April 29, 2024

FORM C-AR: Annual Report

20/20 GeneSystems, Inc.
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ANNUAL REPORT FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023

This Annual Report on Form C-AR is being furnished by 20/20 GeneSystems, Inc., a Delaware corporation for the sole purpose of providing certain information about the convertible promissory notes offered and sold by us pursuant to Regulation Crowdfunding under the Securities Act of 1933, as amended, or the Securities Act, for the fiscal year ended December 31, 2023. A copy of this report may be found on our website at www.2020gene.com.

As of December 31, 2023, 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, or the SEC, does not pass upon the accuracy or completeness of any disclosure document or literature. We are filing this report 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 REPORT DOES NOT CONSTITUTE AN OFFER TO PURCHASE OR SELL SECURITIES.

Use of Terms

Except as otherwise indicated by the context and for the purposes of this report only, references in this report to "we," "us," "our" or "our company" refer to 20/20 GeneSystems, Inc., a Delaware corporation.

Forward Looking Statement Disclosure

This report 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 report 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 report 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 report, 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 report or any documents incorporated by reference herein or therein speaks only as of the date of this report. 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 report. We have not authorized anyone to provide you with information different from that contained in this report. We have sold securities only in jurisdictions where offers and sales are permitted. You should assume that the information contained in this report is accurate only as of the date of this report, regardless of the time of delivery of this report. 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 focus on 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, we believe our test 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 widely deployed technology (see "Carcinoembryonic Antigen, Carbohydrate Antigen 19-9, Cancer Antigen 125, Prostate-Specific Antigen and Other Cancer Markers: A Primer on Commonly Used Cancer Markers" World Journal of Oncology (2023) 14(1):4-14; "Clinically Meaningful Use of Blood Tumor Markers in Oncology" (2016) BioMed Research International, 2016:9795269, doi:10.1155/2016/9795269). Throughout East Asia, these biomarkers are used for screening as part of yearly health checkups. In the U.S. and other Western nations, tumor antigens are widely used to monitor therapy responses or disease recurrence in persons being treated for cancer. Furthermore, each of the biomarkers detected in the OneTest panel uses an existing *in vitro* diagnostic test platform that has been cleared or approved by the U.S. Food and Drug Administration, or the FDA, for at least one disease indication and is automated, easy to use, and widely available. This proteomic approach permits significantly lower costs and easier access as compared to DNA-based testing with little if any 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 (See H.R.2407 - Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act reintroduced in the 118th Congress (2023-2024)). Additionally H.R. 5212 the "Firefighter Investments to Recognize Exposure to Cancer Act," or the FIRE Act, was introduced in August 2023 to allocate $700 million in grants to American firefighters to receive MCED tests. Several states, including Maryland and New Jersey, already provide MCED funds for their firefighters (firefighters have proven higher incidents and death rates for several cancers and is a major segment of our customer base).

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 and machine learning techniques. While ctDNA-based tests are newer and are seeing growing use by scientists, clinicians, and self-insured employers, they are significantly 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. Additionally, ctDNA tests require larger quantities of blood that require venipuncture whereas proteomic-based MCEDs work well with capillary blood that can be easily collected in retail locations or at home without a phlebotomist.

As discussed below, we believe that there are considerable advantages of our unique, patented technical approach to the development of MCED tests via the 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 (see "Improving Multi-Tumor Biomarker Health Check-up Tests with Machine Learning Algorithms" *Cancers* 2020 Jun 1;12(6):1442). We have directly demonstrated this advantage in real-world population studies including 27,938 individuals 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 "Cancers Screening in an Asymptomatic Population by Using Multiple Tumour Markers." *PLoS One*. 2016;11(6) and "Improving Multi-Tumor Biomarker Health Check-up Tests with Machine Learning Algorithms" *Cancers* 2020 Jun 1;12(6):1442). These studies/publications indicate clear and significant improvements in area under the curve (AUC), sensitivity, and specificity for overall cancers as well as individual cancers.

