking process, if initiated, would take 3-5 years to complete. Furthermore, the FDA's legal authority to regulate LDT's without express statutory authority has been questioned by some legal experts.

A bill was introduced in the 117th Congress which ended in December 2022 called "the VALID Act" that would for the first-time mandate FDA pre-market approval of LDTs. That legislation generated significant opposition from stakeholders and failed to pass. In March 2023, the VALID Act bill was re-introduced in the 118th Congress. The likelihood of passage of this bill cannot be predicted at this time. In the event of passage, the VALID Act includes a "Grandfather clause" permitting tests on the market before passage of the law to remain so without FDA approval.

CDSS. On December 13, 2016, the 21st Century Cures Act was signed into law. Among the many provisions of the Cures Act was the exclusion of certain medical decision support software from the FDA's jurisdiction. On December 8, 2017, the FDA issued its first set of Draft Guidance to implement those provisions of the Cures Act relating to CDSS. Based on our reading of this Draft Guidance, we believe that there may be aspects of our current or planned OneTest software package that would be exempt from pre-market approval. If we elect to proceed with an independent software product in the U.S. (as we will likely do overseas), outside laboratories could run the OneTest biomarker panels (all of the detection instruments and kits are FDA approved).

Operating under the assumption that seeking FDA approval for our products is optional, but that approval could improve the adoption rates and permit greater scale, we may seek FDA approval when test volume exceeds the capacity of our CLIA laboratory. In so doing, we will present to the FDA real-world evidence, data from tens of thousands of individuals tested with our products in the U.S. and overseas. On August 31, 2017, the FDA issued Guidance on the "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices." The Guidance provides that "in some cases, a 'traditional' clinical trial may be impractical or excessively challenging to conduct" and that use of real-world data "may in some cases provide similar information with comparable or even superior characteristics to information collected and analyzed through a traditional clinical trial."

Federal and State Fraud and Abuse Laws

We are subject to federal fraud and abuse laws such as the federal Anti-Kickback Statute, or AKS, the federal prohibition against physician self-referral, commonly known as the Stark Law, the Eliminating Kickbacks in Recovery Act, or EKRA, and the federal False Claims Act, or the FCA. We are also subject to similar state and foreign fraud and abuse laws.

The AKS prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any item or service that may be reimbursable, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. There are a number of statutory exceptions and regulatory safe harbors to the AKS that provide protection from AKS liability to arrangements that fully satisfy the applicable requirements.

EKRA prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of certain entities, including laboratories, if the services are covered by a health care benefit program. The term "health care benefit program" is broadly defined such that EKRA extends to referrals reimbursed by both governmental and commercial third-party payers. EKRA includes a number of statutory exceptions that provide protection from EKRA liability if the applicable requirements are met.

The Stark Law generally prohibits, among other things, clinical laboratories and other so-called "designated health services" entities from billing Medicare for any designated health services when the physician ordering the service, or any member of such physician's immediate family, has a financial relationship, such as a direct or indirect investment interest in or compensation arrangement with the billing entity, unless the arrangement meets an exception to the prohibition. The Stark Law also prohibits physicians from making such referrals to a designated health services entity. There are also similar state laws that apply where Medicaid and/or commercial payers are billed.

The FCA imposes penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment to the government that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute also permits a private individual acting as a "qui tam" whistleblower to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $13,508 to $27,018 per false claim or statement for penalties assessed after January 30, 2023, with respect to violations occurring after November 2, 2015.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payer knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular provider, practitioner, or supplier, and contracting with an individual or entity that the person knows or should know is excluded from participation in a federal health care program. In addition, federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition to these federal laws, there are often similar state anti-kickback and false claims laws that typically apply to arrangements involving reimbursement by a state-funded Medicaid or other health care program. Often, these laws closely follow the language of their federal law counterparts, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payers, including commercial payers.

A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other healthcare providers, and, in some states, marketing expenditures. In addition, some state statutes impose outright bans on certain manufacturer gifts to physicians or other health care professionals. Some of these laws, referred to as "aggregate spend" or "gift" laws, carry substantial fines if they are violated.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs and extensive annual trainings for all of our employees and contractors. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Anti-Corruption

The Foreign Corrupt Practices Act of 1977, or the FCPA, and similar international bribery laws make it unlawful for persons or entities to make payments to foreign government officials to assist in obtaining and maintaining business. Specifically, the

anti-bribery provisions of the FCPA prohibit any offer, payment, promise to pay, or authorizing the payment of money or anything of value to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to a foreign official to do or omit to do an act in violation of his or her duty, or to secure any improper advantage in order to assist in obtaining or retaining business for or with, or directing business, to any person. In addition to the anti-bribery provisions of the FCPA, the statute also contains accounting requirements designed to operate in tandem with the anti-bribery provisions. Covered companies are required to make and keep books and records that accurately and fairly reflect the transactions of the company and devise and maintain an adequate system of internal accounting controls. With our international operations through our third-party partnerships, we could incur significant fines and penalties, as well as criminal liability, if we fail to comply with either the anti-bribery or accounting requirements of the FCPA, or similar international bribery laws. Even an unsuccessful challenge of our compliance with these laws could cause us to incur adverse publicity and significant legal and related costs.

Privacy and Data Protection Laws

Numerous federal and state laws and regulations, including HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, govern the collection, dissemination, security, use and confidentiality of protected health information, or PHI, and personal information. In the course of performing our business we obtain personal information, including PHI. Laws and regulations relating to privacy, data protection, and consumer protection are evolving and, in some cases, particularly with regard to newer laws, may be subject to potentially differing interpretations. Under HIPAA and HITECH, the Department of Health & Human Services, or the HHS, issues regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and requirements for protecting the privacy and security of PHI, used or disclosed by covered entities, or CEs, and their authorized business associates, or BAs. Because we electronically transmit health care information, and we also provide certain services to CEs and receive PHI from them, we are at times either a CE or a BA, as defined by HIPAA. Our subcontractors that create, receive, maintain, transmit or otherwise process PHI on our behalf are HIPAA BAs and must also comply with HIPAA, as applicable.

HIPAA and HITECH include the privacy and security rules, breach notification requirements and electronic transaction standards. The privacy rule governs the use and disclosure of PHI, generally prohibits the use or disclosure of PHI except as permitted under the rule, and mandates certain safeguards to protect the privacy of PHI. The privacy rule also sets forth individual rights, such as the right to access or amend certain records containing such individual's PHI, or to request restrictions on the use or disclosure of such individual's PHI. The security rule requires CEs and BAs to safeguard the confidentiality, integrity, and availability of electronically transmitted or stored PHI (also referred to as ePHI) by implementing administrative, physical and technical safeguards. Under HIPAA's breach notification rule, a CE must notify individuals, the Secretary of HHS, and in some circumstances, the media of certain breaches of unsecured PHI or ePHI, and similar breach notification provisions apply to certain BAs under HITECH.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary depending on the number and nature of the violations and any history of prior violations, but can be significant and include civil monetary or criminal penalties. HIPAA is enforced by the HHS, Office for Civil Rights, and HIPAA also authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in improper use, access to or disclosure of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA CEs, such as us, and their BAs for compliance with the HIPAA privacy and security standards and breach notification rules. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

In addition, we may be subject to state privacy, cybersecurity, and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. California, for example, has enacted the Confidentiality of Medical Information Act, which, in addition to HIPAA and HITECH, sets forth standards with which all California health care providers must abide. Colorado has enacted the Colorado Privacy Act, and Virginia has enacted the Consumer Data Protection Act, both of which also have standards that must be complied with that supplement Federal data protection requirements. State laws may be more stringent, broader in scope or offer greater individual rights with respect to PHI than HIPAA, and state laws may differ from each other in regards to personal information treatment, which may complicate compliance efforts. For instance, the California Consumer Privacy Act, or CCPA, became effective on January 1, 2020 and was amended by the passage of the California Privacy Rights Act, or CPRA, in November of 2020, which amendments came into force on January 1, 2023. The CCPA, among other things, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to

California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. Although there are certain exemptions for PHI and clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future and the CCPA may increase our compliance costs and potential liability. Additionally, the CPRA imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency – the California Privacy Protection Agency – specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. Similar laws have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that could continue to make compliance challenging and costly.

Additionally, the Federal Trade Commission, or the FTC, and state attorneys general enforce consumer protection laws that prohibit unfair and deceptive acts and practices, including Section 5 of the FTC Act, which creates standards for the collection, use, dissemination and security of health-related and other personal information. Claims of unfair or deceptive trade practices regarding privacy and security can lead to significant liabilities and consequences, including regulatory investigations, penalties, fines and orders as well as civil claims, which could impact our data practices and operations or cause reputational damage.

We may also be subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may add additional compliance burden and complexity. For example, in the European Economic Area, the collection and use of personal data is governed by the European Union's General Data Protection Regulation, or the GDPR. In the United Kingdom, the GDPR has been adopted in substantially the same form, however the UK may potentially make revisions in the coming years. The GDPR, together with national legislation, regulations and guidelines of the European Union member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze, store, transfer and otherwise process personal data. European and United Kingdom data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which adds to the complexity of processing personal data in or from the European Economic Area or United Kingdom. Guidance on implementation and compliance practices is often updated or otherwise revised. The GDPR applies extra-territorially under certain circumstances and imposes stringent requirements on controllers and processors of personal data, including, for example, requirements to ensure a legal bases to process personal information, provide robust disclosures to individuals, facilitate data subject rights, provide data security breach notifications within 72 hours after discovering a breach in certain circumstances, limit retention of personal information and apply enhanced protections to health data and other categories of sensitive personal information. The GDPR also has requirements around international transfers of personal data. Requirements around transfers to the United States and other jurisdictions have increased since a July 2020 decision by the Court of Justice of the European Union invalidated the Privacy Shield as a basis to transfer personal data from Europe to the United States, and added requirements for reliance on Standard Contractual Clauses. Regulatory guidance on requirements for international transfers, and other GDPR compliance matters, continues to evolve. For example, the European Commission in December 2022 announced that it was beginning the process of drafting a new adequacy decision that would ease regulatory barriers for data transfers to the United States. However, it is widely expected that the new adequacy decision will itself face scrutiny from the Court of Justice, underscoring that GDPR compliance is an ongoing endeavor. Failure to comply with the requirements of the GDPR may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties. To comply with the GDPR and other applicable international data protection laws and regulations, we may be required to put in place additional mechanisms ensuring compliance, which may result in other substantial expenditures.

Cybersecurity

Our business relies on secure and continuous processing of information and the availability of our IT networks and IT resources, as well as critical IT vendors that support our technology, research and other data processing operations. While we take steps to protect our systems and data, security incidents, data breaches, computer malware and computer hacking attacks have become more prevalent across industries, including the life sciences sector, and may occur on our systems or those of our third-party service providers. Unauthorized persons may in the future be able to exploit weaknesses in the security systems of our (or our third-party service providers) IT networks and gain access to PHI and other personal information, sensitive trade secrets, or other proprietary information. Any wrongful use or disclosure of PHI, other personal information, trade secrets or other proprietary information by us or our third-party service providers could subject us to regulatory fines or penalties, third-party claims or otherwise could adversely affect our business and results of operations. Although HIPAA and the regulations promulgated thereunder do not provide for a private right of action, failures to adequately protect PHI or our

IT systems could be viewed as violations of the HIPAA security rule or violations of other applicable information security laws, regulations, contractual obligations or industry standards, and could further result in costly data breach notification obligations that negatively impact our reputation.

Moreover, data security incidents or data breaches, as well as attacks on our IT systems, could result in operational disruptions or data loss or corruption that could adversely impact our business and operations, resulting in substantial investment of resources to investigate, recover and remediate and subject us to heightened regulatory scrutiny.

International Regulations

Many countries in which we may offer any of our diagnostic tests in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national health care program. In situations involving physicians employed by state-funded institutions or national health care agencies, violation of the local anti-kickback law may also constitute a violation of the FCPA.

The FCPA prohibits any United States individual, business entity or employee of a United States business entity to offer or provide, directly or through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign government official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. In addition, it is illegal for a company that reports to the SEC to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We will also be required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions and its anti-bribery provisions.

The standard of intent and knowledge in anti-bribery cases is minimal. Intent and knowledge are usually inferred from that fact that bribery took place. The accounting provisions do not require intent. Violations of the FCPA's anti-bribery provisions for corporations and other business entities are subject to a fine of up to $2 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to $100,000 and imprisonment for up to five years. Other countries, including the United Kingdom and other OECD Anti-Bribery Convention members, have similar anti-corruption regulations, such as the United Kingdom Anti-Bribery Act.

When marketing our diagnostic tests outside of the United States, we may be subject to foreign regulatory requirements governing human clinical testing, prohibitions on the import of tissue necessary for us to perform our diagnostic tests or restrictions on the export of tissue imposed by countries outside of the United States or the import of tissue into the United States, and marketing approval. These requirements vary by jurisdiction, differ from those in the United States and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

Market access, sales and marketing of medical devices in non-U.S. countries are subject to foreign regulatory requirements that vary widely from country to country. For example, in the European Economic Area, a medical device must meet the Medical Devices Directive's/In Vitro Medical Devices Directive's, or MDD/IVDD, Essential Requirements or, applicable on May 26, 2021, the Medical Devices Regulation's, or MDR, or applicable on May 26, 2022, In Vitro Medical Devices Regulation's, or IVDR, General Safety and Performance Requirements which apply to it, taking into account its intended purpose as defined by the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation. Before placing a medical device on the European Economic Area market, the manufacturer must draw up a declaration of conformity, certifying that the device complies with the MDD/IVDD/MDR/IVDR, and must then affix the CE mark. For medium and high-risk devices as well as low risk devices that are placed on the market in sterile condition, have a measuring function, or are reusable surgical instruments, the manufacturer must obtain a CE certificate from a notified body. The notified body typically audits and examines the device's technical documentation, including the clinical evaluation, and the quality system for the manufacture, design and final inspection of the relevant device before issuing a CE certificate. Following the issuance of this CE certificate, manufacturers may draw up the declaration of conformity and affix the CE mark to the devices covered by this CE certificate.

Manufacturers of medical devices must document in a clinical evaluation report, or CER, the evaluation of the clinical data related to the device. The CER is part of the device's technical file. The evaluation shall document that the applicable Essential Requirements/General Safety and Performance Requirements are met and document the evaluation of the undesirable side-effects and the acceptability of the benefit-risk ratio. The CER must be updated based on information from the post-market surveillance and vigilance activities related to the device. The CER shall consist, *inter alia*, of analyzed clinical data collected from a clinical investigation of the device, or the results of other studies on substantially equivalent devices. Reliance on

"substantially equivalent" devices is very restrictive and requires, *inter alia*, that the manufacturer has full access to the technical documentation of the equivalent device on an ongoing basis and, if the "equivalent device" is not its own, that the manufacture has in place a contract with the manufacturer of the "equivalent device."

Environmental, Health and Safety Regulations

We are subject to various federal, state, local, and foreign environmental, health and safety laws and regulations and permitting and licensing requirements. Such laws include those governing laboratory practices, the generation, storage, use, manufacture, handling, transportation, treatment, remediation, release and disposal of, and exposure to, hazardous materials and wastes and worker health and safety. Our operations involve the generation, use, storage and disposal of hazardous materials, and the risk of injury, contamination or non-compliance with environmental, health and safety laws and regulations or permitting or licensing requirements cannot be eliminated. Compliance with environmental laws and regulations has not had a material effect on our capital expenditures, earning or competitive position.

Corporate History

We were incorporated in the State of Delaware on August 7, 2000 under the name 20/20 BioSystems, Inc. On September 19, 2000, our name was changed to 20/20 Gene Systems, Inc. and on June 27, 2021, our name was changed to 20/20 GeneSystems, Inc. We do not have any subsidiaries.

RISK FACTORS

Investing in our securities involves a significant degree of risk. In evaluating our company and an investment in our securities, careful consideration should be given to the following risk factors, in addition to the other information included in this report. Each of these risk factors could materially adversely affect our business, operating results or financial condition, as well as adversely affect the value of an investment in our securities. The following is a summary of the most significant factors. We are still subject to all the same risks that all companies in our industry, and all companies in the economy, are exposed to. These include risks relating to economic downturns, political and economic events and technological developments (such as cyber-security). Additionally, early-stage companies are inherently riskier than more developed companies. You should consider general risks as well as specific risks when deciding whether to invest.

Risks Related to Our Business and Industry

Prior to the establishment of our COVID-19 testing business, we incurred losses, and expect to continue to generate losses now that COVID-19 testing has declined substantially.

While we achieved profitability in 2021 and 2022, such profitability was mainly a result of COVID-19 testing, which has substantially declined in the first quarter of 2023 and might discontinue in the second half 2023. Prior to 2021, we incurred losses since inception. We have financed our operations through the sale of our securities, product revenues and government research grants and contracts. There is no assurance that we will be able to obtain adequate financing that we may need, or that any such financing that may become available will be on terms that are favorable to us and our stockholders. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing our diagnostic tests and technology. Any failure to do so could result in the possible closure of our business or force us to seek additional capital through loans or additional sales of our equity securities to continue business operations, which could dilute the value of any securities you hold, or could result in the loss of your entire investment.

Now that the pandemic emergency has ended, our success will depend heavily on our cancer screening tests.

Beginning in the second half of 2023, the bulk of our revenues will depend almost entirely on the commercial success of our cancer tests unless we can also develop or acquire new tests to other diseases or chronic conditions. The commercial success and our ability to generate revenues will depend on a variety of factors, including the following:

- competitive advantages
- patient acceptance of and demand for our tests;
- acceptance in the medical community;
- successful sales, marketing, and educational programs, including successful direct-to-patient marketing such as online advertising;

- the amount and nature of competition from other multi- cancer screening products and procedures;
- the ease of use of our ordering process for physicians;
- maintaining and defending patent protection of our intellectual property; and
- our ability to establish and maintain adequate commercial manufacturing, distribution, sales and CLIA laboratory testing capabilities.

If we are unable to develop and maintain substantial sales of our tests or if we are significantly delayed or limited in doing so, our business prospects, financial condition and results of operation will be adversely affected.

We will need to attract additional capital to scale our business but have no assurance that we can do so successfully.

We will be incurring significant sales and marketing costs as we commercialize our diagnostic test products. We will need to raise additional capital to pay operating expenses until we are able to generate sufficient revenues from diagnostic test sales, royalties, and license fees, and we will need to sell additional equity or debt securities to meet those capital needs. Our ability to raise additional equity or debt capital will depend not only on progress made marketing and selling our diagnostic tests, but also will depend on access to capital and conditions in the capital markets. There is no assurance that we will be able to raise capital at times and in amounts needed to finance the development and commercialization of our diagnostic tests, maintenance of our CLIA certified diagnostic laboratory, and general operations. Even if capital is available, it may not be available on terms that we or our stockholders would consider favorable. Furthermore, sales of additional equity securities could result in the dilution of the interests of our stockholders.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank Corp., or Signature, and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder.

Although we do not have any funds deposited with SVB, Signature Bank or any financial institution currently in receivership, we regularly maintain cash balances with other financial institutions in excess of the FDIC insurance limit. A failure of a depository institution to return deposits could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. Furthermore, if any of our partners, suppliers or other parties with whom we conduct business are unable to access funds with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to credit agreements and arrangements with these financial institutions, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of these financial institutions and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program.

Our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, any financial institutions with

which we enter into credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These risks include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- inability to enter into credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses or other obligations, financial or otherwise, result in breaches of our financial and/or contractual obligations, or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our partners, vendors or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a partner may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a vendor or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. The bankruptcy or insolvency of any partner, vendor or supplier, or the failure of any partner to make payments when due, or any breach or default by a partner, vendor or supplier, or the loss of any significant supplier relationships, could cause us to suffer material losses and may have a material adverse impact on our business.

We will spend a substantial amount of our capital on test validation, biomarker and data acquisitions, data analytics and algorithm development, but our products might not succeed in gaining widespread market acceptance.

We have developed and will continually refine new biomarker test panels and associated algorithms. The main focus of these products is on early detection of cancer. Our technologies may not prove to be sufficiently efficacious or medically useful to gain widespread adoption or market share. The diagnostics tests and software that we have introduced to the market to date and have not yet generated significant revenues. Without diagnostic test sales or licensing fee revenues, we will not be able to operate at a profit, and we will not be able to cover our operating expenses without raising additional capital.

Medical organizations, physicians and employers may be reluctant to try a new diagnostic test due to the high degree of risk associated with the application of new technologies and diagnostic tests in the field of human medicine, especially if the new test differs from the current standard of care for detecting cancer in patients. Competing tests for the screening or initial diagnosis of cancer are being developed by more established and significantly better financed diagnostics or biotech companies, and academic laboratories.