We have positioned OneTest as a "top of funnel" first screening test rather than as a diagnostic test for cancer. Whereas a diagnostic test is typically used to make a determination of the presence or absence of disease, a screening test is used to

identify individuals at elevated risk for disease and funnel them into further work-up, ultimately including definitive diagnostic tests. By way of example, suspicious results on a "top of funnel" first screening test might be used to indicate a second screening test which could be a molecular (ctDNA sequencing) or imaging modality which in turn might lead to biopsy as the definitive diagnostic. This approach very much differentiates OneTest from competing tests, including other MCED tests whether based on ctDNA, protein biomarkers or other modalities. Most of these other screening tests are placed further down in the funnel and lead directly to more expensive and more invasive definitive diagnostic tests. As such, these competing modalities focus more on achieving the highest levels of specificity in order to reduce the number of false positive results that could lead directly to an expensive and invasive test. Because OneTest is positioned at the "top of the funnel" meaning that immediate follow-up tests are less expensive and generally not invasive (beyond a second blood draw), the performance characteristics of OneTest are more focused on sensitivity, the detection of true positives, while accepting a lower specificity, as false positives will be removed further down the funnel.

On March 22, 2024, we executed an option to exclusively license certain intellectual properties developed and owned by The University of Texas M.D. Anderson Cancer Center, or MD Anderson, and on April 26, 2024, we entered into a collaborative research agreement with MD Anderson, both of which will become effective if we raise at least $23 million within six months (see also Item 2 "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments*"). The research relationship with and intellectual properties from this institution are expected to help lead to improvements to our MCED, including new biomarkers, algorithms, and evidence of clinical utility. Additionally, we believe it will help us 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 $60 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. This test will also be used primarily as a "top of funnel" 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.

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, Minomic International, or Minomic, and helped it validate and launch its 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. However, following the expiration of the public health emergency in May 2023, all testing from both the State of Maryland and the Montgomery County Health Department has ceased, and we do not anticipate additional COVID-19 testing absent a new variant resulting in a significant increase in cases.

Our legacy business also includes a pioneering field test kit for screening suspicious powders for bioterror agents known as BioCheck, which hundreds of first responder organizations use regularly. Our BioCheck kits for screening suspicious powders remain profitable, but with limited growth potential.

Key Products

As of the date of this report, we sell three products: (i) OneTest, rebranded to OneTest Standard, which was first introduced in 2019, (ii) OneTest Premium, which was launched in October 2023 (on a combined basis, we now process and report an average of 800+ OneTests per month), and (iii) BioCheck, which was first introduced in 2001, for which we make and sell approximately 800 kits per month. Our other products are either in development or in a pre-commercial mode.

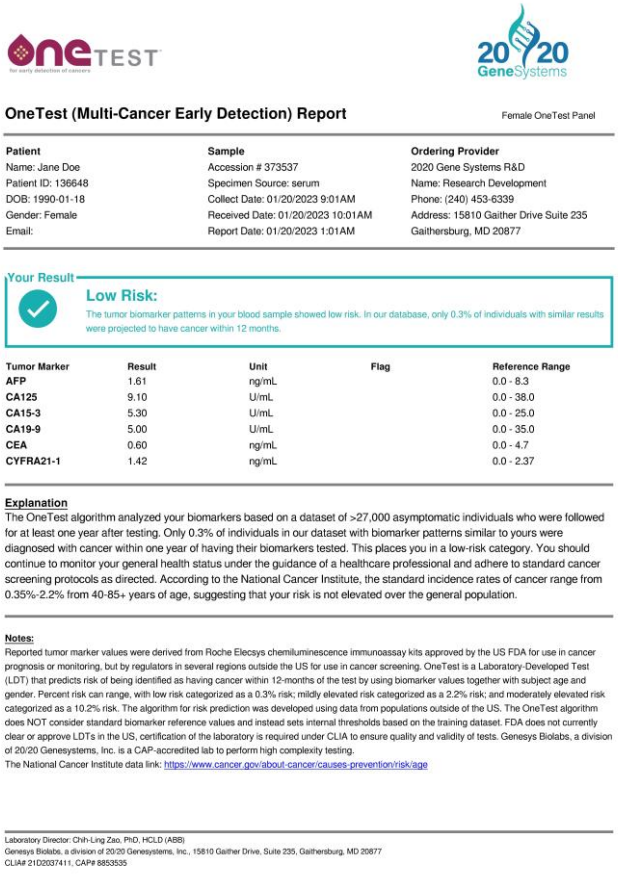
For the years ended December 31, 2023 and 2022, our COVID-19 testing business represented approximately 18% and 95% of our total revenues, respectively, with sales of OneTest accounting for approximately 65% and 3% of our revenues, respectively, and sales of BioCheck accounting for approximately 13% and 1% of our revenues, respectively. The remaining

revenues were generated from our CLIAx, which accounted for approximately 4% and 1% of our revenues for the years ended December 31, 2023 and 2022, respectively.