There also is a risk that our competitors may succeed in developing more accurate or more cost-effective diagnostic tests that could render our diagnostic tests and technologies obsolete or noncompetitive. Even if our tests are technically superior, we may not be able to differentiate our products sufficiently from our competition.

The success of our diagnostic tests depends on the degree of market acceptance by physicians, patients, government agencies others who influence medical decision making.

The value of our diagnostic products is thus far proven mainly with real world evidence, rather than traditional clinical trials; and there is no assurance that real world evidence will gain wide acceptance by the medical establishment or regulators in the countries in which we conduct business. Also, there is no assurance that data derived from East Asia will be accepted in Western nations and generating data from Western populations could be time consuming and expensive. The value of machine learning and artificial intelligence in our algorithms is novel, not entirely proven, and might not be widely embraced by the medical establishment or regulators in the countries in which we conduct business.

Our diagnostics tests may not gain market acceptance by physicians and others in the medical community. The degree of market acceptance of our tests will depend on a number of factors, including:

- demonstrated sensitivity and specificity for detecting cancers;
- price;
- the availability and attractiveness of alternative screening methods;
- the willingness of physicians to recommend or prescribe our tests;
- the ease of use of our ordering process for physicians; and

- evidence that our tests confer a mortality benefit rather than merely shifting the stage of cancer at time of diagnosis.

If our diagnostics tests do not achieve an adequate level of acceptance, we may not generate the substantial revenues we need to generate to remain profitable.

We are expecting patient self-pay to constitute a significant portion of our revenues for the foreseeable future, and our revenues could decline if individuals fail to provide timely and adequate payment for our diagnostic tests and algorithms.

We expect that a substantial portion of the patients for whom we will perform diagnostic tests will have Medicare as their primary medical insurance. Medicare coverage is not expected for several years. Even if our planned tests are otherwise successful, reimbursement for the Medicare-covered portions of our planned tests might not, without Medicare reimbursement, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

Private health insurance company policies may deny coverage or limit the amount they will reimburse us for the performance of our diagnostic tests.

Patients who are not covered by Medicare will generally rely on health insurance provided by private health insurance companies. If we are considered a "non-contracted provider" by a third-party payer, that payer may not reimburse patients for diagnostic tests performed by us or doctors within the payer's network of covered physicians may not use our services to perform diagnostic tests for their patients. As a result, we may need to enter into contracts with health insurance companies or other private payers to provide diagnostic tests to their insured patients at specified rates of reimbursement which may be lower than the rates we might otherwise collect.

We face substantial competition.

The development and commercialization of diagnostics tests, especially MCEDs, is highly competitive and subject to rapid technological advances. We face competition with respect to our current products and any product candidates we may seek to develop or commercialize in the future. Our competitors may develop comparable tests that are safer, more effective, more convenient or less costly than any products that we may develop or market or may obtain marketing approval for their products from the FDA, or equivalent foreign regulatory bodies more rapidly than we may obtain approval for our product candidates. Our competitors may devote greater resources to market or sell their tests, research and development capabilities, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully, or more effectively negotiate third-party licensing and collaborative arrangements. As a result, physicians and other key healthcare decision makers may choose other products over our products, switch from our products to new products or choose to use our products only in limited circumstances, which could adversely affect our business, financial condition, and results of operations.

If our diagnostics tests do not perform as expected, are misused or misinterpreted, or the reliability of the technology is questioned, we could experience delayed or reduced market acceptance of the tests, increased costs and damage to our reputation. False positives or false negatives could cause harm to patients and could result in action taken against our company.

Our success depends on the market's confidence that we can provide a reliable, high-quality diagnostic tests. We believe that customers are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our diagnostic tests may be impaired if they fail to perform as expected or are perceived as difficult to use. Despite clinical verification studies, quality control and quality assurance testing, defects or errors could occur with tests.

In the future, if our diagnostic tests experience a material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could harm our business. Such defects or errors could also prompt us to amend certain warning labels or narrow the scope of the use of our diagnostic tests, either of which could hinder our success in the market. Even after any underlying concerns or problems are resolved, any widespread concerns regarding our technology or any manufacturing defects or performance errors in the test could result in lost revenue, delayed market acceptance, damaged reputation, increased service and warranty costs and claims against us.

Our inability to manage growth could harm our business.

We have added, and expect to continue to add, additional personnel in the areas of sales and marketing, laboratory operations, billing and collections, quality assurance and compliance. As we build our commercialization efforts and expand research and development activities, the scope and complexity of our operations is increasing significantly. As a result of our growth, our operating expenses and capital requirements have also increased, and we expect that they will continue to increase, significantly. Our ability to manage our growth effectively requires us to forecast expenses accurately, and to properly forecast and expand operational and testing facilities, if necessary, to expend funds to improve our operational, financial and management controls, reporting systems and procedures. As we move forward in commercializing our tests, we will also need to effectively manage our growing manufacturing, laboratory operations and sales and marketing needs. If we are unable to manage our anticipated growth effectively, our business could be harmed.

We currently manufacture our tests predominantly in one facility and perform our testing in one laboratory facility. As demand for our tests grow, we may lack adequate facility space and capabilities to meet increased processing requirements. Moreover, if these or any future facilities or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently perform testing in a single laboratory facility in Gaithersburg, Maryland. Our headquarters and manufacturing facilities are also located in Maryland.

As we expand sales and increase the number of tests processed by our laboratory facility, we may need to expand or modify our existing laboratory facility or acquire new laboratory facilities to increase our processing capacity. Any failure to do so on terms acceptable to us, if at all, may significantly delay our processing times and capabilities, which may adversely affect our business, financial condition, and results of operation.

If these, or any future facilities, were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, other inclement weather events or natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, our business could be severely disrupted. If our laboratory is disrupted, we may not be able to perform testing or generate test reports as promptly as patients and healthcare providers require or expect, or possibly not at all. If we are unable to perform testing or generate test reports within a timeframe that meets patient and healthcare provider expectations, our business, financial results, and reputation could be materially harmed.

We currently maintain insurance against damage to our property and equipment and against business interruption and research and development restoration expenses, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

There are a limited number of manufacturers of molecular diagnostic equipment and related chemical reagents necessary for the provision of our diagnostic tests.

The test panels and algorithms that we have developed and will continue to develop rely on certain analytic equipment. There are only a few manufacturers of the equipment we will need and the chemical reagents that are required for use with a

particular manufacturer's equipment will be available only from that equipment manufacturer. If the manufacturer of the equipment we acquire discontinues operation or if we and other testing laboratories experience supply or quality issues with their equipment or reagents, it may become necessary for us to adjust our products for different analytic equipment, which would require additional experiments to ensure reproducibility of our test results using the new equipment. As a result, we may be unable to provide our diagnostic products for a period of time.

Our suppliers may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacturing of our diagnostic tests that could result in delays or shortfalls in production. Suppliers may also face similar delays or shortfalls. In addition, suppliers' production processes may have to change to accommodate any significant future expansion of manufacturing capacity, which may increase suppliers' manufacturing costs, delay production of diagnostic tests, reduce our product gross margin and adversely impact our business. If we are unable to keep up with demand for tests by successfully securing supply and shipping our diagnostic tests in a timely manner, our revenue could be impaired, market acceptance for the tests could be adversely affected and our customers might instead purchase our competitors' diagnostic tests.

To achieve widespread use of our diagnostic test and commercial scale, individual consumers will need convenient access to blood draw services, but we cannot guarantee that these service providers will be willing to perform them.

Currently our cancer tests require venous blood collected by a licensed phlebotomist. While our business customers, such as employers, typically have little difficulty finding phlebotomists, this can be a challenge for many of our individual consumers. To address this need, we have about 600 retail establishments that can draw blood for our test customers. These establishments perform these services based on contracts we have with the companies Any Lab Test Now and My One Medical Source. If those contracts were to terminate or expire or if they are unable to maintain their franchisees or networks of clinics willing to draw blood, this could limit our ability to serve our customers and to grow.

We have limited sales and marketing resources and few distribution resources for the commercialization of any diagnostic tests that we have developed.

We currently have limited sales and marketing resources. If we are successful in developing marketable diagnostic tests, we will need to build our own marketing and sales capability, which would require the investment of significant financial and management resources to recruit, train, and manage a sales force.

The sizes of the markets for our diagnostic tests and services and any future diagnostic tests and services may be smaller than we estimate and may decline.

Our estimates of the annual total addressable market for our diagnostic tests and services are based on a number of internal and third-party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our diagnostic tests and services in the market. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our diagnostic tests and services in different market segments may prove to be incorrect. If the actual number of patients who would benefit from our diagnostic tests, the price at which we can sell them or the annual total addressable market for them is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

If we fail to enter into and maintain successful strategic alliances for diagnostic tests that we elect to co-develop, co-market, or out-license, we may have to reduce or delay our diagnostic test development or increase our expenditures.

To facilitate the development, manufacture, and commercialization of our diagnostic tests we may enter into strategic alliances with hospitals and biomedical research institutes, biotechnology and diagnostics companies, clinical testing reference laboratories, and marketing firms in many of the countries in which we do business. We will face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our product development or research programs, or we may have to increase our expenditures and may need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

In some countries we may license marketing rights to diagnostics or clinical laboratory companies or to a joint venture company formed with those companies. Under such arrangements we might receive only a royalty on sales of the diagnostic

tests developed or an equity interest in a joint venture company that develops the diagnostic test. As a result, our revenues from the sale of those diagnostic tests may be substantially less than the amount of revenues and gross profits that we might receive if we were to market and run the diagnostic tests ourselves.

We may become dependent on possible future collaborations to develop and commercialize many of our diagnostic test candidates and to provide the manufacturing, regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.

We may enter into various kinds of collaborative research and development, manufacturing, and diagnostic test marketing agreements to develop and commercialize our diagnostic tests. There is a risk that we could become dependent upon one or more collaborative arrangements. A collaborative arrangement, upon which we might depend might be terminated by our collaboration partner or they might determine not to actively pursue the co-development of our diagnostic tests. A collaboration partner also may not be precluded from independently pursuing competing diagnostic tests or technologies.

The success of our business is substantially dependent upon the efforts of our senior management team and our ability to attract additional personnel.

Our success depends largely on the skills, experience, and performance of key members of our senior management team who are critical to directing and managing our growth and development in the future. Our success is substantially dependent upon our senior management's ability to lead our company, implement successful corporate strategies and initiatives, develop key relationships, including relationships with collaborators and business partners, and successfully commercialize products and services. While our management team has significant experience developing diagnostic products, we have considerably less experience in commercializing these products or services. The efforts of our management team will be critical to us as we develop our technologies and seek to commercialize our tests and other products and services.

Our success also depends in large part on our ability to attract and retain managerial personnel. Competition for desirable personnel is intense, and there can be no assurance that we will be able to attract and retain the necessary staff. The failure to maintain management or to attract sales personnel could materially adversely affect our business, financial condition, and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could create undue competition and pricing pressures. There is no certainty that our pending or future patent applications will result in the issuance of patents or that our issued patents will be deemed enforceable.

The success of our business depends significantly on our ability to operate without infringing patents and other proprietary rights of others. If the technology that we use infringes a patent held by others, we could be sued for monetary damages by the patent holder or its licensee, or we could be prevented from continuing research, development, and commercialization of diagnostic tests that rely on that technology, unless we are able to obtain a license to use the patent. The cost and availability of a license to a patent cannot be predicted, and the likelihood of obtaining a license at an acceptable cost would be lower if the patent holder or any of its licensees is using the patent to develop or market a diagnostic test with which our diagnostic test would compete. If we could not obtain a necessary license, we would need to develop or obtain rights to alternative technologies, which could prove costly and could cause delays in diagnostic test development, or we could be forced to discontinue the development or marketing of any diagnostic tests that were developed using the technology covered by the patent.

We have issued patents and patent applications pending worldwide that are owned by or exclusively licensed to us. We and our collaborators expect to continue to file and prosecute patent applications covering the products and technology that we commercialize. However, there is no assurance that any of our licensed patent applications, or any patent applications that we have filed or that we may file in the future in the United States or abroad, will result in the issuance of patents.

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful in obtaining and enforcing patents, our competitors could use our technology and create diagnostic tests that compete with our diagnostic tests, without paying license fees or royalties to us.

The relatively recent Supreme Court decisions in *Mayo Collaborative Services v. Prometheus Laboratories*, Inc. and *Alice Corp. v. CLS Bank Int'l* may adversely impact our ability to obtain strong patent protection for some or all of our diagnostic tests and associated algorithms.

The preparation, filing, and prosecution of patent applications can be costly and time consuming.

The preparation and filing of patent applications, and the maintenance of patents that are issued, may require substantial time and money. A patent interference proceeding may be instituted with the United States Patent and Trademark Office, or USPTO, when more than one-person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent. Furthermore, our limited financial resources may not permit us to pursue patent protection of all of our technology and diagnostic tests throughout the world, even where we have legally binding patent protection and trade secret rights. Even if we are able to obtain issued patents covering our technology or diagnostic tests, we may have to incur substantial legal fees and other expenses to enforce our patent rights in order to protect our technology and diagnostic tests from infringing uses. We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights.

Our patents may not protect our diagnostic tests from competition.

We might not be able to obtain any patents beyond those that have been issued by the USPTO, and any patents that we do obtain might not be comprehensive enough to provide us with meaningful patent protection. There will always be a risk that our competitors might be able to successfully challenge the validity or enforceability of any patent issued to us.

If we fail to meet our obligations under various license, license option, and technology transfer agreements, we may lose our rights to key technologies or data sources on which our business depends.

Our business will depend on several critical technologies and data sources that have licenses from various domestic and overseas companies and research centers. Importantly, if we fail to meet our milestones and other obligations our option agreement with MD Anderson it would be unlikely that we could successfully commercialize the lung cancer test developed at that institution. Furthermore, if we fail to meet our obligations under our technology access agreement with BioInfra, this would adversely impact our ability to introduce an enhanced or premium version of our MCED test. These and other license agreements typically impose obligations on us, including payment obligations and obligations to pursue development and commercialization of diagnostic tests under the licensed patents and technology. If licensors believe that we have failed to meet our obligations under a license agreement, they could seek to limit or terminate our license rights, which could lead to costly and time-consuming dispute resolution and, potentially, a loss of the licensed rights. During the period of any such litigation our ability to carry out the development and commercialization of potential diagnostic tests, and our ability to raise any capital that we might then need, could be significantly and negatively affected. If our license rights were restricted or ultimately lost, we would not be able to continue to use the licensed patents and technology in our business.

Certain jurisdictions in which we may do business may not provide the same level of legal protections and enforcement of contract and intellectual property rights to which investors are accustomed in the United States.

We may conduct business in China and other foreign jurisdictions. In order to do business in these countries, we will be required to comply with the laws of those countries, including restrictions on exporting currency, requirements for local partners, tax laws and other legal requirements. Doing business in such foreign jurisdictions also entails political risk over which we have no control and for which we are unable to obtain insurance on acceptable terms. These countries also have different judicial systems, which may not provide the same level of legal protections and enforcement of contract and intellectual property rights to which investors are accustomed in the United States. We can provide no assurance that the applicable laws of such foreign jurisdictions will not be changed in ways unfavorable to us, or that applicable laws will be adequately enforced in order to provide the same levels of protection accorded to us in the United States.

Risks Related to Healthcare Government Regulation, Reimbursement, Product Safety and Effectiveness

We have relied and expect to continue to rely on third parties to conduct studies of our diagnostics tests that will be required to meet our obligations under CLIA, CAP and/or other regulatory authorities and those third parties may not perform satisfactorily.

We rely on third parties, such as academic, medical and commercial entities, to conduct studies for our diagnostics tests. These include MD Anderson, the Chang Gung Memorial Hospital in Taiwan and BioInfra. Our reliance on these third parties will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. We cannot control whether they devote sufficient time, skill, and resources to our studies. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good scientific and clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure

to adhere to our clinical protocols or regulatory requirements under the CLIA and CAP, or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for additional diagnostic tests.

We must successfully maintain and/or upgrade our information technology systems, and our failure to do so could have a material adverse effect on our business, financial condition or results of operations.

We rely on various information technology systems to manage our operations. Recently, we have implemented, and we continue to implement, modifications and upgrades to such systems and acquired new systems with new functionality. These types of activities subject us to inherent costs and risks associated with replacing and changing these systems, including impairment of our ability to fulfill customer orders, potential disruption of our internal control structure, substantial capital expenditures, additional administration and operating expenses, retention of sufficiently skilled personnel to implement and operate the new systems, demands on management time and other risks and costs of delays or difficulties in transitioning to or integrating new systems into our current systems. These implementations, modifications and upgrades may not result in productivity improvements at a level that outweighs the costs of implementation, or at all. In addition, the difficulties with implementing new technology systems may cause disruptions in our business operations and have a material adverse effect on our business, financial condition or results of operations.

Our business and operations could suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of data for our diagnostic test candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. To the extent that any disruption or security breach was to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our diagnostic test candidates could be delayed.

International operations could subject us to risks and expenses that could adversely impact the business and results of operations.

To date, we have not undertaken substantial commercial activities outside the United States. We have evaluated commercialization in Asian countries. If we seek to expand internationally, or launch other products or services internationally, in the future, those efforts would expose us to risks from the failure to comply with foreign laws and regulations that differ from those under which we operate in the U.S., as well as U.S. rules and regulations that govern foreign activities such as the U.S. Foreign Corrupt Practices Act. In addition, we could be adversely affected by other risks associated with operating in foreign countries. Economic uncertainty in some of the geographic regions in which we might operate, including developing regions, could result in the disruption of commerce and negatively impact cash flows from our operations in those areas.

These and other factors may have a material adverse effect on any international operations we may seek to undertake and, consequently, on our financial condition and results of operations.

Our business is subject to various complex laws and regulations. We could be subject to significant fines and penalties if we or our partners fail to comply with these laws and regulations.

As a provider of clinical diagnostic products and services, we and our partners are subject to extensive and frequently changing federal, state, and local laws and regulations governing various aspects of our business. In particular, the clinical laboratory industry is subject to significant governmental certification and licensing regulations, as well as federal and state laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- the Eliminating Kickbacks in Recovery Act of 2018;
- health information privacy and security, including HIPAA, as amended by HITECH, and comparable state laws;
- anti-markup legislation; and

- consumer protection.

We are also required to comply with FDA regulations, including with respect to our labeling and promotion activities. In addition, advertising of our tests is subject to regulation by the FTC. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC requirement could result in injunctions and other associated remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA and FTC regulation. We incur various costs in complying and overseeing compliance with these laws and regulations.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our tests have been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

If we or our partners, including independent sales representatives, fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, our partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business.

We could be unexpectedly required to obtain pre-market regulatory approval of our diagnostic test products in the U.S. or overseas.

Our diagnostic test products are classified as LTDs, which, in general, are not currently regulated by the FDA. However, FDA policies and practices could be interpreted or evolve to deem our products under their jurisdiction and in need of approval as a condition to continued marketing in the U.S. This may also be the case for corresponding foreign regulatory authorities. In 2023, legislation known as the VALID Act was re-introduced in Congress that, if passed into law, would require pre-market FDA approval of many LTDs, especially those that FDA deems to be "high risk." While this legislation would be expected to "grandfather" tests that were on the market at the time of passage, it could limit our ability to introduce new tests or to make substantial refinements to current tests on the market without obtaining FDA approval. Additionally, in March of 2023 an FDA official announced that their agency intends to issue formal regulations covering LTDs independent of action by Congress. Our regulatory counsel has advised us that if the FDA were to promulgate regulations, and those regulations survive court challenges, it would likely take at least four years for these regulations to take effect. However, there can be no guarantees as to this timing.

If we unexpectedly are required to obtain regulatory approval of our diagnostic test products, it may take two years or more to conduct the clinical studies and trials necessary to obtain pre-market approval from the FDA. Even if our clinical trials are completed as planned, we cannot be certain that the results will support our test claims or that the FDA will agree with our conclusions regarding our test results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior clinical trials and studies. If we are required to conduct pre-market clinical trials, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The clinical trial process may fail to demonstrate that our tests are effective for the proposed indicated uses, which could cause us to abandon a test candidate and may delay development of other tests.

We may be required to comply with federal and state laws governing the privacy of health information, and any failure to comply with these laws could result in material criminal and civil penalties.

HIPAA sets forth security regulations that establish administrative, physical, and technical standards for maintaining the confidentiality, integrity and availability of protected health information in electronic form. We also may be required to comply with state laws that are more stringent than HIPAA or that provide individuals with greater rights with respect to the privacy or security of, and access to, their health care records. HITECH established certain health information security breach notification obligations that require covered entities to notify each individual whose protected health information is breached.

We may incur significant compliance costs related to HIPAA and HITECH privacy regulations and varying state privacy regulations and varying state privacy and security laws. Given the complexity of HIPAA and HITECH and their overlap with

state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

We are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include the following:

- The Eliminating Kickbacks in Recovery Act of 2018;

- The federal Anti-Kickback Statute;
- The federal physician self-referral prohibition, commonly known as the Stark Law;
- The federal false claims and civil monetary penalties laws;
- The federal Physician Payment Sunshine Act requirements under the Affordable Care Act; and
- State law equivalents of each of the federal laws enumerated above.

Any action brought against us for violation of these laws or regulations, even if we are in compliance and successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to applicable penalties associated with the violation, including, among others, administrative, civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medicaid programs, including the California Medical Assistance Program (Medi-Cal—the California version of the Medicaid program) or other state or federal health care programs. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations.

If we become subject to claims relating to the receipt and handling of bio-hazardous materials (including infected blood), we could incur significant cost and liability.

Our quality control quality assurance process might involve the receipt and handling of whole blood, serum, or plasma from one or more individuals. We are subject to Federal, state and local regulations governing the use, manufacture, storage, handling and disposal of biological materials and waste products. We may incur significant costs complying with both existing and future environmental laws and regulations. In particular, we are subject to regulation by the Maryland Department of Health, the CLIA, Occupational Safety and Health Administration, or OSHA, and the Environmental Protection Agency, or EPA, and to regulation under the Toxic Substances Control Act and the Resource Conservation and Recovery Act in the United States. OSHA or the EPA may adopt additional regulations in the future that may affect our research and development programs. The risk of accidental contamination or injury from hazardous materials cannot be eliminated completely. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our workers' compensation insurance. We may not be able to maintain insurance on acceptable terms, if at all.

In the event that one or more lawsuits are filed against us, we could be subject to reputational risk.

Our diagnostic tests are intended for use only as screening devices, which trigger more in-depth diagnostic procedures. If our tests failed and the patient sued us, we could incur reputational damage if doctors or patients were dissuaded from using our tests. Repeated lawsuits could also precipitate regulatory scrutiny that could negatively impact our ability to sell our products.

Risks Related to Ownership of Our Common Stock

There is no public market for our common stock. You cannot be certain that an active trading market or a specific share price will be established, and you may not be able to resell your securities at or above the purchase price.

There is currently no public market for our common stock. We may apply for the listing of our common stock on a national exchange (i.e., NYSE or NASDAQ) or for the quotation of our common stock on the OTCQB or OTCQX markets maintained by OTC Markets Group Inc. However, an active trading market may not develop even if we are successful in arranging for

our common stock to be listed or quoted. We also cannot assure you that the market price of our common stock will not fluctuate or decline significantly, including a decline below the offering price, in the future.

The market price of our common stock may fluctuate, and you could lose all or part of your investment.

Our financial performance, our industry's overall performance, changing consumer preferences, technologies and government regulatory action, tax laws and market conditions in general could have a significant impact on the future market price of our common stock. Some of the other factors that could negatively affect our share price or result in fluctuations in our share price include:

- actual or anticipated variations in our periodic operating results;
- increases in market interest rates that lead purchasers of our common stock to demand a higher yield;
- changes in earnings estimates;
- changes in market valuations of similar companies;
- actions or announcements by our competitors;
- adverse market reaction to any increased indebtedness we may incur in the future;
- additions or departures of key personnel;
- actions by stockholders;
- speculation in the press or investment community; and
- our intentions and ability to list our common stock on a national securities exchange and our subsequent ability to maintain such listing.

Future issuances of our common stock or securities convertible into our common stock could cause the market price of our common stock to decline and would result in the dilution of your shareholding.

Future issuances of our common stock or securities convertible into our common stock could cause the market price of our common stock to decline. We cannot predict the effect, if any, of future issuances of our common stock or securities convertible into our common stock on the price of our common stock. In all events, future issuances of our common stock would result in the dilution of your shareholding. In addition, the perception that new issuances of our common stock, or other securities convertible into our common stock, could occur, could adversely affect the market price of our common stock.

Future issuances of debt securities, which would rank senior to our capital stock upon our bankruptcy or liquidation, and future issuances of preferred stock may adversely affect the level of return you may be able to achieve from an investment in our securities.

In the future, we may attempt to increase our capital resources by offering debt securities. Upon bankruptcy or liquidation, holders of our debt securities, and lenders with respect to other borrowings we may make, would receive distributions of our available assets prior to any distributions being made to holders of our capital stock. Moreover, if we issue additional preferred stock, the holders of such preferred stock could be entitled to preferences over existing holders of common stock and preferred stock in respect of the payment of dividends and the payment of liquidating distributions. Because our decision to issue debt or preferred securities in any future offering, or borrow money from lenders, will depend in part on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any such future offerings or borrowings. You must bear the risk that any future offerings we conduct or borrowings we make may adversely affect the level of return you may be able to achieve from an investment in our securities.

We have never paid cash dividends on our common stock and we do not intend to pay dividends for the foreseeable future.

We have paid no cash dividends on our common stock to date, and we do not anticipate paying cash dividends in the near term. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business, and we do not anticipate paying any cash dividends on our stock. Accordingly, investors must be prepared to rely on sales of

their common stock after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our common stock. Any determination to pay dividends in the future will be made at the discretion of our board of directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, and limit attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control of our company or changes in our management. Our authorized but unissued shares of common stock are available for our board of directors to issue without stockholder approval. We may use these additional shares for a variety of corporate purposes, including raising additional capital, corporate acquisitions and employee stock plans. The existence of our authorized but unissued shares of common stock could render it more difficult or discourage an attempt to obtain control of our company by means of a proxy context, tender offer, merger or other transaction since our board of directors can issue large amounts of capital stock as part of a defense to a take-over challenge. In addition, we have authorized in our certificate of incorporation 10,000,000 shares of preferred stock. Our board acting alone and without approval of our stockholders can designate and issue one or more series of preferred stock containing super-voting provisions, enhanced economic rights, rights to elect directors, or other dilutive features, that could be utilized as part of a defense to a take-over challenge.

In addition, various provisions of our bylaws may also have an anti-takeover effect. These provisions may delay, defer or prevent a tender offer or takeover attempt of our company that a stockholder might consider in his or her best interest, including attempts that might result in a premium over the market price for the shares held by our stockholders. Our bylaws contain limitations as to who may call special meetings as well as require advance notice of stockholder matters to be brought at a meeting. Additionally, our bylaws also provide that no director may be removed by less than a majority of the issued and outstanding shares entitled to vote on the removal. Our bylaws also permit the board of directors to establish the number of directors and fill any vacancies and newly created directorships. These provisions will prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

Our bylaws also establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given us timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although our bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of our company.

Moreover, Section 203 of the Genera Corporation Law of the State of Delaware may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We are subject to ongoing public reporting requirements that are less rigorous than rules for more mature public companies, and our stockholders receive less information.

We are required to publicly report on an ongoing basis under the reporting rules set forth in Regulation A for Tier 2 issuers. The ongoing reporting requirements under Regulation A are more relaxed than for public companies reporting under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The differences include, but are not limited to, being required to file only annual and semiannual reports, rather than annual and quarterly reports. Annual reports are due within 120 calendar days after the end of the issuer's fiscal year, and semiannual reports are due within 90 calendar days after the end of the first six months of the issuer's fiscal year.

We may elect to become a public reporting company under the Exchange Act. If we elect to do so, we will be required to publicly report on an ongoing basis as an emerging growth company, as defined in Jumpstart Our Business Startups Act, or

the JOBS Act, under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting 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;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We would expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We would remain an emerging growth company for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our total annual gross revenues exceed $1 billion, (ii) the date that we become a large accelerated filer as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common shares that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

If we decide to apply for the quotation of our Common Stock on the OTCQB or OTCQX market, we will be subject to the OTC Market's Reporting Standards, which can be satisfied in a number of ways, including by remaining in compliance with (i) SEC reporting requirements, if we elect to become a public reporting company under the Exchange Act, or (ii) Regulation A reporting requirements, if we elect not to become a reporting company under the Exchange Act.

In either case, we will be subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, and our stockholders could receive less information than they might expect to receive from more mature public companies.

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

Overview

We are a commercial stage diagnostics company with the core mission of developing and commercializing clinical laboratory tests for early disease detection and prevention and associated software that is powered by machine learning and real-world data to improve diagnostic accuracy and clinical utility.

Our lead tests currently assist in early cancer detection. Of the ten deadliest cancers in the U.S., only three—breast, colon, and prostate—have widely adopted screening modalities. This is despite growing evidence that early detection saves or extends lives for cancers of the lung, liver, pancreas, esophagus, and ovaries which are not yet the subject of widespread asymptomatic screening. To address this deficiency, we are offering what we believe to be one of the MCED blood tests to enter the American market. Known as OneTest, ours may be the first and only MCED test to enter the U.S. market based on the levels of tumor antigens rather than ctDNA. Tumor antigen measurement is a proven technology and each of the antigens detected in the OneTest panel uses an existing FDA-cleared *in vitro* diagnostic test that has been approved for other indications. This approach permits significantly lower costs and easier access with no demonstrable loss in test accuracy, especially for early-stage detection of the major cancers for which there is no widespread screening.

We are also planning to bring to market a blood test specifically for the early detection of lung cancer in smokers and former smokers. That test was developed by a team at MD Anderson with over $50 million in funding from federal and state agencies as well as various philanthropies. Validated using blood specimens from diverse, blinded cohorts comprising thousands of pre-symptomatic individuals, the lung cancer test analyzes several of the same tumor antigens that are part of OneTest, along with a novel biomarker (ProSurfactant B) discovered by members of that team. The test will be used primarily to screen

individuals with a history of tobacco use to improve both the compliance and effectiveness of LDCT scans which are now part of U.S. screening guidelines.

To increase our menu of innovative tests faster and at a lower cost and risk than through internal development, in 2021 we established our CLIAx, which permits diagnostics start-up companies from around the world to launch their laboratory developed tests in our CLIA licensed laboratory using shared equipment and laboratory personnel. To date, we have enrolled one company in our CLIAx, Minomics of Australia, and helped them validate and launch their blood test to help determine whether specific antigen, or PSA, levels should be followed up with a biopsy. Our CLIAx, which we believe to be the first such shared CLIA laboratory facility in the U.S., reduces the costs and expense for start-up companies to launch their novel tests in the American market while providing us with sales and marketing rights to additional products. In 2022, it earned an "Honorable Mention" in *Fast Company* magazine's list of "World Changing Ideas."

In response to the novel coronavirus pandemic that began in early 2020, we expanded our business and offered several COVID-19 testing solutions, both rapid kits and laboratory-based tests. In the third quarter of 2020, in response to substantial and urgent demand for expanded viral testing in Maryland, we also began to provide COVID-19 viral testing using polymerase chain reaction (PCR) analytical equipment in our clinical laboratory. This pandemic associated testing resulted in several years of profitability and forged business alliances that are being leveraged to support our core business.

Our legacy business also includes a pioneering field test kit for screening suspicious powders for bioterror agents known as BioCheck that is used regularly by hundreds of first responder organizations worldwide. Our BioCheck kits for screening suspicious powders remains profitable, but with limited growth potential. We are also working with IDenta of Israel to develop and validate a disposable device for testing whether illicit drugs like cocaine contain trace amounts of fentanyl.

Recent Developments

On January 6, 2023, we entered into an option agreement with MD Anderson, pursuant to which MD Anderson granted us an option to negotiate a royalty-bearing, exclusive license to certain patent rights, which optionally includes non-exclusive rights to access certain mass spectrometry data, in each case, solely for *in vitro* diagnostics for lung cancer blood-based predisposition evaluation, screening, detection, diagnosis, prognosis, relapse monitoring, monitoring of response to therapy, and development of companion diagnostics for therapies but excluding the involvement or utilization of mass spectroscopy and any *in vivo* use. During the term of the option, we have the right to use the patent rights and mass spectrometry data for internal research and evaluation purposes only, and MD Anderson shall automatically own all rights in any intellectual property created or conceived through the use of such patent rights or data. As consideration for the option, we paid MD Anderson a fee of $70,000.

The option agreement provides that MD Anderson shall not be obligated to enter into negotiations for the license until we have, in MD Anderson's sole discretion, achieved at least one of the following criteria: (i) we have entered into negotiations with at least one company listed on the Fortune 500, the Fortune 500 Global, other company with revenues above $100 million or a market cap above $1 billion, and/or at least one advocacy group such as American Lung Association or the American Cancer Society acting on their own or with the support of the Ad Council, in which such organizations in aggregate have committed to provide at least $2 million of direct funding over a period of twenty-four (24) months, solely to develop and commercialize the licensed patent rights, or (ii) we have raised from a public offering or private placement at least $7 million, solely to develop and commercialize the licensed patent rights. Notwithstanding the foregoing, MD Anderson shall not be obligated to enter into negotiations related to the license even after we achieve one of the foregoing criteria unless and until (i) we present MD Anderson with credible plans for follow-on investments of at least $18 million during the eighteen (18) month period immediately following the option period, (ii) we provide MD Anderson documentary evidence we have $7 million of cash available as shown on our audited balance sheet, (iii) we provide a business plan addressing, at a minimum, regulatory strategy, manufacturing strategy, and a financial plan that is reasonably acceptable to MD Anderson, and (iv) we provide to MD Anderson true and accurate copies of all documents that we relied on in support of our achievement of the criteria described above. Furthermore, the option agreement only requires that the parties negotiate in good faith to attempt to enter into a license agreement and does not require that either party enter into such agreement unless the terms and conditions are satisfactory to such party in its sole discretion.

The option period is for six (6) months commencing on the date of the option agreement, which may be extend up to a maximum of three (3) times, with each extension lasting for an additional one month period, upon written notice to MD Anderson requesting an extension and showing, in MD Anderson's sole discretion, that we are making commercially reasonable progress on meeting at least one of the option criteria. We are required to pay an extension fee of $10,000 for each extension request.

The option agreement may be terminated by MD Anderson upon ten (10) days written notice if we fail to perform any of our obligations under the option agreement. Upon the expiration or termination of the option agreement, we must cease and desist all use of the patent rights and not use the results of any research conducted pursuant to the option agreement unless the parties have entered into a license agreement for the patent rights.

Principal Factors Affecting our Financial Performance

Our operating results are primarily affected by the following factors:

- our ability to access additional capital and the size and timing of subsequent financings;
- the costs of acquiring additional data, technology, and/or intellectual property to successfully reach our goals and to remain competitive;
- personnel and facilities costs in any region in which we seek to introduce and market our products;
- the costs of sales, marketing, and customer acquisition;
- average price per test paid by consumers;
- the number of tests ordered per quarter;
- costs of third-party laboratories to run our tests;
- willingness of healthcare providers (including telemedicine providers) to prescribe and encourage our tests and the fees charged by them to do so;
- the costs of compliance with any unforeseen regulatory obstacles or governmental mandates in any states or countries in which we seek to operate;
- the costs of any additional clinical studies which are deemed necessary for us to remain viable and competitive in any region of the world;
- the extent and duration of demand for COVID-19 viral and serology testing; and
- our ability to identify additional tests and revenue sources to make up for the anticipated drop in COVID-19 testing.

Results of Operations

The following table sets forth key components of our results of operations during the years ended December 31, 2022 and 2021, both in dollars and as a percentage of our revenues.

	December 31, 2022		December 31, 2021	
	Amount	% of Revenues	Amount	% of Revenues
Revenues	$ 11,059,145	100.00%	$ 9,622,332	100.00%
Cost of revenues	5,937,398	53.69%	4,927,374	51.21%
Gross profit	5,121,747	46.31%	4,694,958	48.79%
Operating expenses:				
Sales, general and administrative	3,322,835	30.05%	2,559,493	26.60%
Research and development	120,043	1.09%	193,368	2.01%
Total operating expenses	3,442,878	31.13%	2,752,861	28.61%
Operating income	1,678,869	15.18%	1,942,097	20.18%
Other income (expense):				
Interest expense	(15,685)	(0.14)%	(12,930)	(0.13)%
Interest income	68,421	0.62%	2,994	0.03%
Gain on sale of asset	2,371	0.02%	-	-
Other expense	-	-	(5,900)	(0.06)%
Other income	452,899	4.01%	145,516	1.51%

Total other (income) expense	508,006	4.59%	129,680	1.35%
Net income	$ 2,186,875	19.77%	$ 2,071,777	21.53%

Revenues. We generated revenues from sales of COVID-19 tests, OneTest, BioCheck and from our CLIAx during the years ended December 31, 2022 and 2021. Our total revenues were increased by $1,436,813, or 14.93%, to $11,059,145 for the year ended December 31, 2022 from 9,622,332 for the year ended December 31, 2021. Such increase was due to an increase in revenues from sales of our COVID-19 tests and the new revenues from our CLIAx, offset by decreases in revenues from sales of OneTest and BioCheck. The following table summarizes our revenues by product:

	December 31, 2022		December 31, 2021	
	Amount	% of Revenues	Amount	% of Revenues
COVID-19 PCR Tests	$ 10,393,256	93.98%	$ 8,669,557	90.10%
COVID-19 Antibody/Antigen Tests	97,452	0.88%	399,422	4.15%
OneTest	323,414	2.92%	360,290	3.74%
BioCheck	154,660	1.40%	193,063	2.01%
CLIAx	90,363	0.82%	-	-
Total revenues	$ 11,059,145		$ 9,622,332	

Revenues from our COVID-19 tests are derived from two classes of tests: (i) rapid point-of-care tests (antibody and antigen) that we distributed after validating and (ii) lab-based PCR testing of nasal swabs sent to our CLIA lab from area nursing homes, numerous county school systems in the State of Maryland and the Montgomery County Health Department. Revenues from our COVID-19 tests increased by $1,421,729, or 15.68%, to $10,490,708 for the year ended December 31, 2022 from $9,068,979 for the year ended December 31, 2021. Such increase was due to a 19.88% increase in PCR tests resulting from a significant increase in the volume of tests, offset by a 75.60% decrease in rapid tests. As of the date of this report, the demand for COVID-19 PCR testing has declined significantly and future demand cannot be predicted.

Revenues from sales of OneTest decreased by $36,876, or 10.24%, to $323,414 for the year ended December 31, 2022 from $360,290 for the year ended December 31, 2021. The decrease in overall revenue recognized on OneTest was the result of a large sale to a fire and rescue department in 2021 of which a majority of the tests were completed in 2021. Although revenue was down in 2022, the number of tests sold increased by 14% in 2022 over 2021. Many of these tests will be performed in 2023 and recognized as revenue in 2023.

Revenues from sales of BioCheck decreased by $38,403, or 19.89%, to $154,660 for the year ended December 31, 2022 from $193,063 for the year ended December 31, 2021. The decrease in revenue in BioCheck is the result of a number of factors, including increased competition, decreased sales focus due to COVID-19 activities and a portion of the shipping revenue was classified as BioCheck when it pertained to OneTest.

We signed our first CLIAx customer in late 2021 and generated revenues of $90,363 from this customer for the year ended December 31, 2022. The revenue was for tech transfer of their lab developed test and ongoing laboratory activities billed to them monthly. The agreement with the CLIAx customer includes future revenue sharing and co-marketing of their test into the US market.

Cost of revenues. Our cost of revenues includes materials, labor, and laboratory expenses. Our cost of revenues increased by $1,010,024, or 20.50%, to $5,937,398 for the year ended December 31, 2022 from $4,927,374 for the year ended December 31, 2021. As a percentage of revenues, cost of revenues was 53.69% and 51.21% for the years ended December 31, 2022 and 2021, respectively. We moved to a larger lab space in March 2022 which contributed to an increase in overall direct and indirect lab costs.

Gross profit and gross margin. Our gross profit increased by $426,789, or 9.09%, to $5,121,747 for the year ended December 31, 2022 from $4,694,958 for the year ended December 31, 2021. Gross profit as a percentage of revenues (gross margin) was 46.31% and 48.79% for the years ended December 31, 2022 and 2021, respectively.

Sales, general and administrative expenses. Our sales, general and administrative expenses include sales, marketing, office leases, overhead, executive compensation, legal, regulatory, government relations, and similar expenses. Our sales, general and administrative expenses increased by $763,342, or 29.82%, to $3,322,835 for the year ended December 31, 2022 from $2,559,493 for the year ended December 31, 2021. As a percentage of revenues, sales, general and administrative expenses were 30.05% and 26.60% for the years ended December 31, 2022 and 2021, respectively. Such increase was primarily due to an increase in professional fees and sales and marketing expenses.