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

The survival rate for the deadliest cancers is closely linked to the stage at the 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 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 (a sample lab report is shown below).



OneTest

20/20 GeneSystems

OneTest (Multi-Cancer Early Detection) Report

Female OneTest Panel

Patient	Sample	Ordering Provider
Name: Jane Doe	Accession # 373537	2020 Gene Systems R&D
Patient ID: 136648	Specimen Source: serum	Name: Research Development
DOB: 1990-01-18	Collect Date: 01/20/2023 9:01AM	Phone: (240) 453-6339
Gender: Female	Received Date: 01/20/2023 10:01AM	Address: 15810 Gaither Drive Suite 235
Email:	Report Date: 01/20/2023 1:01AM	Gaithersburg, MD 20877

Your Result

Low Risk:

The tumor biomarker patterns in your blood sample showed low risk. In our database, only 0.3% of individuals with similar results were projected to have cancer within 12 months.

Tumor Marker	Result	Unit	Flag	Reference Range
AFP	1.61	ng/mL		0.0 - 8.3
CA125	9.10	U/mL		0.0 - 38.0
CA15-3	5.30	U/mL		0.0 - 25.0
CA19-9	5.00	U/mL		0.0 - 35.0
CEA	0.60	ng/mL		0.0 - 4.7
CYFRA21-1	1.42	ng/mL		0.0 - 2.37

Explanation

The OneTest algorithm analyzed your biomarkers based on a dataset of >27,000 asymptomatic individuals who were followed for at least one year after testing. Only 0.3% of individuals in our dataset with biomarker patterns similar to yours were diagnosed with cancer within one year of having their biomarkers tested. This places you in a low-risk category. You should continue to monitor your general health status under the guidance of a healthcare professional and adhere to standard cancer screening protocols as directed. According to the National Cancer Institute, the standard incidence rates of cancer range from 0.35%-2.2% from 40-85+ years of age, suggesting that your risk is not elevated over the general population.

Notes:

Reported tumor marker values were derived from Roche Elecsys chemiluminescence immunoassay kits approved by the US FDA for use in cancer prognosis or monitoring, but by regulators in several regions outside the US for use in cancer screening. OneTest is a Laboratory-Developed Test (LDT) that predicts risk of being identified as having cancer within 12-months of the test by using biomarker values together with subject age and gender. Percent risk can range, with low risk categorized as a 0.3% risk; mildly elevated risk categorized as a 2.2% risk; and moderately elevated risk categorized as a 10.2% risk. The algorithm for risk prediction was developed using data from populations outside of the US. The OneTest algorithm does NOT consider standard biomarker reference values and instead sets internal thresholds based on the training dataset. FDA does not currently clear or approve LDTs in the US, certification of the laboratory is required under CLIA to ensure quality and validity of tests. Genesys Biolabs, a division of 20/20 Genesystems, Inc. is a CAP-accredited lab to perform high complexity testing.

The National Cancer Institute data link: https://www.cancer.gov/about-cancer/causes-prevention/risk/age

Laboratory Director: Chih-Ling Zao, PhD, HCLD (ABB)

Genesys Biolabs, a division of 20/20 Genesystems, Inc., 15810 Gaither Drive, Suite 235, Gaithersburg, MD 20877

CLIA# 21D2037411, CAP# 8853535

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 (see "Improving Multi-Tumor Biomarker Health Check-up Tests with Machine Learning Algorithms" *Cancers* 2020 Jun 1;12(6):1442). 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 of 45-75, the optimal ages for cancer screening. Thus, we estimate that OneTest addresses a market of over $15 billion annually in the U.S. alone based on our current list price. We believe that for cancer screening to be impactful it must be affordable and accessible. Our technical approach will help advance that goal.

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. While we are using these approved kits in an off-label manner, this practice is permitted under the laboratory-developed test CLIA framework. One advantage to using these kits is that the analytical performance of these kits has been fully vetted by regulatory authorities ensuring the accuracy of individual marker value results. Furthermore, 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. In many cases these tumor markers are tested using the same kits and instrumentation that we use in our CLIA laboratory. 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. One further advantage is that these markers are known and are meaningful to clinicians and specifically to oncologists. While their use in an MCED test is novel and proprietary, the individual marker values are always listed as a part of the OneTest standard report, and these values can help healthcare professionals to better guide follow-up testing and year-over-year monitoring.

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 July 2023, a report "A panel of seven protein tumor markers for effective and affordable multi-cancer early detection by artificial intelligence: a large-scale and multicenter case–control study," appeared in *The Lancet*, eClinical Medicine, Vol. 61. This study uses essentially the same biomarker panel (AFP, CA125, CA15-3, CA19-9, CA72-4, CEA and CYFRA 21-1) and algorithm approach (machine learning/AI) as our OneTest and provides further validation and confirmation of our accuracy levels from independent cohorts from China and the U.S. The test developed from the study has a reported sensitivity of 51.7% at a specificity of 92.9% with an overall accuracy of 84.3%. In comparison, OneTest at the moderate cutoff yields a sensitivity of 22.8% at a specificity of 98.4% (accuracy 97.8%) and at the mild cutoff a sensitivity of 73.2% at a specificity of 80.9% (accuracy 80.8%).

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.

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. Additionally, in January 2024 we received a Notice of Allowance from the U.S. Patent and Trademark office for a second patent covering OneTest. Similar notices of patentability have also been received in early 2024 from patent offices in Japan and China. Our inventors were among the first to apply machine learning and AI to prospective outcome data from thousands of persons tested with protein tumor markers to predict a newly tested individual's likelihood of having cancer. We expect to continue to build out a formidable patent estate in this arena. We are aware of several large companies that have expressed interest in MCEDs with technical approaches covered by our patents which may create opportunities for licensing revenues.

MCED Research, Development and Product Improvements

In October 2023, we introduced 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 several inflammatory markers such as C-reactive protein, Transthyretin, Beta-2-Microglobulin, etc. that BioInfra has demonstrated to result in improved accuracy. This data is reported in the peer-reviewed journal article "Diagnostic value of combining tumor and inflammatory biomarkers in detecting common cancers in Korea," *Clinica Chimica Acta* 516 (2021) 169–178.

BioInfra developed its I-Finder/OneTest Premium using case-control cohorts. Resulting data from these training/validation cohorts are reported in the table below:

Cancer	Stage	% Sensitivity @98% Specificity	Cancer	Stage	% Sensitivity @98% Specificity
Lung	Overall	51	Prostate	Overall	75.5
	Stage I	33.3		Stage I	100
	Stage II	61.1		Stage II	58.3
	Stage Ill	52.9		Stage III	88.9
	Stage IV	90.5			
Liver	Overall	88.6	Ovary	Overall	73.7
	Stage I	85.7		Stage I	25
	Stage II	90.9		Stage II	100
	Stage Ill	100		Stage III	100
	Stage IV	100		Stage IV	80
Colorectal	Overall	72.1	Gastric	Overall	33.3
	Stage I	64.3		Stage I	27.3
	Stage II	80		Stage II	50
	Stage Ill	75.9		Stage III	80
	Stage IV	100	Breast	Overall	18.8
Pancreas	Overall	92.7		Stage I	15.4
	Stage I	85.7		Stage II	15.4
	Stage II	95.7		Stage III	57.1
	Stage Ill	100			
	Stage IV	85.7			

In the first quarter of 2023, BioInfra conducted a real-world analysis of their test performance based on data from Korean governmental cancer registries. This study is currently being prepared for peer-reviewed publication. It looked at results of the BioInfra test as reported in the health records of individual clients who purchased the test over several years (n=42,364) and correlated these results to health outcomes (cancer diagnoses) in the ensuing 12 months. The test performance was excellent compared to testing individual biomarkers alone, without our algorithms. BioInfra in their peer-reviewed publication, "Diagnostic value of combining tumor and inflammatory biomarkers in detecting common cancers in Korea" (2021) *Clinica Chimica Acta*, 516, 169-178, directly compared the AUC of the ROC curves for the MCED to that of single tumor markers (CEA for colon cancer, Cyfra 21.1 or CEA for lung cancer, PSA for prostate cancer). Note that a higher AUC indicates better performance and that the best possible AUC is 1.0.