Research and development expenses. Our research and development expenses include clinical data acquisitions, laboratory validation and bridging studies, data analysis algorithms and non-capitalizable machine learning software development. It also includes laboratory test validation and technical consultation. Our research and development expenses decreased by $73,325, or 37.92%, to $120,043 for the year ended December 31, 2022 from $193,368 for the year ended December 31, 2021. As a percentage of revenues, research and development expenses were 1.09% and 2.01% for the years ended December 31, 2022 and 2021, respectively. The decrease was due to a decrease of R&D staffing resources related to our cancer test products in 2022 compared to 2021.

Total other income (expense). We had total other income, net, of $508,006 for the year ended December 31, 2022, as compared to other income, net, of $129,680 for the year ended December 31, 2021. Total other income, net, for the year ended December 31, 2022 consisted of other income of $452,899 related to the reversal of contingent liabilities and other estimated accruals no longer deemed a liability, interest income of $68,421 and a gain on sale of asset of $2,371 related to equipment sales, offset by interest expense of $15,685, while total other income, net, for the year ended December 31, 2021 consisted of other income of $145,516 related to the forgiveness of debt and interest income of $2,994, offset by interest expense of $12,930 and other expense of $5,900.

Net income. As a result of the cumulative effect of the factors described above, our net income increased by $115,098, or 5.56%, to $2,186,875 for the year ended December 31, 2022 from $2,071,777 for the year ended December 31, 2021.

Liquidity and Capital Resources

As of December 31, 2022, we had cash and cash equivalents of $8,807,575. Historically, our sources of cash have included private placements of equity securities and cash generated from revenues.

Management has prepared estimates of operations believes that sufficient funds will be generated from operations to fund our operations and to service our debt obligations for at least the next twelve months. We may, however, in the future require additional cash resources due to changing business conditions, implementation of our strategy to expand our business, or investments or acquisitions we may decide to pursue. If our own financial resources are insufficient to satisfy our capital requirements, we may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity securities could result in dilution to our stockholders. The incurrence of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Financing may not be available in amounts or on terms acceptable to us, if at all. Any failure by us to raise additional funds on terms favorable to us, or at all, could limit our ability to expand our business operations and could harm our overall business prospects.

Summary of Cash Flows

	Years Ended December 31,	
	2022	2021
Net cash provided by (used in) operating activities	$ 5,803,059	$ (1,074,003)
Net cash used in investing activities	(462,552)	(228,150)
Net cash provided by financing activities	112,599	1,188,430
Net increase (decrease) in cash and cash equivalents	5,453,106	(113,723)
Cash and cash equivalents at beginning of period	3,354,469	3,468,192
Cash and cash equivalent at end of period	$ 8,807,575	$ 3,354,469

Net cash provided by operating activities was $5,803,059 for the year ended December 31, 2022, as compared to net cash used in operating activities of $1,074,003 for the year ended December 31, 2021. The increase in cash provided by operating activities was primarily a result of significant increases in accounts receivable and other receivables and increased inventory, offset by decreased accounts payable and accrued liabilities.

Net cash used in investing activities was $462,552 for the year ended December 31, 2022, as compared to $228,150 for the year ended December 31, 2021. The net cash used in investing activities for the year ended December 31, 2022 consisted of purchases of capital equipment of $261,793, acquisition of technology under a license agreement and related validation costs of $206,509, offset by proceeds from sale of equipment of $5,750, while the net cash used in investing activities for the year ended December 31, 2021 consisted of entirely of purchases of capital equipment.

Net cash provided by financing activities was $112,599 for the year ended December 31, 2022, as compared to $1,188,430 for the year ended December 31, 2021. The net cash provided by financing activities for the year ended December 31, 2022

consisted of proceeds from notes payable of $183,166, net of debt discount costs of $11,715, and proceeds from the exercise of warrants of $12, offset by principal payments on financing lease liabilities of $58,864, while the net cash provided by financing activities for the year ended December 31, 2021 consisted of net proceeds from the issuance of preferred stock of $1,246,088 and proceeds from the exercise of warrants of $34, offset by principal payments on financing lease liabilities of $57,692.

Convertible Note Offering

On August 15, 2022, we launched an equity crowdfunding offering under Section 4(a)(6) of the Securities Act and Regulation Crowdfunding promulgated thereunder, pursuant to which we offered convertible promissory notes. As of December 31, 2022, we issued convertible promissory notes in the aggregate principal amount of $213,010. The notes bear interest at rates ranging from 6% to 11.10% and are due and payable twenty-four (24) months after the date of issuance. The notes are unsecured, contain customary events of default and are convertible into common stock upon certain events. As of December 31, 2022, the outstanding balance of these notes is $213,010 net of unamortized debt issuance cost of $10,187 and an accrued interest balance of $4,423.

Regulation A Offering

On January 8, 2020, we launched an offering under Regulation A of Section 3(6) of the Securities Act for Tier 2 offerings, pursuant to which we offered up to 3,340,909 shares of Series C Preferred Stock at an offering price of $4.40 per share for gross proceeds of up to $14,700,000 on a "best efforts" basis. This offering was terminated on June 15, 2021.

During the year ended December 31, 2021, we raised approximately $1,510,076 in gross proceeds through the sale of 369,750 shares of our Series C Preferred Stock for net proceeds of $1,246,087.

Capital Expenditures

We incurred capital expenditures of $261,793 and $228,150 in the years ended December 31, 2022 and 2021, respectively. We estimate that our total capital expenditures in fiscal year 2023 will reach approximately $130,000. Such funds will be used primarily to add laboratory equipment and computers for new employees.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles, or U.S. GAAP, requires our management to make assumptions, estimates and judgments that affect the amounts reported, including the notes thereto, and related disclosures of commitments and contingencies, if any. We have identified certain accounting policies that are significant to the preparation of our financial statements. These accounting policies are important for an understanding of our financial condition and results of operation. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require management's difficult, subjective, or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Certain accounting estimates are particularly sensitive because of their significance to financial statements and because of the possibility that future events affecting the estimate may differ significantly from management's current judgments. We believe the following critical accounting policies involve the most significant estimates and judgments used in the preparation of our financial statements:

Revenue Recognition. In accordance with Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, we recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods and services. To determine revenue recognition for arrangements that we deem are within the scope of ASC Topic 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) calculate transfer price; (iv) allocate the transaction price to the performance obligation in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Performance obligations for four different types of services are discussed below:

- OneTest – Revenues from the sale of OneTest is recognized when returned serum specimens are analyzed in our CLIA laboratory and the results are reported. Due to the nature of OneTest, revenue per test is recorded based on historical average receipts from patients.

- BioCheck – Revenues for kits is recognized when purchase orders are processed and kits are shipped to customers.

- COVID-19 Tests:

    - Point-of-Care (POC) Test Kits – Revenues for COVID-19 distributed test kits for use at the POC (i.e., rapid antigen and antibody tests) are recognized when purchase orders are processed, and test kits are shipped to customers.

    - COVID-19 Lab Tests (PCR) – Revenues from the sale of COVID-19 viral (PCR) tests is recognized when returned nasal swabs are analyzed in our CLIA laboratory and the results are reported. Due to the nature of PCR tests, revenue per test is recorded based on historical average receipts from insurance payers, Medicare, Medicaid, nursing homes or County government.

- CLIAx – Revenue from providing CLIAx customers with laboratory services and co-marketing activities of the CLIAx clients laboratory developed tests. Revenue for laboratory services are recognized monthly based on agreed laboratory activities for space, equipment use and contracted personnel. Additional revenue can be earned through the selling of the customer's products.

Inventories. Inventories are stated at the lower of cost or market using the first-in, first out (FIFO) method. Inventories consisted entirely of finished goods as of December 31, 2022 and 2021.

Intangible Assets – Patents. We capitalize patent filing fees, and we expense legal fees, in connection with internally developed pending patents. We also will capitalize patent defense costs to the extent these costs enhance the economic value of an existing patent. We evaluate the capitalized costs annually to determine if any amounts should be written down. Patent costs begin amortizing upon approval by the corresponding government and are generally amortized over the expected period to be benefitted, not to exceed the patent lives, which may be as long as 20 years.

Impairment of Long-Lived Assets. The long-lived assets held and used by us are reviewed for impairment no less frequently than annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In the event that facts and circumstances indicate that the cost of any long-lived assets may be impaired, an evaluation of recoverability is performed. There were no impairment losses during the years ended December 31, 2022 and 2021. There can be no assurance, however, that market conditions will not change or demand for our products and services will continue, which could result in impairment of long-lived assets in the future.

Offering Costs. We comply with the requirements of ASC 340 with regards to offering costs. Prior to the completion of an offering, offering costs will be capitalized as deferred offering costs on the balance sheet. The deferred offering costs will be charged to stockholders' equity upon the completion of an offering or to expense if the offering is not completed.

Preferred Stock. ASC 480, *Distinguishing Liabilities from Equity*, includes standards for how an issuer of equity (including equity shares issued by consolidated entities) classifies and measures on its balance sheet certain financial instruments with characteristics of both liabilities and equity. Management is required to determine the presentation for the Preferred Stock as a result of the redemption and conversion provisions, among other provisions in the agreement. Specifically, management is required to determine whether the embedded conversion feature in the Preferred Stock is clearly and closely related to the host instrument, and whether the bifurcation of the conversion feature is required and whether the conversion feature should be accounted for as a derivative instrument. If the host instrument and conversion feature are determined to be clearly and closely related (both more akin to equity), derivative liability accounting under ASC 815, *Derivatives and Hedging*, is not required. Management determined that the host contract of the Preferred Stock is more akin to equity, and accordingly, derivative liability accounting is not required by us. Costs incurred directly for the issuance of the Preferred Stock are recorded as a reduction of gross proceeds received by us.

Research and Development. We incur research and development costs during the process of researching and developing our technologies and future manufacturing processes. Our research and development costs consist primarily of materials and services. We expense these costs as incurred until the resulting product has been completed, tested, and made ready for commercial use.

Stock-Based Compensation. We account for stock awards issued under ASC 718, *Compensation – Stock Compensation*. Under ASC 718, stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award. Stock-based compensation is recognized as expense over the employee's requisite vesting period and over the nonemployee's period of providing goods or services. The fair value of each stock option or warrant award is estimated on the date of grant

using the Black-Scholes option valuation model. Restricted shares are measured based on the fair market value of the underlying stock on the grant date.

Recently Issued Accounting Pronouncements

Management does not believe that any recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

DIRECTORS AND OFFICERS

Directors and Executive Officers

The following table sets forth the name and position of each of our current executive officers, directors, and significant employees.

Name	Position	Age	Term of Office	Approximate hours per week for part-time employees
Jonathan Cohen	Chief Executive Officer, President and Director	60	From August 2000	N/A
Anne Shiflett	Acting Chief Financial Officer	57	From April 2023	30
Jiming Zhou, Ph.D.	Chief Operating Officer	56	From August 2020	N/A
Michael Lebowitz. Ph.D.	Chief Scientific Officer	55	From January 2020	16
John G. Compton, Ph.D.	Chairman of the Board	74	From July 2016	N/A
Richard M. Cohen	Director	72	From July 2016	N/A
Ming ("Jack") Li	Director	37	From August 2022	N/A
John W. Rollins	Director	78	From November 2017	N/A
Michael A. Ross, M.D.	Director	73	From July 2016	N/A

Jonathan Cohen. Mr. Cohen is the founder of our company and has served as Chief Executive Officer, President, and a director since its inception. He is a co-inventor of two of our most successful products, OneTest and BioCheck, and has led the commercial launch and sales of both. He has also spearheaded license, research, technology transfer, investment, and sales and marketing agreements with Fortune 500 companies such as Eastman Kodak, Abbott Diagnostics, Johnson & Johnson, IBM, and Ping An, the largest health insurance company in China. Mr. Cohen has also been a leading advocate in Annapolis, MD and on Capitol Hill on behalf of small and emerging biotechnology and diagnostics companies. Before founding our company, Mr. Cohen was patent and general counsel for two publicly traded companies, Ventana Medical Systems Inc. (acquired by Roche diagnostics in 2008), from 1999 to 2000, and Oncor Inc., from 1997 to 1999. Mr. Cohen is a registered patent attorney with more than 25 years of experience in biotechnology patents and licensing matters. Mr. Cohen has a Master of Science Degree in Biotechnology from Johns Hopkins University and a law degree from the American University.

Anne Shiflett. Ms. Shiflett has served as our Acting Chief Financial Officer since April 1, 2023 and previously served as our Director of Finance from February 21, 2022 to March 31, 2023. Ms. Shiflett has over 30 years of managerial, financial and accounting experience, including expertise in leading the start-up and rapid growth of new and emerging companies in information technology, real estate brokerage and life sciences. She has been in the life sciences industry for the past eighteen years, most recently as chief business officer of Gypsy Basin Genomics from December 2020 to January 2022 and vice president, finance and administration at Catalent Pharma Solutions, Cell and Gene Therapy Business Unit (formerly known as Paragon Bioservices, Inc.) from August 18, 2014 to September 1, 2020. Ms. Shiflett has been involved in raising over $100 million in various forms of financing to include preferred stock, bridge financing, bank financing and venture back debt and in facilitating the sale of Paragon Bioservices, Inc. to Catalent Pharma Solutions for $1.2 billion dollars in May 2019. Ms. Shiflett received a BBA in Accounting and an MBA in Business Management from Loyola College of Maryland.

Jiming Zhou, PhD. Dr. Zhou has served as our Chief Operating Officer since August 2020. He is an expert in healthcare and biotech industries, with over 20 years of experience in both academia and industry. Dr. Zhou began his academic career as an associate professor at Sichuan University in China, where he received his PhD of Biology. Afterward, he moved to the United States to conduct research at the University of Iowa, where he spent 7 years publishing over 30 peer-reviewed research papers and receiving numerous grants and patents. In 2005, Dr. Zhou transitioned into industrial R&D, where he led a joint pharmaceutical project that reached significant milestones totaling $330 million. He then went on to manage multiple clinical labs and co-founded companies, collaborating with prominent healthcare institutes both in the US and China. Prior to joining

us in July 2019, Dr. Zhou held various leadership roles, including serving as president and co-founder of Baltimore-based biotech firm Firefox Pharmaceuticals, LLC from April 2017 to July 2019, partner and co-founder of Virginia-based Fairfax Medical Consulting International, LLC from October 2013, and managing director of Diagnostic Operation and Strategic Alliance of the Genetics and IVF Institute, an international company based in Virginia, from September 2009 to September 2013. Dr. Zhou's extensive experience in the biotech industry, along with his research expertise, make him a valuable member of our team. He continues to play a crucial role in our success and growth.

Michael Lebowitz, Ph.D. Dr. Lebowitz has served our Chief Scientific Officer since January 2020 and was previously our Director of Research & Development from 2009-2012. Dr. Lebowitz has more than 30 years of research experience, including 22 years in our industry and more than 18 years in research management. He has been directly involved in the commercial launch of six LDTs for the early detection of cancer and the establishment of two CLIA-certified labs. He has also spearheaded the R&D supporting an anti-cancer vaccine from discovery through phase I clinical development. He is concurrently chief scientific officer of Athanor Biosciences, Inc., a cancer therapeutics company he cofounded in 2020. Prior to his current positions, he was senior director and vice president of research at Sensei Biotherapeutics from 2014-2019. Dr. Lebowitz holds a Ph.D. from the Johns Hopkins University School of Medicine in biochemistry, cellular, and molecular biology where he subsequently completed a three-year fellowship in immunology in the department of pathology, division of immunopathology. He is currently an adjunct faculty at both Johns Hopkins University and University of Maryland, Baltimore County teaching in their respective Biotechnology programs.

John G. Compton, Ph.D. Dr. Compton has served as Chairman of the Board since July 2016. He has over 30 years of experience in the development and application of molecular biological techniques to answer questions about genetics and epidermal differentiation, and has authored more than 80 publications in the field. Dr. Compton served as vice-president of BioReference Laboratories from 2007 to 2013. Previously, Dr. Compton was founder, and served as scientific director and co-president of GeneDx Inc, from 2000 to 2006, the assets of which were acquired by BioReference Laboratories (now part of Opko) in September 2006. Dr. Compton also serves as Mayor of the Town of Washington Grove, MD (2000-2008, 2018-present), on the Board of Directors of Quertle Inc. and chairs the Boards of the non-profit BlackRock Center for the Arts and the Pinkney Center for Science and Technology at Montgomery College Germantown Campus. Dr. Compton holds B.S. degrees in Physics and Biology from the Massachusetts Institute of Technology, received his Ph.D. from the University of California, Berkeley, in Biophysics, and was a Staff Scientist at the NIAMS, National Institutes of Health, Bethesda, from 1991-2000. In 2003, he was awarded the Entrepreneur of the Year award by the Technology Council of Maryland.

Richard M. Cohen. Mr. Cohen has served as a member of our board of directors since July 2016. He is an experienced CEO/CFO at public and private companies. His professional experience includes biotech, financial services and diversified media and he maintains excellent contacts with capital financing sources on and off Wall Street. He has been the president of Richard M Cohen Consultants since 1995, a company providing financial consulting services to both public and private companies. From March 2012 to July 2015, he was the founder and managing partner of Chord Advisors, a firm providing outsourced CFO services to both public and private companies. He was the chief executive officer and chief financial officer of CorMedix Inc., a publicly traded medical device/biotechnology company with an intrapericardial therapy product targeted to markets in the U.S. and Europe, from 2010 to 2013. He has served on the board of directors and audit committees of Ondas Holdings Inc. (2018 to present), Helix BioMedix, Inc. (2006 to present), CorMedix Inc. (2010 to 2013), and Rodman & Renshaw (2008 to 2012). Mr. Cohen's academic credentials include an MBA from Stanford University and B.S. with honors from Wharton School, University of Pennsylvania.

Ming ("Jack") Li. Mr. Li has served as a member of our board of directors since August 2022. He has over 10 years of experience in private equity investment. Since March 2022, Mr. Li has served as the general manager of Ping An Ventures. At Ping An Ventures, he covers investment opportunities in biotech, medical equipment, and medical services. Before joining Ping An Ventures, Mr. Li was the executive director at Ping An Bright Fortune Capital and investment director at Fosun Capital covering medical service and TMT investment businesses. Mr. Li holds an MBA degree from Cheung Kong Graduate School of Business.

John W. Rollins. Mr. Rollins has served as a member of our board of directors since November 2017. He has served on multiple boards and chairs the board of directors of the MedStar Southern Maryland Hospital Center (2014 to present). From 2001 to 2010, he taught Entrepreneurship at the George Washington University School of Business and founded the GW New Venture Competition and served as its Director from 2007 to 2014. In 2003, Mr. Rollins founded StreamCenter, Inc., a firm that pioneered online education using video streaming, and served as chair of the board of directors from 2003 to 2008, and chief executive officer from 2008 to 2010. Prior to 2001, he founded and served for three decades as the chief executive officer and chairman of AZTECH Software Corporation, the nation's first specialized provider of information technology services to non-profit organizations. Mr. Rollins's board experience has included serving as Trustee of the National Park Trust (Vice Chair and Treasurer) (1990 to present), Director of the MedStar Georgetown University Hospital (Vice Chair)

(2002 to 2013), the Washington Hospital Center (Vice Chair and Treasurer) (1977 to 2002), and the U.S. Association for Small Business & Entrepreneurship (2004 to 2006). Mr. Rollins earned his A.B. in Mathematics from Dartmouth and his M.B.A. in Finance from the Stanford University Graduate School of Business.

Michael A. Ross, M.D. Dr. Ross has served as a member of our board of directors since July 2016. He has served as the chairman and chief executive officer of Euclid Systems Corporation since 2015, where he led the growth of this ophthalmic medical device company from $3.1 million to over $20 million in five years. The bulk of Euclid's sales are in China and East Asia where Dr. Ross visits 4-5 times per year. Prior to joining Euclid, he was chief executive officer of E-P Therapeutics from 2010 to 2012, and was a medical and scientific advisor to StemCyte, Inc. 2009 to 2010. He is Board-certified in Obstetrics and Gynecology and is a founding member of an OB-GYN-Infertility practice in Northern Virginia from 1980 to 2007. Dr. Ross has been a Clinical Professor of Obstetrics and Gynecology, George Washington University Medical Center since 1979, and has served on the boards of directors of several biotech and medical device companies. He has a B.S. in Chemistry and Biology from Dickinson College and an M.D. from George Washington University.

Directors are elected until their successors are duly elected and qualified.