Cancer	MCED AUC	Single Marker AUC
Colon	0.9603	0.7183
Liver	0.9685	0.7943
Lung	0.9424	0.7609
Prostate	0.9848	0.9635

Based on the data available to date, the premium version is expected to have improved sensitivity and better organ specificity to help identify the tumor of origin. The following table summarizes the data available to date.

Cancer	Sensitivity	Specificity
Liver	47.1%	98.7%
Lung	45.5%	94.9%
Pancreatic	42.9%	99.2%
Prostate	42.2%	98.3%
Colorectal	34.0%	97.8%
Ovarian	29.7%	97.5%
Breast	20.2%	96.5%
Stomach	8.6%	98.4%

Typically, data generated from a pre-diagnostic cohort (i.e. specimens collected before a diagnosis) such as that shown above is less compelling data from newly diagnosed patients. It should also be noted that reducing the specificity to around 85% would substantially boost the sensitivity in a manner that would avoid missing many cancers while not a consequential number of false positives.

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, having paid the requisite up-front license fee of $300,000 and commenced bridging studies to validate those algorithms on a Western population. In addition, we have agreed to pay per-test royalty fees in the range of $12-$25 per test for sales of our products using BioInfra's technology. Our agreement with BioInfra is for a term of three (3) years and may be extended for an additional three (3) years if certain minimum royalties are met or if we conduct, or arrange for another party to conduct, a prospective clinical trial in the U.S. BioInfra may terminate the agreement upon thirty (30) days written notice.

Another promising source for improvements to our MCED may be our potential collaboration with MD Anderson discussed above. Of the $23 million that we plan to raise within six months, $4 million would be allocated to collaborative research funding. The biomarkers, methodology, and intellectual property associated with the lung cancer test panel that they developed and validated over ten years overlaps with that of our MCED, and the MD Anderson team has access to one million blood specimens from individuals collected before any cancer diagnoses. If the agreement becomes effective upon the payment of fees before the deadline, we believe these unique resources, coupled with the scientific and clinical acumen of MD Anderson's team, may yield several important and novel biomarkers and algorithms in the months and years to come that may function to improve the performance of the biomarkers measured in our current OneTest.

In 2024, our scientific and laboratory personnel successfully demonstrated the equivalency in the performance of OneTest 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 have shown that 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 a phlebotomist should permit our test to be more easily accessed at pharmacy counters and even at home thereby increasing uptake and adoption.

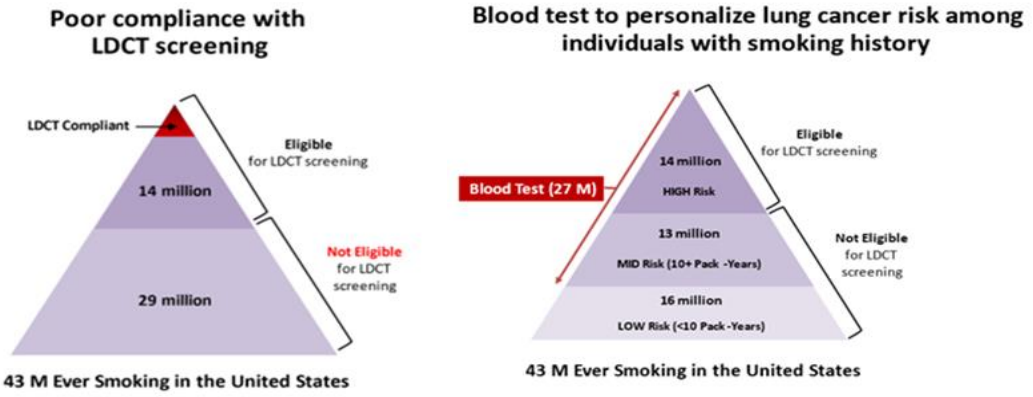
In terms of establishing clinical utility (i.e., demonstrating a mortality benefit), the U.S. National Cancer Institute, or NCI, is planning to sponsor randomized clinical trials of various MCEDs as part of the White House "Cancer Moonshot" program. We have taken steps to have our test evaluated by NCI for possible inclusion in those trials which will likely commence in 2025 and 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. The intellectual properties developed and owned by MD Anderson which we have an option to license include a lung cancer blood test developed by one of the world's leading experts in early cancer detection. The MD Anderson team, led by Sam Hanash, MD, Ph.D., has received over $60 million in funding from federal and state governments as well as philanthropies in support of developing this test.