Mr. Li was elected by the holders of our Series A-1 Preferred Stock and Mr. Rollins was elected by the holders of our Preferred Stock. Except for the rights of such holders to elect a director, which will expire upon conversion of such shares, there are no agreements or understandings for any of our executive officers or directors to resign at the request of another person and no officer or director is acting on behalf of nor will any of them act at the direction of any other person.

There are no family relationships between any director, executive officer, person nominated or chosen to become a director or executive officer or any significant employee.

To the best of our knowledge, none of our directors or executive officers has, during the past five years:

- been convicted in a criminal proceeding (excluding traffic violations and other minor offences); or
- had any petition under the federal bankruptcy laws or any state insolvency law was filed by or against, or a receiver, fiscal agent or similar officer was appointed by a court for the business or property of such person, or any partnership in which he was general partner at or within two years before the time of such filing, or any corporation or business association of which he was an executive officer at or within two years before the time of such filing.

Corporate Governance

Our board of directors currently has three standing committees, an audit committee, a compensation committee and nominating and corporate governance committee, which perform various duties on behalf of and report to the board of directors. From time to time, the board of directors may establish other committees.

The Board's Role in Risk Oversight

The board of directors oversees that the assets of our company are properly safeguarded, that the appropriate financial and other controls are maintained, and that our business is conducted wisely and in compliance with applicable laws and regulations and proper governance. Included in these responsibilities is the board's oversight of the various risks facing our company. In this regard, our board seeks to understand and oversee critical business risks. Our board does not view risk in isolation. Risks are considered in virtually every business decision and as part of our business strategy. Our board recognizes that it is neither possible nor prudent to eliminate all risk. Indeed, purposeful and appropriate risk-taking is essential for our company to be competitive on a global basis and to achieve its objectives.

While the board oversees risk management, company management is charged with managing risk. Management communicates routinely with the board and individual directors on the significant risks identified and how they are being managed. Directors are free to, and indeed often do, communicate directly with senior management.

Our board administers its risk oversight function as a whole by making risk oversight a matter of collective consideration; however, much of the work is delegated to committees, which meet regularly and report back to the full board. We have established a standing audit committee, compensation committee and nominating and corporate governance committee of our board of directors. The audit committee oversees risks related to our financial statements, the financial reporting process, and accounting and legal matters, the compensation committee evaluates the risks and rewards associated with our compensation philosophy and programs, and the nominating and corporate governance committee evaluates risks associated with management decisions and strategic direction.

Audit Committee

Richard M. Cohen, John G. Compton and Michael A. Ross currently serve on our audit committee, with Mr. Cohen serving as chairman. The audit committee oversees our accounting and financial reporting processes and the audits of the financial statements of our company.

The audit committee is responsible for, among other things: (i) retaining and overseeing our independent accountants; (ii) assisting the board in its oversight of the integrity of our financial statements, the qualifications, independence and performance of our independent auditors and our compliance with legal and regulatory requirements; (iii) reviewing and approving the plan and scope of the internal and external audit; (iv) pre-approving any audit and non-audit services provided by our independent auditors; (v) approving the fees to be paid to our independent auditors; (vi) reviewing with our chief executive officer and chief financial officer and independent auditors the adequacy and effectiveness of our internal controls; (vii) reviewing hedging transactions; and (viii) reviewing and approving related party transactions; and (ix) reviewing and assessing annually the audit committee's performance and the adequacy of its charter.

Compensation Committee

Richard M. Cohen, John G. Compton and John Rollins currently serve on our compensation committee, with Mr. Rollins serving as chairman. The compensation committee assists the board in reviewing and approving the compensation structure, including all forms of compensation relating to our directors and executive officers.

The compensation committee is responsible for, among other things: (i) reviewing and approving the remuneration of our executive officers; (ii) determining the compensation of our independent directors; (iii) making recommendations to the board regarding equity-based and incentive compensation plans, policies and programs; and (iv) reviewing and assessing annually the compensation committee's performance and the adequacy of its charter.

Nominating and Corporate Governance Committee

Richard M. Cohen, John G. Compton and Michael A. Ross currently serve on our nominating and corporate governance committee, with Mr. Ross serving as the chair. The nominating and corporate governance committee assists the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees.

The nominating and corporate governance committee is responsible for, among other things: (i) recommending the number of directors to comprise our board; (ii) identifying and evaluating individuals qualified to become members of the board; (iii) recommending to the board the director nominees for each annual stockholders' meeting; (iv) recommending to the board the candidates for filling vacancies that may occur between annual stockholders' meetings; (v) reviewing independent director compensation and board processes, self-evaluations and policies; (vi) overseeing compliance with our code of ethics; and (vii) monitoring developments in the law and practice of corporate governance.

The nominating and corporate governance committee's methods for identifying candidates for election to our board of directors (other than those proposed by our stockholders, as discussed below) will include the solicitation of ideas for possible candidates from a number of sources - members of our board of directors, our executives, individuals personally known to the members of our board of directors, and other research. The nominating and corporate governance committee may also, from time-to-time, retain one or more third-party search firms to identify suitable candidates.

In making director recommendations, the nominating and corporate governance committee may consider some or all of the following factors: (i) the candidate's judgment, skill, experience with other organizations of comparable purpose, complexity and size, and subject to similar legal restrictions and oversight; (ii) the interplay of the candidate's experience with the experience of other board members; (iii) the extent to which the candidate would be a desirable addition to the board and any committee thereof; (iv) whether or not the person has any relationships that might impair his or her independence; and (v) the candidate's ability to contribute to the effective management of our company, taking into account the needs of our company and such factors as the individual's experience, perspective, skills and knowledge of the industry in which we operate.

A stockholder may nominate one or more persons for election as a director at an annual meeting of stockholders if the stockholder complies with the notice and information provisions contained in our bylaws. Such notice must be in writing to our company not less than 90 days and not more than 120 days prior to the anniversary date of the preceding year's annual meeting of stockholders or as otherwise required by requirements of the Exchange Act. In addition, stockholders furnishing

such notice must be a holder of record on both (i) the date of delivering such notice and (ii) the record date for the determination of stockholders entitled to vote at such meeting.

Compensation of Directors and Executive Officers

Summary Compensation Table

The following table sets forth the annual compensation of each of the three highest paid persons who were executive officers or directors during our last completed fiscal year:

Name	Capacities in which compensation was received	Cash Compensation ($)	Other Compensation ($)	Total Compensation ($)
Jonathan Cohen[(1)]	Chief Executive Officer and President	$325,000	$44,936	$444,936
Jiming Zhou[(2)]	Chief Operating Officer	$380,730	$8,776	$389,506
Michael Lebowitz[(3)]	Chief Scientific Officer	$103,200	-	$103,200

(1) Cash compensation for the fiscal year ended December 31, 2022 consisted of base salary of $250,000 and bonuses of $150,000. Other compensation represents fringe benefits for insurance and employer 401K match in the amount of $44,936.

(2) Cash compensation for the fiscal year ended December 31, 2022 consisted of base salary of $200,004 and bonuses of $180,726. Other compensation represents fringe benefits for employer 401K match in the amount of $8,776.

(3) Cash compensation for the fiscal year ended December 31, 2022 consisted of base salary of $83,200 and bonuses of $20,000.

Employment Agreements

On May 6, 2019, we entered into an employment agreement with Jonathan Cohen, our founder, Chief Executive Officer and President, with an initial term commencing as of January 1, 2019 and ending on December 31, 2019, which automatically renews for additional one (1) year periods unless either party provides written notice at least sixty (60) days prior to the expiration of the initial term or any renewal period. Pursuant to the employment agreement, Mr. Cohen is entitled to an annual base salary of $250,000. Mr. Cohen will also be entitled to a cash bonus for 2019 of up to 30% of the base salary at the discretion of the compensation committee and based on certain criteria set forth in the employment agreement, which shall be paid within 60 days after year end. Following sharp increases in revenues resulting from COVID-19 testing the cash bonus cap was increased to 60% and 80% of base salary for 2021 and 2022.

Mr. Cohen is also permitted during the term, if and to the extent eligible, to participate in all employee benefit plans, policies and practices maintained by or on behalf of our company commensurate with Mr. Cohen's position. Either party may terminate the employment agreement at any time without cause (as defined in the employment agreement) upon sixty (60) days' written notice. In addition, we may terminate the employment agreement immediately for cause. If we terminate the employment agreement without cause, all compensation payable to Mr. Cohen under the employment agreement shall cease as of the date of termination, and we shall pay to Mr. Cohen the following sums: (i) the base salary on the termination date for twelve (12) months (the applicable period being referred to as the severance period), payable in equal installments in accordance with our normal payroll procedures beginning with the termination date; (ii) benefits under group health and life insurance plans in which Mr. Cohen participated prior to termination through the severance period; (iii) all previously earned, accrued, and unpaid benefits from us and our employee benefit plans, including any such benefits under our pension, disability, and life insurance plans, policies, and programs; and (iv) bonus, if any, at the discretion of the compensation committee; provided that if, prior to the date on which our foregoing obligations cease, Mr. Cohen violates certain covenants set forth in the employment agreement, then we shall have no obligation to make any of the payments that remain payable by us under clauses (i), (ii) and (iv) above on or after the date of such violation. The payment of severance may be conditioned by us on the delivery by Mr. Cohen of a release of any and all claims that he may have against our company. In addition, if the employment agreement is terminated by us for cause, then Mr. Cohen is only entitled to receive the amounts specified in clause (iii), and if the employment agreement is terminated by Mr. Cohen or due to his death or disability, then Mr. Cohen (or his estate or representative as applicable) shall receive only the amounts specified in clauses (iii) and (iv). In the event that the term expires and is not renewed by us, then Mr. Cohen shall receive the amounts specified in clauses (i), (ii), (iii) and (iv), provided however, that this shall not apply if we enter into a new employment agreement with Mr. Cohen. Finally, in the event that the employment agreement is terminated by us within one year following a change of control (as defined in the

employment agreement), then Mr. Cohen shall receive, in addition to the amount of any accrued and unpaid salary then due Mr. Cohen, the amounts specified in clauses (i), (ii), (iii) and (iv). Mr. Cohen's employment agreement contains restrictive covenants prohibiting him from owning or operating a business that competes with our company or soliciting our customers or employees for one year following the termination of his employment.

As of April 1, 2023, we have agreed to pay Jiming Zhou, our Chief Operating Officer, an annual salary of $220,000 and he is also eligible for (i) a bonus equal to 4% of our gross profit and (ii) a bonus equal to 20% of our revenues derived from China and Taiwan, each as determined by our independent registered public accounting firm in accordance with U.S. GAAP. He is also eligible for discretionary bonuses, as determined by our board of directors, for all investments or business endeavors in China and Taiwan, for all new products launched in 2023 and based on efficiency, execution, speed, and regulatory compliance of all clinical laboratory operations. Mr. Zhou is also permitted, if and to the extent eligible, to participate in all employee benefit plans, policies and practices maintained by or on behalf of our company commensurate with his position.

As of April 1, 2023, we have agreed to pay Michael Lebowitz, our Chief Scientific Officer, an annual salary of $76,800 and he is also eligible discretionary bonuses, as determined by our board of directors. Mr. Lebowitz is also permitted, if and to the extent eligible, to participate in all employee benefit plans, policies and practices maintained by or on behalf of our company commensurate with his position.

Director Compensation

During 2022, our non-executive directors received total cash compensation of $38,200 for serving as directors. The total number of directors in the group was five. During 2022, our independent directors, Messrs. Compton, Rollins, Ross and Richard Cohen, were each granted (i) an option for the purchase of 37,583 shares of common stock that vested immediately and (ii) an option for the purchase of 37,584 shares of common stock that vests monthly over one year, each at an exercise price of $1.0643 per share.

Effective as of January 1, 2022, our independent directors, except for Jayson Lee and Ming Li, who represent an investor, are paid a cash fee of $15,000 per year, payable quarterly, with the chairman receiving an additional $5,000 per year and the committee chairs receiving an additional $2,500 per year.

Stock Incentive Plan

On January 26, 2022, our board of directors adopted the 20/20 GeneSystems, Inc. 2022 Stock Incentive Plan, or the Plan, which was approved by stockholders on June 15, 2022. Awards that may be granted include incentive stock options as described in section 422(b) of Internal Revenue Code of 1986, as amended, or the Code, non-qualified stock options (i.e., options that are not incentive stock options) and awards of restricted stock. These awards offer our employees, consultants, advisors and outside directors the possibility of future value, depending on the long-term price appreciation of our common stock and the award holder's continuing service with our company or one or more of its subsidiaries.

All of the permissible types of awards under the Plan are described in more detail as follows:

Purposes of Plan: The purpose of the Plan is to offer selected employees, consultants, advisors and outside directors the opportunity to acquire equity in our company.

Administration of the Plan: Administration of the Plan is entrusted to the compensation committee of the board of directors. Among other things, the committee has the authority to select persons who will receive awards, determine the types of awards and the number of shares to be covered by awards, and to establish the terms, conditions, restrictions and other provisions of awards.

Eligible Recipients: Persons eligible to receive awards under the Plan will be those employees, consultants, advisors and outside directors of our company and its subsidiaries who are selected by the compensation committee.

Shares Available Under the Plan: The maximum number of shares of common stock that may be delivered to participants under the Plan is 3,000,000, subject to adjustment for certain corporate changes affecting the shares, such as stock splits. Shares subject to an award under the Plan for which the award is canceled, forfeited or expires again become available for grants under the Plan. Shares subject to an award that is settled in cash will not again be made available for grants under the Plan.

Stock Options:

General. Subject to the provisions of the Plan, the compensation committee has the authority to determine all grants of stock options. That determination will include: (i) the number of shares subject to any option; (ii) the exercise price per share; (iii) the expiration date of the option; (iv) the manner, time and date of permitted exercise; (v) other restrictions, if any, on the option or the shares underlying the option; and (vi) any other terms and conditions as the compensation committee may determine.

Option Price. The exercise price for stock options will be determined at the time of grant. Normally, the exercise price will not be less than the fair market value on the date of grant, as determined in good faith by the compensation committee. As a matter of tax law, the exercise price for any incentive stock option awarded may not be less than the fair market value of the shares on the date of grant. However, incentive stock option grants to any person owning more than 10% of our voting stock must have an exercise price of not less than 110% of the fair market value on the grant date.

Exercise of Options. An option may be exercised only in accordance with the terms and conditions for the option agreement as established by the compensation committee at the time of the grant. The option must be exercised by notice to us, accompanied by payment of the exercise price. Payments may be made in cash or, at the option of the compensation committee, by actual or constructive delivery of shares of common stock to the holder of the option based upon the fair market value of the shares on the date of exercise.

Expiration or Termination. Options, if not previously exercised, will expire on the expiration date established by the compensation committee at the time of grant; provided that such term cannot exceed ten years and that such term of an incentive stock option granted to a holder of more than 10% of our voting stock cannot exceed five years. Options will terminate before their expiration date if the holder's service with us terminates before the expiration date. The option may remain exercisable for specified periods after certain terminations of service, including terminations as a result of death, disability or retirement, with the precise period during which the option may be exercised to be established by the compensation committee and reflected in the grant evidencing the award.

Stock Awards: Stock awards can also be granted under the Plan. A stock award is a grant of shares of common stock. These awards will be subject to such conditions, restrictions and contingencies as the compensation committee shall determine at the date of grant. Those may include requirements for continuous service and/or the achievement of specified performance goals.

Other Material Provisions: Awards will be evidenced by a written agreement, in such form as may be approved by the compensation committee. In the event of various changes to the capitalization of our company, such as stock splits, stock dividends and similar re-capitalizations, an appropriate adjustment will be made by the compensation committee to the number of shares covered by outstanding awards or to the exercise price of such awards. The compensation committee is also permitted to include in the written agreement provisions that provide for certain changes in the award in the event of a change of control of our company, including acceleration of vesting. Except as otherwise determined by the compensation committee at the date of grant, awards will not be transferable, other than by will or the laws of descent and distribution. Prior to any award distribution, we are permitted to deduct or withhold amounts sufficient to satisfy any employee withholding tax requirements. The board also has the authority, at any time, to discontinue the granting of awards. The board also has the authority to alter or amend the Plan or any outstanding award or may terminate the Plan as to further grants, provided that no amendment will, without the approval of our stockholders, increase the number of shares available under the Plan or change the persons eligible for awards under the Plan. No amendment that would adversely affect any outstanding award made under the Plan can be made without the consent of the holder of such award.

Except as set forth above, we do not have any ongoing plan or arrangement for the compensation of directors and executive officers.

SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN SECURITYHOLDERS

The following table sets forth information regarding beneficial ownership of our voting stock as of April 28, 2023 (i) by each of our executive officers and directors who beneficially owns more than 10% of any class of our voting securities; (ii) by all of our executive officers and directors as a group; and (iii) by each person who is known by us to beneficially own more than 10% of any class our voting securities. Since none of the foregoing own any of our series A-1 preferred stock, series B preferred stock or series C preferred stock, we have excluded columns for these shares from the table below. Unless otherwise specified, the address of each of the persons set forth below is in care of our company at 15810 Gaither Road, Suite 235, Gaithersburg, MD 20877.

Name and Address of Beneficial Owner	Amount Acquirable[1]			Percent of Common Stock[2]	Percent of Series A Preferred Stock[3]	Percent of Series A-2 Preferred Stock[4]	Percent of Total Voting Stock[5]
	Total Common Stock	Series A Preferred Stock	Series A-2 Preferred Stock				
Jonathan Cohen[6]	1,605,679	0	0	32.08%	*	*	16.69%
All directors and officers as a group[7]	2,698,797	13,029	21,535	54.05%	1.54%	4.87%	28.45%

*Less than 1%.

(1) Beneficial Ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Each of the beneficial owners listed above has direct ownership of and sole voting power and investment power with respect to the shares. For each beneficial owner above, any securities acquirable within 60 days have been included in the denominator in accordance with SEC Rule 13d-3(d)(1).

(2) Based on 4,765,311 shares of our common stock outstanding as of April 28, 2023.

(3) Based on 846,368 shares of our Series A Preferred Stock outstanding as of April 28, 2023.

(4) Based on 442,402 shares of our Series A-2 Preferred Stock outstanding as of April 28, 2023.

(5) percentage of total voting stock represents total ownership with respect to all shares of our common stock, series A preferred stock, series A-1 preferred stock, series A-2 preferred stock, series B preferred stock and series C preferred stock, as a single class and on an as-converted to common stock basis. As of April 28, 2023, there were 651,465 shares of series A-1 preferred stock, 1,471,487 shares of series B preferred stock and 1,204,040 shares of series C preferred stock issued and outstanding. Shares of series A preferred stock, series A-1 preferred stock, series A-2 preferred stock, series B preferred stock and series C preferred stock are convertible into shares of common stock on the basis of 1 share of common stock for each share of such preferred stock (subject to adjustment). Holders of series A preferred stock, series A-1 preferred stock, series A-2 preferred stock, series B preferred stock and series C preferred stock vote with the holders of common stock on all matters on an as-converted to common stock basis.

(6) Includes 1,366,400 shares of common stock and options for the purchase of 239,279 shares of common stock exercisable within 60 days.

(7) Includes 1,384,177 shares of common stock, options for the purchase of 1,311,954 shares of common stock and warrants for the purchase of 2,666 shares of common stock exercisable within 60 days.

INTEREST OF MANAGEMENT AND OTHERS IN CERTAIN TRANSACTIONS

The following includes a summary of transactions since the beginning of our 2021 fiscal year, or any currently proposed transaction, in which we were or are to be a participant and the amount involved exceeded or exceeds the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any related person had or will have a direct or indirect material interest (other than compensation described under "*Directors and Officers—Compensation of Directors and Executive Officers*"). We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

We utilize the services of Barry Cohen, the brother of the Chief Executive Officer, who is trained as a computer engineer and has over seven years' experience with clinical lab operations, to oversee our laboratory information systems and patient/physician portals. During the years ended December 31, 2022 and 2021, we paid Mr. Cohen $58,078 and $122,410, respectively.

DESCRIPTION OF SECURITIES

Capitalization

We are authorized to issue 25,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, $0.01 par value per share, of which 1,303,000 have been designated as series A preferred stock, 978,000 have been

designated as series A-1 preferred stock, 800,000 have been designated as series A-2 preferred stock, 3,569,405 have been designated as series B preferred stock and 3,340,909 have been designated as series C preferred stock.

As of the date of this report, there were issued and outstanding 4,765,311 shares of common stock held by 347 holders of record, 846,368 shares of series A preferred stock held by 71 holders of record, 651,465 shares of series A-1 preferred stock held by one holder of record, 442,402 shares of series A-2 preferred stock held by 1,831 holders of record, 1,471,487 shares of series B preferred stock held by 30 holders of record and 1,204,040 shares of series C preferred stock held by 2,512 holders of record.