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 "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 and get a yearly scan, according to the National Cancer Institute. The MD Anderson team believes 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. As illustrated in the figure below left, of the 43 million Americans with a smoking history, only 14 million are eligible to get yearly LDCTs (based on age and 20-pack year smoking history) but only about 6% of these individuals (about 840,000 people) actually do so. Under a new screening paradigm advocated by MD Anderson (right figure), the blood test would be provided to those with at least a 10-pack year smoking history (27 million Americans) with compliance approaching 40% (the current compliance rate for PSA testing among American men). Those with a positive blood test would be encouraged by their physician to follow-up with a CT scan, thereby saving more lives.



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 $170 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.

Self-insured employers and 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.

We are also laying the groundwork for "OneTest for Longevity" that will measure biomarkers associated with healthy aging, especially markers of inflammation. Evidence suggests that many of these biomarker levels fall within weeks of implementing health diet and exercise programs.

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 test menu faster and with less expense than organic research and development.

COVID-19 Tests

In the third quarter of 2020, in response to a 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. However, following the expiration of the public health emergency in May 2023, all testing from both the State of Maryland and the Montgomery County Health Department has ceased, and we do not anticipate additional COVID-19 testing absent a new variant resulting in a significant increase in cases.

Profits from COVID-19 testing were 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

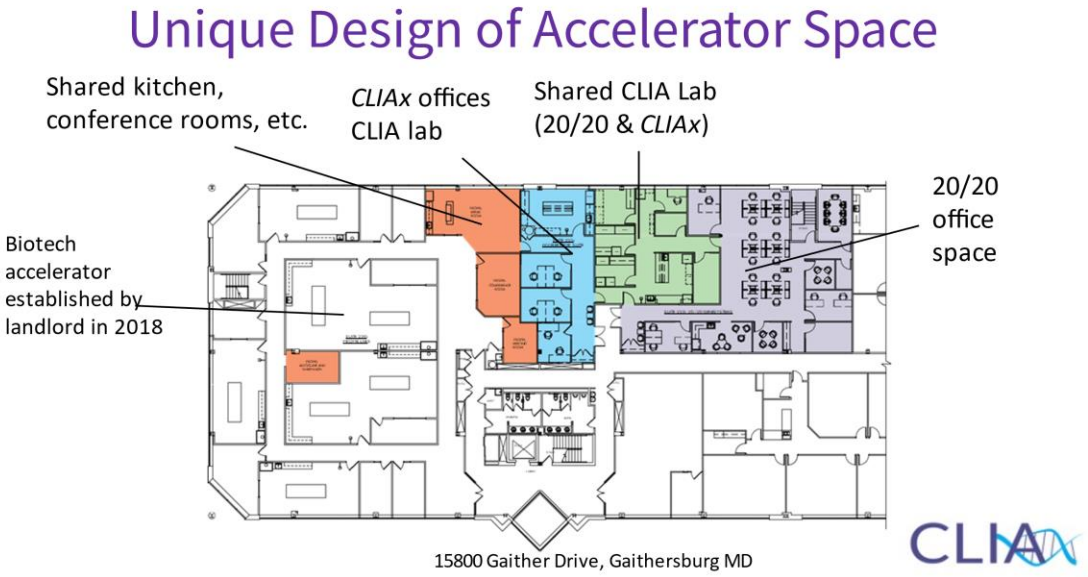
Lab Facility

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 August 2022, Minomic, which we helped to launch a novel blood test and algorithm to help predict prostate cancer following an abnormal PSA test.