Common Stock

Voting Rights. The holders of common stock are entitled to one (1) vote for each share held of record on all matters submitted to a vote of the stockholders. Under our certificate of incorporation and bylaws, any corporate action to be taken by vote of stockholders other than for election of directors shall be authorized by the affirmative vote of the majority of votes cast. Directors are elected by a plurality of votes. Stockholders do not have cumulative voting rights.

Dividends. Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation Rights. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Other Rights. Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock.

Preferred Stock

Our certificate of incorporation authorize our board to issue up to 10,000,000 shares of preferred stock in one or more series, to determine the designations and the powers, preferences and 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.

As noted above, we have designated multiple series of preferred stock, which we collectively refer to as the "Designated Preferred Stock." Below is a summary of the terms of the Designated Preferred Stock

Ranking. With respect to dividend rights and rights on liquidation, winding up and dissolution, shares of Designated Preferred Stock rank *pari passu* to each other and senior to all shares of common stock.

Voting Rights. Shares of Designated Preferred Stock vote together with the holders of common stock on an as-converted basis on all matters for which the holders of common stock vote at an annual or special meeting of stockholders or act by written consent, except as required by law. For so long as shares of Designated Preferred Stock are outstanding, the holders of such shares vote together, as a separate class, to elect one director to our board, and for so long as shares of series A-1 preferred stock are outstanding, the holders of Series A-1 Preferred Stock vote together, as a separate class, to elect one director to our board.

Conversion Rights. Each share of Designated Preferred Stock is convertible at any time at the option of the holder at the then current conversion rate. The conversion rate for the Designated Preferred Stock is currently one share of common stock for each share of Designated Preferred Stock, calculated by dividing the liquidation preference of such share by the conversion price then in effect. In addition, all outstanding shares of Designated Preferred Stock, plus accrued but unpaid dividends thereon, shall automatically be converted into shares of common stock, at the then effective conversion rate, upon the earlier to occur of (a) the closing of the sale of shares of common stock to the public at a price of at least $8.15 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with

respect to the common stock) in a public offering pursuant to an effective registration statement or offering statement under the Securities Act resulting in at least $5,000,000 of gross proceeds to us, (b) the date on which the shares of common stock are listed on a national stock exchange, including without limitation the New York Stock Exchange or the Nasdaq Stock Market, or (c) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least 67% of the then outstanding shares of Designated Preferred Stock, voting together on an as-converted to common stock basis (which vote or consent shall include the holders of at least 67% of the shares of series A-1 preferred stock outstanding voting as a separate class).

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of our company or a deemed liquidation event, each holder of Designated Preferred Stock then outstanding shall be entitled to be paid out of the cash and other assets of our company available for distribution to its stockholders, prior and in preference to all shares of common stock, an amount in cash equal to the aggregate liquidation preference of all shares held by such holder. The shares of series A preferred stock, series A-1 preferred stock, series A-2 preferred stock, series B preferred stock and series C preferred stock have a liquidation preference of $3.07, $3.07, $3.26, $3.53 and $4.40, respectively (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization) plus any accrued and unpaid dividends. If upon any liquidation or deemed liquidation event the remaining assets available for distribution are insufficient to pay the holders of Designated Preferred Stock the full preferential amount to which they are entitled, the holders of Designated Preferred Stock shall share ratably in any distribution of the remaining assets and funds in proportion to the respective full preferential amounts which would otherwise be payable, and we shall not make or agree to make any payments to the holders of common stock. A "deemed liquidation event" means, unless otherwise determined by the holders of at least a majority of the Designated Preferred Stock then outstanding (voting together as a single class on an as-converted basis), (a) a sale of all or substantially all of our assets to a non-affiliate, (b) a merger, acquisition, change of control, consolidation or other transactions or series of transactions in which stockholders prior to such transaction or series of transactions do not retain a majority of the voting power of the surviving entity immediately following such transaction or series of transactions, or (c) the grant of an exclusive license to all or substantially all of our technology or intellectual property rights except where such exclusive license is made to one or more wholly-owned subsidiaries.

Dividends. The Designated Preferred Stock will not be entitled to dividends or distributions unless and until the board declares a dividend or distribution in cash or other property to holders of outstanding shares of common stock, in which event, the aggregate amount of such each distribution shall be distributed as follows: (a) first, seventy percent (70%) of the distribution amount to the holders of shares of Designated Preferred Stock, on a pro rata basis, until such time as such holders have received an aggregate amount in distributions or other payments in respect of such holder's shares that is equal to the number of shares owned by such holders multiplied by the liquidation preference stated above, and (b) second, thirty percent (30%) of the distribution amount to the holders of shares of common stock, on a pro rata basis. Notwithstanding the foregoing, at such time as the holders of Designated Preferred Stock and common stock have received the amounts described above, the holders of the Designated Preferred Stock shall receive distributions *pari passu* with the holders of the common stock on an as-converted basis, using the then-current conversion rate of such shares of Designated Preferred Stock.

Preemptive Rights. Until our initial public offering of common stock occurs and unless otherwise waived by the prior express written consent of the holders of the majority of the voting power of all then outstanding Designated Preferred Stock, voting together on an as-converted to common stock basis, in the event that we propose to issue any common stock or shares convertible or exercisable for common stock, except for certain excluded issuances, we must first offer those additional equity securities to holders of Designated Preferred Stock for a period of no less than thirty (30) days prior to selling or issuing any such additional equity securities to any person, in accordance with the procedures set forth in our certificate of incorporation, as amended. For purposes hereof, "excluded securities" means the issuance of shares of common stock or securities convertible into shares of common stock (a) granted pursuant to or issued upon the exercise of stock options granted under an equity incentive plan to employees, officers, directors, consultants or strategic partners, (b) granted to employees, officers, directors, consultants or strategic partners for services, including in connection with an incentive plan, or other fair value received or committed, (c) in consideration for a transaction approved by the board which does not result in the issuance for cash of more than five percent (5%) of the outstanding shares of common stock, (d) in connection with an acquisition transaction approved by the board, (e) to vendors, commercial partners, financial institutions or lessors in connection with commercial credit transactions, equipment financings or similar transaction approved by the board (provided that such securities do not exceed 10% of the consideration in such transaction), (f) pursuant to conversion or exchange rights included in securities previously issued by us or (g) in connection with a stock split, stock division, reclassification, stock dividend or other recapitalization.

Redemption. Shares of each series of Designated Preferred Stock are not redeemable without the prior express written consent of the holders of the majority of the voting power of all then outstanding shares of such applicable series of Designated Preferred Stock, voting as a separate class.

Protective Rights. So long as at least twenty-five percent (25%) of the Designated Preferred Stock collectively remains outstanding, in addition to any other vote or consent of stockholders required by law, the vote or consent of the holders of at least a majority of all shares of Designated Preferred Stock then outstanding and entitled to vote thereon, voting together and on an as-converted to common stock basis, given in person or by proxy, either in writing without a meeting or by vote at any meeting called for the purpose, including the consent of the holders of series A-1 preferred stock, shall be necessary for effecting or validating, either directly or indirectly by amendment, merger, consolidation or otherwise:

(a) the authorization, creation and/or issuance of any equity security, other than shares of common stock or options to purchase common stock issued to investors, employees, managers, officers or directors of, or consultants or advisors to, our company or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the board;

(b) the amendment, alteration or repeal of any provision of the certificate of incorporation or bylaws or otherwise alter or change any right, preference or privilege of any Designated Preferred Stock in a manner adverse to the holders thereof;

(c) any increase or decrease in the size of the board;

(d) the purchase, redemption, or acquisition of any shares other than from a selling holder pursuant to the provisions of the certificate of incorporation or any other restriction provisions applicable to any shares in agreements approved by the board or in the operating agreement of any limited liability company utilized for the purpose of facilitating investment in our company;

(e) the liquidation or dissolution of our company or the sale, lease, pledge, mortgage, or other disposal of all or substantially all of its assets;

(f) any election to engage in any business that deviates in any material respect from our business as contemplated under any operating plan approved by the board;

(g) the waiver of any adjustment to the conversion price applicable to the Designated Preferred Stock; or

(h) any declaration or payment of any cash dividend or other cash distribution to any holders of capital stock.

Stock Options

As of the date of this report, we have issued options to purchase an aggregate of 1,834,585 shares of common stock at a weighted average exercise price of $1.70 per share.

Warrants

As of the date of this report, we have issued warrants to purchase an aggregate of 71,993 shares of common stock at a weighted average exercise price of $1.02 per share.

Convertible Notes

On August 15, 2022, we launched an equity crowdfunding offering under Section 4(a)(6) of the Securities Act and Regulation Crowdfunding promulgated thereunder, pursuant to which we offered convertible promissory notes, which such offering was terminated on December 15, 2022. As of December 31, 2022, we issued convertible promissory notes in the aggregate principal amount of $213,010. The notes bear interest at rates ranging from 6% to 11.10% and are due and payable twenty-four (24) months after the date of issuance. The notes are unsecured and contain customary events of default. The notes are convertible into our common stock as follows:

- In the event that we issue and sell common stock or preferred stock to investors in a transaction or series of transactions resulting in gross proceeds of at least $100,000, excluding debt or the issuance of common stock or preferred stock in asset purchase or strategic merger or acquisition, which we refer to as a Qualified Financing, then the entire unpaid principal amount and all accrued, but unpaid interest shall convert into common stock at conversion price equal to the lesser of (i) 10% of the per share price paid by such investors or (ii) the price equal to the quotient of $58,400,000 divided by the aggregate number of outstanding shares of common stock as of immediately prior to the initial closing of the Qualified Financing (assuming full conversion or exercise of all convertible and exercisable securities then outstanding other than these notes);

- In the event we complete an equity financing in which we sell common stock or preferred stock in a transaction that

does not constitute a Qualified Financing, then the note holder has the option to treat such equity financing as a Qualified Financing on the same terms set forth herein;

- Upon the earlier to occur of (i) the closing of the sale of common stock to the public at a price of at least $8.15 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock) in a public offering pursuant to an effective registration statement or offering statement (Regulation A) under the Securities Act resulting in at least $5,000,000 of gross proceeds, (ii) the date on which our common stock is listed on a national stock exchange, including without limitation, NYSE American or the Nasdaq Capital Market, or (iii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least a majority in principal amount of the then outstanding notes, then the entire unpaid principal amount and all accrued, but unpaid interest shall convert into common stock at conversion price equal to the quotient of $58,400,000 divided by the aggregate number of outstanding shares of common stock as of immediately prior to the consummation of the event described above; and

- The entire outstanding principal balance and all unpaid accrued interest shall automatically be converted into common stock at a conversion price equal to the quotient of $58,400,000 divided by the aggregate number of outstanding shares of common stock as of immediately prior to the conversion (assuming full conversion or exercise of all convertible and exercisable securities then outstanding other than these notes) as soon a reasonably practicable following the maturity date.

Transfer Agent

VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598, telephone 212-828-8436, is the transfer agent for our common stock and preferred stock.

OTHER INFORMATION

We have not failed to comply with the ongoing reporting requirements of Regulation CF in the past.

SIGNATURE

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding, the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C-AR and has duly caused this Form to be signed on its behalf by the duly authorized undersigned.

Date: May 1, 2023

20/20 GENESYSTEMS, INC.

/s/ Jonathan Cohen
Name: Jonathan Cohen
Title: Chief Executive Officer
(Principal Executive Officer)

/s/ Anne Shiflett
Name: Anne Shiflett
Title: Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding, this Form C-AR has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Jonathan Cohen Jonathan Cohen	Chief Executive Officer, President and Director (principal executive officer)	May 1, 2023
/s/ Anne Shiflett Anne Shiflett	Acting Chief Financial Officer (principal financial and accounting officer)	May 1, 2023
/s/ John G. Compton John G. Compton	Chairman of the Board	May 1, 2023
/s/ Richard M. Cohen Richard M. Cohen	Director	May 1, 2023
/s/ John W. Rollins John W. Rollins	Director	May 1, 2023
/s/ Michael A. Ross Michael A. Ross	Director	May 1, 2023

EXHIBIT A
FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
20/20 GeneSystems, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of 20/20 GeneSystems, Inc. (the "Company") as of December 31, 2022 and 2021, and the related statement of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes (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, 2022 and 2021, and the results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

The 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 the 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 audits 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/ dbb*mckennon*
Newport Beach, California
May 1, 2023
We have been the Company's auditor since 2018.

20/20 GENESYSTEMS, INC.
BALANCE SHEETS
DECEMBER 31, 2022 AND 2021

	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 8,807,575	$ 3,354,469
Accounts receivable, net	764,924	4,215,465
Inventory	87,074	246,658
Prepaid expenses	72,270	125,664
Total current assets	9,731,843	7,942,256
License agreement, net	547,438	367,713
Property and equipment, net	580,911	511,910
Intangible assets, net	179,403	213,885
Right of use assets	1,088,783	1,168,471
Due from affiliated entities	2,699	2,699
Other assets	83,944	65,347
Total assets	$ 12,215,021	$ 10,272,281
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 464,282	$ 834,269
Accrued liabilities	649,795	1,121,607
Deferred revenue	316,222	152,698
Financing lease liabilities – current	46,575	56,714
Lease liability – current	153,297	88,314
Total current liabilities	1,630,171	2,253,602
Long-term liabilities:		
Convertible note payable, net of unamortized debt discount	207,246	-
Financing lease liabilities – long term	-	48,725
Lease liability – long term	1,003,338	1,080,157
Total long-term liabilities	1,210,584	1,128,882
Total liabilities	2,840,755	3,382,484
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Series C preferred stock, $0.01 par value; 3,340,909 authorized; 1,204,040 and 1,205,069 shares issued and outstanding as of December 31, 2022 and 2021, respectively; liquation preference of $5,297,776 and $5,302,304	12,043	12,051
Series B preferred stock, $0.01 par value; 3,569,405 authorized; 1,471,487 shares issued and outstanding as of December 31, 2022 and 2021; liquation preference of $5,194,349	14,715	14,715
Series A-2 preferred stock, $0.01 par value; 800,000 authorized; 442,402 shares issued and outstanding as of December 31, 2022 and 2021; liquation preference of $1,442,231	4,424	4,424
Series A-1 preferred stock, $0.01 par value; 978,000 authorized; 651,465 shares issued and outstanding as of December 31, 2022 and 2021; liquation preference of $1,999,998	6,515	6,515
Series A preferred stock, $0.01 par value; 1,303,000 authorized; 846,368 shares issued and outstanding as of December 31, 2022 and 2021; liquation preference of $2,598,350	8,464	8,464
Common stock, $0.01 par value; 25,000,000 authorized; 4,764,811 and 4,762,572 shares issued and outstanding as of December 31, 2022 and 2021, respectively	47,648	47,626
Additional paid-in capital	26,845,879	26,548,299

Accumulated deficit	(17,565,422)	(19,752,297)
Total stockholders' equity	9,374,266	6,889,797
Total liabilities and stockholders' equity	$ 12,215,021	$ 10,272,281

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	2022	2021
Revenues	$ 11,059,145	$ 9,622,332
Cost of revenues	5,937,398	4,927,374
Gross profit	5,121,747	4,694,958
Operating expenses:		
Sales, general and administrative	3,322,835	2,559,493
Research and development	120,043	193,368
Total operating expenses	3,442,878	2,752,861
Operating income	1,678,869	1,942,097
Other income (expense):		
Interest expense	(15,685)	(12,930)
Interest income	68,421	2,994
Gain on sale of asset	2,371	-
Other expense	-	(5,900)
Other income	452,899	145,516
Total other income (expense)	508,006	129,680
Provision for income taxes	-	-
Net income	$ 2,186,875	$ 2,071,777
Basic net income per common share	$ 0.46	$ 0.44
Diluted net income per common share	$ 0.23	$ 0.22
Weighted-average common shares outstanding, basic	4,763,561	4,729,415
Weighted-average common shares outstanding, diluted	9,487,385	9,463,282

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	Series C Preferred Stock		Series B Preferred Stock		Series A-2 Preferred Stock		Series A-1 Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2020	858,327	$ 8,584	1,471,487	$ 14,715	442,402	$ 4,424	651,465	$ 6,515	846,368	$ 8,464	4,728,833	$ 47,288	$25,123,303	$ (21,824,074)	$ 3,389,219
Stock based compensation	-	-	-	-	-	-	-	-	-	-	-	-	182,680	-	182,680
Exercise of warrants	-	-	-	-	-	-	-	-	-	-	3,374	34	-	-	34
Issuance of preferred stock, net of offering costs	377,107	3,771	-	-	-	-	-	-	-	-	-	-	1,242,316	-	1,246,087
Conversion of preferred stock	(30,365)	(304)	-	-	-	-	-	-	-	-	30,365	304	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	-	2,071,777	2,071,777
Balance, December 31, 2021	1,205,069	$ 12,051	1,471,487	$ 14,715	442,402	$ 4,424	651,465	$ 6,515	846,368	$ 8,464	4,762,572	$ 47,626	$26,548,299	$ (19,752,297)	$ 6,889,797
Stock based compensation	-	-	-	-	-	-	-	-	-	-	-	-	297,582	-	297,582
Exercise of warrants	-	-	-	-	-	-	-	-	-	-	1,210	12	-	-	12
Conversion of preferred stock	(1,029)	(8)	-	-	-	-	-	-	-	-	1,029	10	(2)	-	-
Net income	-	-	-	-	-	-	-	-	-	-	-	-	-	2,186,875	2,186,875
Balance, December 31, 2022	1,204,040	$ 12,043	1,471,487	$ 14,715	442,402	$ 4,424	651,465	$ 6,515	846,368	$ 8,464	4,764,811	$ 47,648	$26,845,879	$ (17,565,422)	$ 9,374,266

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 2,186,875	$ 2,071,777
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	194,053	101,161
Stock based compensation	176,082	182,680
Amortization of license fees	26,784	22,500
Forgiveness of debt (PPP loan)	-	(144,107)
Amortization of ROU assets, net of liabilities	67,852	-
Amortization of debt discount	1,529	-
Gain on sale of asset	3,379	-
Impairment of intangibles	24,091	-
Changes in operating assets and liabilities:		
Accounts receivable	1,937,689	(4,010,394)
Other receivables	1,547,118	-
Inventory	159,584	(143,217)
Prepaid expenses and other	34,798	(118,928)
Accounts payable	(248,487)	363,214
Accrued liabilities	(471,812)	519,069
Deferred revenue	163,524	82,242
Net cash provided by (used in) operating activities	5,803,059	(1,074,003)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(261,793)	(228,150)
Acquisition of license agreement	(206,509)	-
Proceeds from the sales of equipment	5,750	-
Net cash used in investing activities	(462,552)	(228,150)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from convertible notes payable	183,166	-
Convertible notes payable financing costs	(11,715)	-
Principal payments on financing lease liabilities	(58,864)	(57,692)
Proceeds from exercise of warrant	12	34
Proceeds from sale of preferred stock, net of offering costs	-	1,246,088
Net cash provided by financing activities	112,599	1,188,430
Increase (decrease) in cash and cash equivalents	5,453,106	(113,723)
Cash and cash equivalents, beginning of period	3,354,469	3,468,192
Cash and cash equivalents, end of period	$ 8,807,575	$ 3,354,469
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
Non-cash disclosures of cash flow information:		
Conversion of Series C Preferred Stock to Common Stock	$ 8	$ 304
Escrow of convertible notes payable principal	$ 29,843	$ -
Accrued liability reclassed to equity	$ 121,500	$ -
Forgiveness of debt (PPP loan)	$ -	$ 144,107
Operating lease, ROU assets and liabilities	$ 103,276	$ 1,168,470
Equipment acquired under a financing lease	$ -	$ 173,915

20/20 GENESYSTEMS, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

See accompanying notes to the financial statements

NOTE 1 – BUSINESS AND NATURE OF OPERATIONS

20/20 GeneSystems, Inc. (the "Company"), founded in May 2000, is a commercial stage diagnostics company with the core mission of developing and commercializing clinical laboratory tests for early disease detection and prevention and associated software that is powered by machine learning and real-world data to improve diagnostic accuracy and clinical utility.

For early cancer detection, the Company uses machine learning and real-world data analytics approaches to substantially improve the accuracy of tumor biomarkers that are currently tested in millions of individuals around the world. The Company's cancer product, known as OneTest, is a multi-cancer test for screening at least five types of cancer from one blood sample.

In response to the novel coronavirus pandemic that began in early 2020, the Company expanded its business and acquired and commercialized several COVID-19 serology (antibody) and viral (RT-PCR) tests, both rapid kits and laboratory-based tests.