In July 2021, we entered a lab services and marketing agreement with Minomic under which its testing technology and reagents were transferred to our CLIA lab, installed, and validated under CLIA regulations. Under the agreement, Minomic maintains its ownership of all intellectual property. Minomic compensates us on a "cost plus" basis (i.e., our fully burdened costs for labor, materials, space and testing analyzers plus a 10% profit). Furthermore, we have the right, but not the obligation, to help market their test with a 25% commission. We have not yet opted to promote the Minomic test since it does not target our typical consumer base. However, we believe this framework will be apt for other lab tests that address the early detection, disease prevention and wellness market. The agreement with Minomic is for a term of three years and may be terminated by either party upon 30 days' written notice if there has been a material breach of the agreement that has not been cured with 60 days of notice of such breach. Either party may also terminate the agreement in the event of insolvency, bankruptcy, assignment for the benefit of creditors of the other party or an admission of the party's inability to pay its debts as they become due.

We plan to 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.



Supply Chain

For OneTest, we rely on a supply chain through Roche Diagnostics IVD kits for Cobas E411, with all reagents used also available on other immunoassay platforms offered by major companies such as Abbott, Beckman, Siemens, and ThermoFisher, except for one reagent, CYFRA. CYFRA is only available in the United States on our current Roche equipment; however, we can also source this assay on a Luminex system.

In addition to our OneTest, we also rely on a supply chain for general chemistry markers. Currently, these markers are run on Abbott Alinity C, but they are available through all major manufacturers, including Roche.

We have established reagent contracts with Roche and Abbott that guarantee pricing for all immunoassay and chemistry markers currently used in our diagnostic test panels. These contracts ensure that we can continue to provide our customers with high-quality diagnostic tests at predictable pricing. Additionally, these contracts provide us with supply chain stability and allow us to manage cost fluctuations associated with reagent pricing.

We depend on our suppliers and contract manufacturers to provide us and our customers with materials in a timely manner that meets our and their quality, quantity, and cost requirements. We have initiated a second source qualification process for most of these critical components, but we may not be successful in securing second sourcing for all of them on a timely basis. Moreover, while we are confident that other suppliers could meet our quality, quantity and cost requirements, the time required to transition to a new supplier could have negative impact on our ability to perform these tests until an alternative supplier could be validated. Our supply chain for OneTest is critical to our ability to deliver high-quality diagnostic tests to our customers.

Overall, we remain committed to building strong relationships with our suppliers and contract manufacturers to ensure that our supply chain for all our diagnostic tests is reliable, resilient, and able to meet the needs of our customers. We continuously monitor and improve our supply chain processes to minimize the risk of disruptions and ensure that we can provide high-quality diagnostic tests to our customers when they need them.

Please see "*Risk Factors—Risks Related to Our Business and Industry*" for a description of the risks related to our supplier relationships.

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 incidences of cancer than normal (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 2024, we estimate that the percentage of our sales from each of these three market segments for this year will be approximately 42%, 4% and 54% 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 Standard has become a popular tool for cancer screening of current and former firefighters.

Penetration of this large occupational health market will require significant business-to-business sales and marketing campaigns as well as consumer-initiated test 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 consumer-initiated test market for OneTest Standard and OneTest Premium.

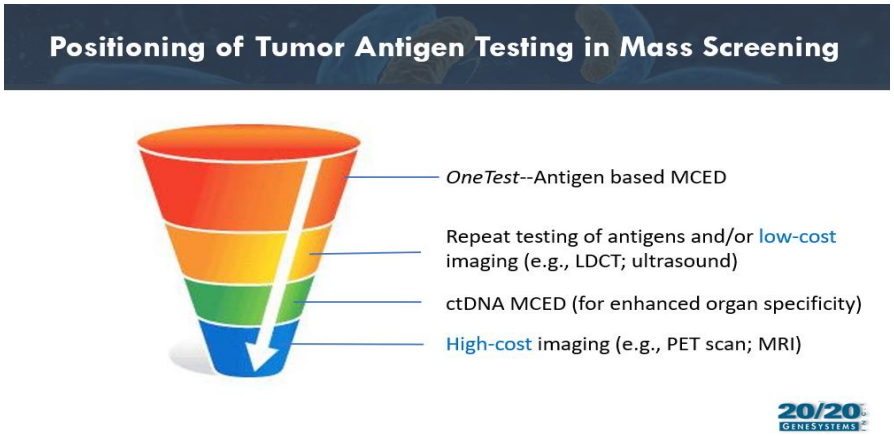
We currently have engagements in place with over 1,000 retail clinics located throughout the U.S., mostly urgent care centers, to conduct blood draws for OneTest products and include over 200 locations of AnyLabTestNow. These clinics, coupled with a dedicated telemedicine service, have made it practical for us to initiate a consumer-initiated test campaign. In the future we expect to offer capillary collection options at retail venues and at home.