The Company's legacy business includes a patented field test kit for screening suspicious powders for bioterror agents that is used regularly by hundreds of first responder organizations worldwide, known as BioCheck.

To increase its menu of innovative tests faster and at a lower cost and risk than through internal development, in 2021, the Company established its Clinical Laboratory Innovation Accelerator ("CLIAx"), which permits diagnostics start-up companies from around the world to launch their laboratory developed tests in the Company's CLIA (Clinical Laboratory Improvement Amendments) licensed laboratory using shared equipment and laboratory personnel.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles ("U.S. GAAP") requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements, and the reported amount of revenues and expenses during the reporting periods. Actual results could materially differ from these estimates. It is reasonably possible that changes in estimates will occur in the near term. The use of estimates include revenue recognition, impairment of long-lived assets, stock-based compensation and expense accruals.

Business Segments

The Company has determined that its current business and operations consist of one reporting segment.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants as of the measurement date. Applicable accounting guidance provides an established hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors that market participants would use in valuing the asset or liability. There are three levels of inputs that may be used to measure fair value:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 – Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

Fair value estimates discussed herein are based upon certain market assumptions and pertinent information available to management as of December 31, 2022 and 2021. The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values. These financial instruments include cash, accounts payable and accrued liabilities. Fair values for these items were assumed to approximate carrying values because of their short-term nature or they are payable on demand.

Cash and Cash Equivalents

The Company considers time deposits, certificates of deposit, and certain investments with an original maturity of three months or less to be cash equivalents.

Accounts Receivable

Accounts receivable represent amounts due from commercial customers. On December 31, 2022 and 2021, customer accounts receivable totaled $764,924 and $4,215,465, respectively. Receivables through a third-party provider for insurance claims of $547,438 and $2,060,695 are included in this balance at December 31, 2022 and 2021, respectively. The payment of consideration related to these third-party receivables is subject only to the passage of time. Management reviews open accounts monthly and takes appropriate steps for collection. When needed, an allowance for doubtful accounts is recorded to reflect management's determination of the amount deemed uncollectable. An allowance for doubtful accounts of $62,460 and $40,100 is included in accounts receivable at December 31, 2022 and 2021, respectively.

Inventories

Inventories are stated at the lower of cost or market using the first-in, first out (FIFO) method. Inventories consisted entirely of finished goods as of December 31, 2022 and 2021.

Internal Use Software

The Company incurs software development costs to develop software programs to be used solely to meet its internal needs and cloud-based applications used to deliver its services. In accordance with Accounting Standards Codification ("ASC") 350-40, *Internal-Use Software*, the Company capitalizes development costs related to these software applications once the preliminary project stage is complete and it is probable that the project will be completed, the software will be used to perform the function intended, and the value will be recoverable. Reengineering costs, minor modifications and enhancements that do not significantly improve the overall functionality of the software are expensed as incurred.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful life of three (3) to seven (7) years. Significant renewals and betterments are capitalized while maintenance and repairs are charged to expense as incurred. Leasehold improvements are amortized on the straight-line basis over the lesser of their estimated useful lives or the term of the related lease, whichever is shorter. Gains or losses on dispositions of assets are reflected in other income or expense.

Intangible Assets – Patents

The Company capitalizes patent filing fees, and it expenses legal fees, in connection with internally developed pending patents. The Company also will capitalize patent defense costs to the extent these costs enhance the economic value of an existing patent. The Company evaluates the capitalized costs annually to determine if any amounts should be written down. Patent costs begin amortizing upon approval by the corresponding government and are generally amortized over the expected period to be benefitted, not to exceed the patent lives, which may be as long as 20 years.

Impairment of Long-Lived Assets

The long-lived assets held and used by the Company are reviewed for impairment no less frequently than annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In the event that facts and circumstances indicate that the cost of any long-lived assets may be impaired, an evaluation of recoverability is performed. The impairment losses for the years ended December 31, 2022 and 2021 were $24,091 and $0 for certain patent costs, respectively. There can be no assurance, however, that market conditions will not change or demand for the Company's products and services will continue, which could result in impairment of long-lived assets in the future.

Offering Costs

The Company complies with the requirements of ASC 340 with regards to offering costs. Prior to the completion of an offering, offering costs will be capitalized as deferred offering costs on the balance sheet. The deferred offering costs will be charged to stockholders' equity upon the completion of an offering or to expense if the offering is not completed.

Preferred Stock

ASC 480, *Distinguishing Liabilities from Equity*, includes standards for how an issuer of equity (including equity shares issued by consolidated entities) classifies and measures on its balance sheet certain financial instruments with characteristics of both liabilities and equity.

Management is required to determine the presentation for the Preferred Stock as a result of the redemption and conversion provisions, among other provisions in the agreement. Specifically, management is required to determine whether the embedded conversion feature in the Preferred Stock is clearly and closely related to the host instrument, and whether the bifurcation of the conversion feature is required and whether the conversion feature should be accounted for as a derivative instrument. If the host instrument and conversion feature are determined to be clearly and closely related (both more akin to equity), derivative liability accounting under ASC 815, *Derivatives and Hedging*, is not required. Management determined that the host contract of the Preferred Stock is more akin to equity, and accordingly, derivative liability accounting is not required by the Company.

Costs incurred directly for the issuance of the Preferred Stock are recorded as a reduction of gross proceeds received by the Company.

Basic and Diluted Loss Per Share

The Company follows Financial Accounting Standards Board ("FASB") ASC 260, *Earnings per Share*, to account for earnings per share. Basic earnings per share calculations are determined by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted earnings per share calculations are determined by dividing net income by the weighted average number of common shares and dilutive common share equivalents outstanding. Dilutive common share equivalents include the dilutive effect of in-the-money share equivalents, which are calculated, based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an award, if any, the amount of compensation cost, if any, for future service that the Company has not yet recognized, and the estimated tax benefits that would be recorded in paid-in capital, if any, when an award is settled are assumed to be used to repurchase shares in the current period. During periods when common stock equivalents, if any, are anti-dilutive they are not considered in the computation.

The following is a summary of outstanding securities which have been included in the calculation of diluted net income per share and reconciliation of net income to net income available to common stockholders for the years ended December 31, 2022 and 2021.

	2022	2021
Weighted average common shares outstanding used in calculating basic earnings per share	4,763,561	4,729,415
Warrants to purchase Common Stock	54,751	64,093
Options to purchase Common Stock	53,311	52,983
Series C Preferred Stock	1,204,040	1,205,069
Series B Preferred Stock	1,471,487	1,471,487
Series A-2 Preferred Stock	442,402	442,402
Series A-1 Preferred Stock	651,465	651,465
Series A Preferred Stock	846,368	846,368
Weighted average common shares outstanding used in calculating diluted earnings per share	9,487,385	9,463,282

The Company excluded 163,196 options and 15,069 warrants from the computation of diluted net income per share for the year ended December 31, 2022 as their exercise prices were in excess of the most recent valuation of the Company's common stock during that period.

The Company excluded 191,152 options and 15,005 warrants from the computation of diluted net income per share for the year ended December 31, 2021 as their exercise prices were in excess of the most recent valuation of the Company's common stock during that period. There are no material reconciling items to net income to diluted net income for common shareholders.

Revenue Recognition

In accordance with ASC Topic 606, *Revenue from Contracts with Customers*, the Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which it expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements that the Company deems are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) calculate transfer price; (iv) allocate the transaction price to the performance obligation in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Disaggregated Revenue – The Company disaggregates revenue from contracts with customers by contract type, as it believes it best depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors.

The Company's revenue by contract type is as follows:

	For the Years Ended December 31,	
	2022	**2021**
Revenues		
BioCheck	$ 154,660	$ 193,063
OneTest	323,414	360,290
COVID-19 PCR Tests	10,393,256	8,669,557
COVID-19 Antibody/Antigen Tests	97,452	399,422
CLIAx	90,363	-
Total revenues	$ 11,059,145	$ 9,622,332

Performance Obligations – Performance obligations for four different types of services are discussed below:

- OneTest – Revenues from the sale of OneTest is recognized when returned serum specimens are analyzed in the Company's CLIA laboratory and the results are reported. Due to the nature of OneTest, revenue per test is recorded based on historical average receipts from patients.

- BioCheck – Revenues for kits is recognized when purchase orders are processed and kits are shipped to customers.

- COVID-19 Tests:
    - Point-of-Care (POC) Test Kits – Revenues for COVID-19 distributed test kits for use at the POC (i.e., rapid antigen and antibody tests) are recognized when purchase orders are processed, and test kits are shipped to customers.
    - COVID-19 Lab Tests (PCR) – Revenues from the sale of COVID-19 viral (PCR) tests is recognized when returned nasal swabs are analyzed in the Company's CLIA laboratory and the results are reported. Due to the nature of PCR tests, revenue per test is recorded based on historical average receipts from insurance payers, Medicare, Medicaid, nursing homes or County government.
- CLIAx – Revenue from providing CLIAx customers with laboratory services and co-marketing activities of the CLIAx clients laboratory developed tests. Revenue for laboratory services are recognized monthly based on agreed laboratory activities for space, equipment use and contracted personnel. Additional revenue can be earned through the selling of the customer's products.

Deferred revenue represents contract liabilities that are recorded when cash payments are received or are due in advance of our satisfaction of performance obligations. The deferred revenue for the years ended December 31, 2022 and 2021 were $316,222 and $152,698, respectively, and are related to OneTest.

Seasonality

The Company's significant growth in COVID-19 viral testing solutions is affected by the pattern of seasonality subject to the unpredictable demand for viral testing in Maryland. With the significant decline in incidences and requirement for testing, the Company has anticipated the material decrease in revenue and cash flow related to the COVID-19 testing.

Shipping and Handling

Amounts billed to a customer for shipping and handling are reported as revenues. Costs related to shipments to the Company are classified as cost of sales and totaled $258,837 and $172,722 for the years ended December 31, 2022 and 2021, respectively.

Research and Development

The Company incurs research and development costs during the process of researching and developing the Company's laboratory tests, algorithms, information technologies, and other intellectual properties. The Company's research and development costs consist primarily of data acquisition and personnel costs of scientists and laboratory technicians. The Company expenses these costs as incurred until the resulting product has been completed, tested, validated, and made ready for commercial use.

Advertising

The Company expenses advertising costs as incurred. Advertising expenses were $358,337 and $243,591 for the years ended December 31, 2022 and 2021, respectively.

Stock-Based Compensation

The Company accounts for stock awards issued under ASC 718, *Compensation – Stock Compensation*. Under ASC 718, stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award. Stock-based compensation is recognized as expense over the employee's requisite vesting period and over the nonemployee's period of providing goods or services. The fair value of each stock option or warrant award is estimated on the date of grant using the Black-Scholes option valuation model. Restricted shares are measured based on the fair market value of the underlying stock on the grant date.

Income Taxes

The Company applies ASC 740, *Income Taxes*. Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial statement reported amounts at each period end, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The provision for income taxes represents the tax expense for the period, if any and the change during the period in deferred tax assets and liabilities. At December 31, 2022 and 2021, the Company has established a full allowance against all deferred tax assets.

ASC 740 also provides criteria for the recognition, measurement, presentation, and disclosure of uncertain tax positions. A tax benefit from an uncertain position is recognized only if it is "more likely than not" that the position is sustainable upon examination by the relevant taxing authority based on its technical merit. Interest and penalties, if any, are accrued as a component of operating expenses when assessed.

Concentrations

The Company maintains its cash at various financial institutions located in the United States of America which it believes to be credit worthy. Balances are insured by the Federal Deposit Insurance Corporation up to $250,000. At times, the Company maintains balances in excess of the federally insured limits. The Company has not experienced any losses with respect to its cash balances.

As of December 31, 2022, approximately 51% of total accounts receivable were due from one source. As of December 31, 2021, approximately 91% of total accounts receivable were due from two sources. During the year ended December 31, 2022, approximately 94% of total revenues were received from two sources. During the year ended December 31, 2021, approximately 76% of total revenues were received from two sources. With the decline in COVID-19 incidences, one of the Company's customers stopped testing in September 2022 and the other has slowed down considerably with the possibility of ceasing their COVID-19 testing in May 2023. The Company anticipated the significant impact the slow-down in demand for this testing in its 2023 forecasted revenue and cash flow.

Risks and Uncertainties

In response to the novel coronavirus pandemic that began in early 2020, the Company expanded its business and offered several COVID-19 testing solutions, both rapid kits and laboratory-based tests. In the fourth quarter of 2022 and into 2023, revenues from COVID-19 have decreased substantially.

Recent Accounting Pronouncements

Management does not believe that any recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

NOTE 3 – PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31, 2022	December 31, 2021
Office equipment	$ 160,669	$ 162,100
Furniture and fixtures	54,112	31,118
Laboratory equipment	896,636	864,734
Vehicles	40,555	-
Leasehold improvements	12,221	5,700
Total property and equipment	1,164,193	1,063,652
Less accumulated depreciation	(583,282)	(551,742)
	$ 580,911	$ 511,910

Depreciation expense was $183,662 and $84,377 for the years ended December 31, 2022 and 2021, respectively.

NOTE 4 – INTANGIBLE ASSETS

Intangible assets consisted of the following:

	December 31, 2022	December 31, 2021
Issued patents (amortized)	$ 31,840	$ 31,840
Unissued patents (unamortized)	177,423	201,514
Software development costs	45,575	45,575
Total patents	254,838	278,929
Less accumulated amortization	(75,435)	(65,044)
	$ 179,403	$ 213,885

Amortization expense for intangible assets was $10,391 and $16,784 for the years ended December 31, 2022 and 2021, respectively.

NOTE 5 – FINANCING LEASES

In January 2021, the Company leased certain equipment under separate non-cancelable equipment loan and security agreements. The agreements mature in December 2023. The agreements require various monthly payments of principal and interest through maturity and are secured by the assets under lease. As of December 31, 2022, $173,915 of financing lease equipment and $47,507 of accumulated depreciation are included in property and equipment on the balance sheets. The weighted average interest rate was 6.2% at December 31, 2022.

Future minimum lease payments under the leases as of December 31, 2022 are as follows:

2023	$ 59,210
Total lease payments	59,210
Less: amount representing interest	(1,851)
Total lease payments	$ 57,359

As of December 31, 2022, the weighted-average remaining lease term for all finance leases is 1.0 years.

NOTE 6 – OPERATING LEASES

In August 2011, the Company entered into a lease commencing in December 2011 which expired in November 2016. Under the lease agreement, the Company was to pay an annual rent of $134,975, plus additional operating expenses. Upon expiration, this lease had continued on a month-to-month basis until March 2022. Total rent expense, including additional operating expenses related to this property, was $22,720 and $173,351 for the years ended December 31, 2022 and 2021, respectively. In early 2022, the Company vacated the property and entered into an agreement to settle any remaining obligations due.

On March 18, 2021, the Company entered into a lease agreement with Shady Grove Development Park IX L.L.L.P. for a new office and laboratory space totaling 5,511 square feet in Gaithersburg, Maryland. The term of the lease commenced on December 1, 2021 and shall expire 88 months thereafter. The initial monthly rent is $10,676 with annual increases to $17,308 for the final year of the lease. The Company will also pay its 7.75% pro rata portion of the property taxes, operating expenses and insurance costs and is also responsible to pay for the utilities used on the premises.

On September 29, 2022, the Company entered into a lease agreement with Abbott Laboratories, Inc. for laboratory equipment (analyzer). The term of the lease commenced on December 1, 2022 and shall expire 84 months thereafter. The monthly rental payments are $1,488 throughout the term of the lease. The Company also has a commitment to purchase $86 thousand of consumables annually during the term of the lease.

Supplemental balance sheet information related to this lease is as follows:

	December 31, 2022
Operating lease right-of-use lease asset	$ 1,242,936
Accumulated amortization	(154,153)
Net balance	$ 1,088,783
Lease liability, current portion	153,296
Lease liability, long term	1,003,339
Total operating lease liabilities	$ 1,156,635
Weighted Average Remaining Lease Term – operating leases	79 months
Weighted Average Discount Rate – operating leases	9.026%

Future minimum lease payments under this operating lease as of December 31, 2022, were as follows:

2023	194,758
2024	199,629
2025	204,632
2026	209,767
Thereafter	503,790
Total lease payments	1,312,576
Less imputed interest	(155,941)
Maturities of lease liabilities	$ 1,156,635

NOTE 7 – CONVERTIBLE NOTE PAYABLE

On August 15, 2022, the Company launched an equity crowdfunding offering under Section 4(a)(6) of the Securities Act of 1933, as amended (the "Securities Act"), and Regulation Crowdfunding promulgated thereunder, pursuant to which the Company offered convertible promissory notes. As of December 31, 2022, the Company issued convertible promissory notes in the aggregate principal amount of $213,010. The notes bear interest at rates ranging from 6% to 11.10%, cannot be prepaid without a majority investor vote and are due and payable twenty-four (24) months after the date of issuance. The notes are unsecured, contain customary events of default and are convertible into Common Stock as follows:

- In the event that the Company issues and sells Common Stock or Preferred Stock to investors in a transaction or series of transactions resulting in gross proceeds of at least $100,000, excluding debt or the issuance of Common Stock or Preferred Stock in asset purchase or strategic merger or acquisition (a "Qualified Financing"), then the entire unpaid principal amount and all accrued, but unpaid interest shall convert into Common Stock at conversion price equal to the lesser of (i) 10% of the per share price paid by such investors or (ii) the price equal to the quotient of $58,400,000 divided by the aggregate number of outstanding shares of Common Stock as of immediately prior to the initial closing of the Qualified Financing (assuming full conversion or exercise of all convertible and exercisable securities then outstanding other than these notes);

- In the event the Company completes an equity financing in which it sells Common Stock or Preferred Stock in a transaction that does not constitute a Qualified Financing, then the note holder has the option to treat such equity financing as a Qualified Financing on the same terms set forth above;

- Upon the earlier to occur of (i) the closing of the sale of Common Stock to the public at a price of at least $8.15 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock) in a public offering pursuant to an effective registration statement or offering statement (Regulation A) under the Securities Act resulting in at least $5,000,000 of gross proceeds, (ii) the date on which the Company's Common Stock is listed on a national stock exchange, including without limitation, NYSE American or the Nasdaq Capital Market, or (iii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least a majority in principal amount of the then outstanding notes, then the entire unpaid principal amount and all accrued, but unpaid interest shall convert into Common Stock at conversion price equal to the quotient of $58,400,000 divided by the aggregate number of outstanding shares of Common Stock as of immediately prior to the consummation of the event described above; and

- The entire outstanding principal balance and all unpaid accrued interest shall automatically be converted into Common Stock at a conversion price equal to the quotient of $58,400,000 divided by the aggregate number of outstanding shares of Common Stock as of immediately prior to the conversion (assuming full conversion or exercise of all convertible and exercisable securities then outstanding other than these notes) as soon a reasonably practicable following the maturity date.

As of December 31, 2022, the outstanding balance of these notes is $213,010 net of unamortized debt issuance cost of $10,187 and an accrued interest balance of $4,423.

Interest expense on the notes totaled $4,423 for the year ended December 31, 2022, and the Company recorded amortization of debt discount in the amount of $1,529 during the year ended December 31, 2022.

NOTE 8 – NOTE PAYABLE

On May 19, 2020, the Company received a $144,107 paycheck protection program ("PPP") loan from the U.S. Small Business Administration (the "SBA") under provisions of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The PPP loan had a two-year term and bore interest at a rate of 1.0% per annum. The PPP provides that the PPP loans may be partially or wholly forgiven if the funds are used for certain qualifying expenses as described in the CARES Act. The Company received notice from Eagle Bank that its loan had been forgiven in its entirety by the SBA on September 9, 2021.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

Royalties and License Agreements

The Company has entered into various agreements since its inception that provided funds and access to technology for research and development of products and services. These agreements were executed between 2000 and 2017. The agreements committed the Company to paying certain royalty, patent and license fees upon the attainment of certain milestones and/or events. Since the technology and/or underlying products derived from the technologies are no longer part of the Company's commercial operation, the amount of liability, if any, cannot be reasonably estimated. In addition, the Company has concluded that the parties to those agreements have not, for many years, manifested any intention of pursuing any claim(s) against the Company, thereby leading the Company to conclude that it is not probable that any such claims will be pursued. Accordingly, no liability has been recorded in the accompanying financial statements.

In November 2000, the Company entered into a licensing agreement with a government agency that provided the Company with exclusive rights to the use of several patents. The agreement was subsequently amended in 2005 and 2011. Under the most current agreement, the Company was required to pay minimum annual royalty fees and certain patent fees. As of December 31, 2021, the Company estimated it owed unreimbursed patent expenses of $195,794. In 2022, the Company reviewed the agreement and has determined that a liability, if any, is remote. Accordingly, the previously accrued liability has been removed from the financial statements.

In November 2017, the Company executed a License Agreement with a foreign entity to obtain and secure an exclusive license to certain technology, intellectual property, and data relating to the Company's OneTest in exchange for certain up-front fees, Common Stock and ongoing royalty fees. The Company has amortized the license agreement over the term amounting to an amortization expense of $26,784 and $22,500 for the years ended December 31, 2022 and 2021, respectively.

NOTE 10 – STOCKHOLDERS' EQUITY

Preferred Stock

The Company has authorized the issuance of 10,000,000 shares of Preferred Stock with par value of $0.01, of which 1,303,000 have been designated as Series A Preferred Stock, 978,000 have been designated as Series A-1 Preferred Stock, 800,000 shares have been designated as Series A-2 Preferred Stock, 3,569,405 shares have been designated as Series B Preferred Stock and 3,340,909 shares have been designated as Series C Preferred Stock (collectively, the "Designated Preferred Stock"). Below is a summary of the terms of the Designated Preferred Stock.

Ranking. With respect to dividend rights and rights on liquidation, winding up and dissolution, shares of Designated Preferred Stock rank *pari passu* to each other and senior to all shares of Common Stock.

Voting Rights. Shares of Designated Preferred Stock vote together with the holders of Common Stock on an as-converted basis on all matters for which the holders of Common Stock vote at an annual or special meeting of stockholders or act by written consent, except as required by law. For so long as shares of Designated Preferred Stock are outstanding, the holders of such shares vote together, as a separate class, to elect one director to the Company's board, and for so long as shares of Series A-1 Preferred Stock are outstanding, the holders of Series A-1 Preferred Stock vote together, as a separate class, to elect one director to the Company's board.

Conversion Rights. Each share of Designated Preferred Stock is convertible at any time at the option of the holder at the then current conversion rate. The conversion rate for the Designated Preferred Stock is currently one share of Common Stock for each share of Designated Preferred Stock, calculated by dividing the liquidation preference of such share by the conversion price then in effect. In addition, all outstanding shares of Designated Preferred Stock, plus accrued but unpaid dividends thereon, shall automatically be converted into shares of Common Stock, at the then effective conversion rate, upon the earlier to occur of (a) the closing of the sale of shares of Common Stock to the public at a price of at least $8.15 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a public offering pursuant to an effective registration statement or offering statement under the Securities Act of 1933, as amended (the "Securities Act"), resulting in at least $5,000,000 of gross proceeds to the Company, (b) the date on which the shares of Common Stock are listed on a national stock exchange, including without limitation the New York Stock Exchange or the Nasdaq Stock Market, or (c) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least 67% of the then outstanding shares of Designated Preferred Stock, voting together on an as-converted to Common Stock basis (which vote or consent shall include the holders of at least 67% of the shares of Series A-1 Preferred Stock outstanding voting as a separate class).

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, each holder of Designated Preferred Stock then outstanding shall be entitled to be paid out of the cash and other assets of the Company available for distribution to its stockholders, prior and in preference to all shares of Common Stock, an amount in cash equal to the aggregate liquidation preference of all shares held by such holder. The shares of Series A Preferred Stock, Series A-1 Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock and Series C Preferred Stock have a liquidation preference of $3.07, $3.07, $3.26, $3.53 and $4.40, respectively (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization) plus any accrued and unpaid dividends. If upon any liquidation or deemed liquidation event the remaining assets available for distribution are insufficient to pay the holders of Designated Preferred Stock the full preferential amount to which they are entitled, the holders of Designated Preferred Stock shall share ratably in any distribution of the remaining assets and funds in proportion to the respective full preferential amounts which would otherwise be payable, and the Company shall not make or agree to make any payments to the holders of Common Stock. A "deemed liquidation event" means, unless otherwise determined by the holders of at least a majority of the Designated Preferred Stock then outstanding (voting together as a single class on an as-converted basis), (a) a sale of all or substantially all of the Company's assets to a non-affiliate of the Company, (b) a merger, acquisition, change of control, consolidation or other transactions or series of transactions in which stockholders prior to such transaction or series of transactions do not retain a majority of the voting power of the surviving entity immediately following such transaction or series of transactions, or (c) the grant of an exclusive license to all or substantially all of the Company's technology or intellectual property rights except where such exclusive license is made to one or more wholly-owned subsidiaries of the Company.

Dividends. The Designated Preferred Stock will not be entitled to dividends or distributions unless and until the board declares a dividend or distribution in cash or other property to holders of outstanding shares of Common Stock, in which event, the aggregate amount of such each distribution shall be distributed as follows: (a) first, seventy percent (70%) of the distribution amount to the holders of shares of Designated Preferred Stock, on a pro rata basis, until such time as such holders have received an aggregate amount in distributions or other payments in respect of such holder's shares that is equal to the number of shares owned by such holders multiplied by the liquidation preference stated above, and (b) second, thirty percent (30%) of the distribution amount to the holders of shares of Common Stock, on a pro rata basis. Notwithstanding the foregoing, at such time as the holders of Designated Preferred Stock and Common Stock have received the amounts described above, the holders of the Designated Preferred Stock shall receive Distributions *pari passu* with the holders of the Common Stock on an as-converted basis, using the then-current conversion rate of such shares of Designated Preferred Stock.

Preemptive Rights. Until the Company's initial public offering of Common Stock occurs and unless otherwise waived by the prior express written consent of the holders of the majority of the voting power of all then outstanding Designated Preferred Stock, voting together on an as-converted to Common Stock basis, in the event that the Company proposes to issue any Common Stock or shares convertible or exercisable for Common Stock, except for excluded issuances, the Company must first offer those additional equity securities to holders of Designated Preferred Stock for a period of no less than thirty (30) days prior to selling or issuing any such additional equity securities to any person, in accordance with the procedures set forth in the Company's certificate of incorporation, as amended. For purposes hereof, "excluded securities" means the issuance of shares of Common Stock or securities convertible into shares of Common Stock (a) granted pursuant to or issued upon the exercise of stock options granted under an equity incentive plan to employees, officers, directors, consultants or strategic partners, (b) granted to employees, officers, directors, consultants or strategic partners for services, including in connection with an incentive plan, or other fair value received or committed, (c) in consideration for a transaction approved by the board which does not result in the issuance for cash of more than five percent (5%) of the outstanding shares of Common Stock, (d) in connection with an acquisition transaction approved by the board, (e) to vendors, commercial partners, financial institutions or lessors in connection with commercial credit transactions, equipment financings or similar transaction approved by the board (provided that such securities do not exceed 10% of the consideration in such transaction), (f) pursuant to conversion or exchange rights included in securities previously issued by the Company or (g) in connection with a stock split, stock division, reclassification, stock dividend or other recapitalization.

Redemption. Shares of each series of Designated Preferred Stock are not redeemable without the prior express written consent of the holders of the majority of the voting power of all then outstanding shares of such applicable series of Designated Preferred Stock, voting as a separate class.

Protective Rights. So long as at least twenty-five percent (25%) of the Designated Preferred Stock collectively remains outstanding, in addition to any other vote or consent of stockholders required by law, the vote or consent of the holders of at least a majority of all shares of Designated Preferred Stock then outstanding and entitled to vote thereon, voting together and on an as-converted to Common Stock basis, given in person or by proxy, either in writing without a meeting or by vote at any meeting called for the purpose, including the consent of the holders of Series A-1 Preferred Stock, shall be necessary for effecting or validating, either directly or indirectly by amendment, merger, consolidation or otherwise:

(a) the authorization, creation and/or issuance of any equity security, other than shares of Common Stock or options to purchase Common Stock issued to investors, employees, managers, officers or directors of, or consultants or advisors to, the Company or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the board;

(b) the amendment, alteration or repeal of any provision of the certificate of incorporation or bylaws or otherwise alter or change any right, preference or privilege of any Designated Preferred Stock in a manner adverse to the holders thereof;

(c) any increase or decrease in the size of the board;

(d) the purchase, redemption, or acquisition of any shares other than from a selling holder pursuant to the provisions of the certificate of incorporation or any other restriction provisions applicable to any shares in agreements approved by the board or in the operating agreement of any limited liability company utilized for the purpose of facilitating investment in the Company;

(e) the liquidation or dissolution of the Company or the sale, lease, pledge, mortgage, or other disposal of all or substantially all of its assets;

(f) any election to engage in any business that deviates in any material respect from the Company's business as contemplated under any operating plan approved by the board;

(g) the waiver of any adjustment to the conversion price applicable to the Designated Preferred Stock; or

(h) any declaration or payment of any cash dividend or other cash distribution to any holders of capital stock.

Series A Preferred Stock

As of December 31, 2022 and 2021, there were 846,368 shares of Series A Preferred Stock issued and outstanding. No shares of Series A Preferred Stock were issued during the years ended December 31, 2022 and 2021.

Series A-1 Preferred Stock

As of December 31, 2022 and 2021, there were 651,465 shares of Series A-1 Preferred Stock issued and outstanding. No shares of Series A-1 Preferred Stock were issued during the years ended December 31, 2022 and 2021.

Series A-2 Preferred Stock

As of December 31, 2022 and 2021, there were 442,402 shares of Series A-2 Preferred Stock issued and outstanding. No shares of Series A-2 Preferred Stock were issued during the years ended December 31, 2022 and 2021.

Series B Preferred Stock

As of December 31, 2022 and 2021, there were 1,471,487 shares of Series B Preferred Stock issued and outstanding. No shares of Series B Preferred Stock were issued during the years ended December 31, 2022 and 2021.

Series C Preferred Stock

As of December 31, 2022 and 2021, there were 1,204,040 and 1,205,069 shares of Series C Preferred Stock issued and outstanding, respectively.

On January 8, 2020, the Company launched an offering under Regulation A of Section 3(6) of the Securities Act for Tier 2 offerings, pursuant to which the Company offered up to 3,340,909 shares of Series C Preferred Stock at an offering price of $4.40 per share for gross proceeds of up to $14,700,000 on a "best efforts" basis. This offering was terminated on June 15, 2021.

During the year ended December 31, 2021, the Company issued 369,750 shares of Series C Preferred Stock for gross proceeds of $1,510,076 and net proceeds of $1,246,088. The Company also issued 7,357 shares of Series C Preferred Stock to the placement agent as partial compensation for its services. Additionally, 30,365 shares of Series C Preferred Stock were converted into 30,365 shares of Common Stock.

In March 2022, an aggregate of 1,029 shares of series C preferred stock were converted into 1,029 shares of common stock.

Common Stock

As of December 31, 2022 and 2021, there were 4,764,811 and 4,762,572 shares of Common Stock and outstanding, respectively.

During the year ended December 31, 2022, the Company issued 1,210 shares of Common Stock upon the exercise of warrants for proceeds of $12.

During the year ended December 31, 2022, the Company issued 1,029 shares of Common Stock upon the conversion of 1,029 shares of Series C Preferred Stock.

During the year ended December 31, 2021, the Company issued 3,374 shares of Common Stock upon the exercise of warrants for proceeds of $34.

During the year ended December 31, 2021, the Company issued 30,365 shares of Common Stock upon the conversion of 30,365 shares of Series C Preferred Stock.

Stock Options

In 2007, the board of directors adopted the 20/20 GeneSystems 2007 Equity Compensation Plan (the "2007 Plan"). The 2007 Plan provided for the grant of equity awards to employees and non-employees, including stock options and stock-based awards. Up to 500,000 shares of Common Stock could be issued pursuant to awards granted under the 2007 Plan. The 2007 Plan was administered by the board of directors and expired in 2017, ten years after adoption.

On January 26, 2022, the board of directors adopted the 20/20 GeneSystems, Inc. 2022 Stock Incentive Plan (the 2022 Plan"), which was approved by stockholders on June 15, 2022. Awards that may be granted include incentive stock options as described in section 422(b) of Internal Revenue Code of 1986, as amended, non-qualified stock options (i.e., options that are not incentive stock options) and awards of restricted stock. Up to 3,000,000 shares of Common Stock may be issued under the 2022 Plan.

On January 28, 2021, the Company granted non-qualified stock options for the purchase of 306,512 shares of Common Stock at an exercise price of $1.044 per share, all of which vested in full on the date of grant, to certain directors of the Company. On February 1, 2022, the Company granted non-qualified stock options under the 2022 Plan for the purchase of 300,668 shares of Common Stock at an exercise price of $1.0643 per share to certain directors of the Company. An aggregate of 150,332 shares vested in full on the date of grant and an aggregate of 150,336 shares vest monthly over one year. Management determines the value of options granted using the calculated value method and the Black-Scholes option pricing model. The fair value of the stock options issued in 2021 was determined using the Black Scholes option pricing model with the following assumptions: dividend yield: 0%; volatility: 69.9%; risk free rate: 0.42%; estimated term five years for a value of $182,680 and recorded in general and administrative costs.

The risk-free interest rate assumption for options granted is based upon observed interest rates on the United States government securities appropriate for the expected term of the Company's employee stock options.

The expected term of employee stock options is calculated using the simplified method which takes into consideration the contractual life and vesting terms of the options.

The Company determined the expected volatility assumption for options granted using the historical volatility of comparable public companies' common stock. The Company will continue to monitor peer companies and other relevant factors used to measure expected volatility for future stock option grants, until such time that the Company's Common Stock has enough market history to use historical volatility.

The dividend yield assumption for options granted is based on the Company's history and expectation of dividend payouts. The Company has never declared or paid any cash dividends on its Common Stock, and the Company does not anticipate paying any cash dividends in the foreseeable future.

The Company recognizes stock option forfeitures as they occur as there is insufficient historical data to accurately determine future forfeitures rates.

At times, the Company granted stock options under the 2007 Plan in excess of the authorized shares under the plan. However, as of December 31, 2022 and 2021, due to forfeitures the number of options outstanding under the 2007 Plan are less than the authorized shares. The Company does not believe that such non-compliance with the 2007 Plan limits causes significant exposure to the Company as any options in excess have been forfeited and any such compensation expense has been recognized in historical financial information in compliance with applicable accounting standards. In 2017, the 2007 Plan expired.

A summary of the incentive stock option activity is as follows:

	Total Options	Weighted Average Exercise Price Per Share	Total Weighted Average Remaining Contractual Life
Options outstanding, December 31, 2020	153,362	$ 4.50	2.0
Granted	-	-	-
Exercised	-	-	-
Expired	-	-	-
Options outstanding, December 31, 2021	153,362	$ 4.50	1.0
Granted	-	-	-
Exercised	-	-	-
Expired	(132,000)	4.50	-
Options outstanding, December 31, 2022	21,362	$ 4.50	0.83
Options exercisable, December 31, 2022	21,362	$ 4.50	0.83

There is no remaining unvested expense related to these stock options.

A summary of the Company's non-qualified stock option activity is as follows:

	Total Options	Weighted Average Exercise Price Per Share	Total Weighted Average Remaining Contractual Life
Options outstanding, December 31, 2020	342,235	$ 1.35	7.65
Granted	306,512	1.04	10.0
Exercised	-	-	-
Forfeited	-	-	-
Expired	(22,000)	4.50	-
Options outstanding, December 31, 2021	626,747	$ 1.09	8.07
Granted	300,668	1.06	10.0
Exercised	-	-	-
Forfeited	-	-	-
Expired	-	-	-
Options outstanding, December 31, 2022	927,415	$ 1.08	7.72
Options exercisable, December 31, 2022	914,887	$ 1.08	7.71

As of December 31, 2022, there was approximately $7,655 of total unrecognized share-based compensation related to unvested stock options, which the Company expects to recognize within one year.

Warrants

In connection with the Series C Preferred Offering described above, the Company issued five-year warrants to the placement agents to purchase 206 shares of the Company's Common Stock at a per share exercise price of $4.84 in the year ended December 31, 2021.

On April 19, 2022, the Company issued a five-year warrant for the purchase of 91 shares of Common Stock at an exercise price of $4.40 (subject to standard adjustments) to a consultant for a value of $28 as partial compensation for services rendered and recorded in general and administrative costs.

A summary of the Company's warrant activity is as follows:

	Warrants	Weighted Average Exercise Price Per Share	Total Weighted Average Remaining Contractual Life
Warrants outstanding, December 31, 2020	106,805	$ 0.68	2.88
Granted	206	4.84	5.00
Exercised	(3,374)	0.01	-
Forfeited/Expired	-	-	-
Warrants outstanding, December 31, 2021	103,637	$ 0.71	2.70
Granted	91	4.40	5.00
Exercised	(1,210)	0.01	-
Forfeited/Expired	(30,025)	0.01	-
Warrants outstanding, December 31, 2022	72,493	$ 1.02	2.63
Warrants exercisable, December 31, 2022	72,493	$ 1.02	2.63

NOTE 11 – RELATED PARTY TRANSACTIONS

The Company utilizes the services of the brother of the Chief Executive Officer, who is trained as a computer engineer and has over seven years' experience with clinical lab operations, to oversee the Company's laboratory information systems and patient/physician portals. During the years ended December 31, 2022 and 2021, the Company paid $58,078 and $122,410, respectively, to this related party.

The Chief Executive Officer founded an organization in January 2021 to create an alliance of clinical labs, entrepreneurs, scientists, healthcare providers, and concerned citizens who oppose Congressional legislation to require FDA pre-approval for new laboratory tests, known as the VALID Act. The Company contributed $75,000 in 2022 to this organization.

NOTE 12 – INCOME TAXES

The following table presents the current and deferred income tax provision for federal and state income taxes for the years ended December 31, 2022 and 2021:

	2022	2021
Current provision for income taxes	$ -	$ -
Deferred income tax benefit	-	-
Total provision for income taxes	$ -	$ -

The provision for federal income taxes differs from that computed by applying federal and state statutory rates to the loss before federal income tax provision, as indicated in the following analysis:

	2022	2021
Expected federal tax (expense) benefit	$ (459,200)	$ (435,100)
Expected state tax (expense) benefit	(180,400)	(170,900)
Nondeductible expenses and other	(126,900)	(7,000)
(Increase) decrease in valuation allowance	766,500	613,000
Total provision for income taxes	$ -	$ -

The major components of the deferred taxes are as follows at December 31, 2022 and 2021:

	2022	2021
Account receivable, net	$ 18,300	$ 11,800
Accumulated depreciation	(1,500)	(1,500)
Intangible assets, net	(78,000)	(71,000)
Accrued expenses	39,400	328,100
Net operating loss	4,644,800	5,122,200
Deferred tax asset valuation allowance	(4,623,000)	(5,389,600)
	$ -	$ -

The Company files income tax returns for U.S. federal income tax purposes and in Maryland, Virginia, and Pennsylvania. Based on federal tax returns filed or to be filed through December 31, 2022, the Company had available approximately $15.9 million in U.S. tax net operating loss carryforwards which assesses the utilization of a Company's net operating loss carryforwards resulting from retaining continuity of its business operations and changes within its ownership structure. Net operating loss carryforwards expire in 20 years for federal income tax reporting purposes. For Federal income tax purposes, the net operating losses begin to expire in 2020, however, carryforward losses for years beginning in 2018 have no expiration. State net operating loss carryforwards through December 31, 2022 are approximately $15.8 million and have begun to expire in 2020. There is a full valuation allowance as of December 31, 2022 and 2021 which may be reversed in future periods at a point when the Company can make the determination that the recoverability will be probable. The valuation allowance for deferred tax assets decreased by approximately $766,500 and $613,000 during the years ended December 31, 2022 and 2021, respectively.

The United States Federal and applicable state returns from 2018 forward are still subject to tax examination by the United States Internal Revenue Service; however, the Company does not currently have any ongoing tax examinations.

NOTE 13 – SUBSEQUENT EVENTS

The Company has evaluated subsequent events that occurred after December 31, 2022 through May 1, 2023, the issuance date of these financial statements. Except as set forth below, there have been no events or transactions during this time which would have a material effect on these financial statements.

License Agreement

On January 6, 2023, the Company entered into an option agreement to license certain proprietary technology from a leading cancer research institute. The initial six-month option costs the Company $70,000 and a portion of the patent fees. The agreement provides the potential for an exclusive license to the technology upon achievement of certain financing and partnership goals that need to be accomplished by early July 2023. The Option agreement provides for a month-to-month extension if needed upon mutual consent and additional option fees of $10,000 for each month extended.

Option Grants

On January 1, 2023, the Company issued non-qualified stock options for the purchase of an aggregate of 1,485,000 shares of common stock at an exercise price of $1.74 per share under the 2022 Plan.