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 for 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 its 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 they have not publicly announced when they plan to launch their test CancerGuard 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 lower cost OneTest Standard with a list price of under $200 could be followed up with more expensive ctDNA tests and/or imaging 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 in various publications (it is important to note that this comparison is on the basis of reported data, and no head-to-head studies have been performed). 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 may consistently fail to hold up in real-world screening practice. A recent report, Jamshidi, et al., "Evaluation of cell-free DNA approaches for multi-cancer early detection" (2022) *Cancer Cell* 40, 1537–1549, concluded that a whole genome methylation pattern approach yielded the highest sensitivities for cancer when specificity was held at 98%. The overall sensitivity was reported as 34%. This was a case-control study and interestingly when broken down by stage the sensitivities drop significantly to only 20% for stage II and 10% for stage I cancers. The corresponding authors on this study were from Grail Inc., which was acquired by Illumina for $8 billion in 2020. In September of 2022, Grail reported interim results of its Pathfinder real-world (prospective) clinical trial of its Galleri MCED test which is based on cfDNA methylation patterns. In this interim analysis, they report a sensitivity of 29% at a 99% specificity. OneTest, which was developed in a real-world cohort of over 27,000 asymptomatic individuals, achieves an overall sensitivity of 23.2% at 98% specificity; however, given that it is positioned as a "top of funnel," a significantly greater overall sensitivity (79%) can be achieved if the specificity is allowed to drop to 80%. OneTest Premium achieved a sensitivity of 30.4% at 97.7% specificity in a Korean real-world study of over 42,000 subjects.

- ***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 $189 (with bulk discounts provided to companies). In contrast, the list price for Grail's Galleri test which is listed as $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 have been developed to improve the volume of capillary blood collected from the finger or upper arm while reducing the pain and anxiety associated with traditional large needle blood draws. In April 2023, one such device, the TAP II manufactured by YourBio Health received a 510K clearance from the FDA 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, pharmacy counters, and at-home***. 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 Standard and OneTest Premium currently require a venipuncture blood collection. For those consumers without easy access to a phlebotomist, we currently make

available over 1,000 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, we plan to validate both OneTest products 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. The OneTest capillary panel, which utilizes capillary collection instead of venous draws, has already undergone rigorous analytic validation. Currently, we are in the final stages of completing the necessary paperwork under CLIA/CAP regulations, and we expect to have everything finalized by the end of June 2024. In summary, we are right on schedule to launch the OneTest capillary panel in the seven selected Giant Food stores as planned.

- ***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 our test menu.*** We are now offering our MCED consumers different versions of that test (standard and premium). We soon expect to offer optional biomarker add-ons that address other routine disease conditions. The volume of venous blood collected can easily facilitate multiple tests. We are finishing OneTest Standard capillary validation, and expect to launch commercially soon. We are conducting trials for OneTest Premium markers, and within 1- 3 months, we plan to finish capillary validation for OneTest Premium. 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. To date, we have made our algorithms available over the cloud to a commercial partner in Taiwan.

- ***Consumer initiated testing***. We have had considerable success to date with consumer initiated testing by leveraging digital marketing platforms such as Facebook, Google, and LinkedIn. 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 multiplies the revenues derived from these advertisements. Based on our first quarter 2024 sales, we anticipate that approximately 33% of our sales will come directly from consumers who purchase on-line (as opposed to the other two segments of self-insured employers and medical providers). 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. Usually, a telemedicine provider we have engaged provides these services.

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 for paying 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

The following table summarizes our patent portfolio. All of these patents and patent applications are owned by us.

	Description	Serial No./Patent No.	Jurisdiction	Projected Expiry
Algorithms and AI for the Early Detection of Lung and other Cancers				
1	Algorithm for assessing the likelihood a patient has lung cancer	US 9,753,043; US 10,156,575; 11,733,249	US and CA	2032
2	Methods for aiding in distinguishing between benign and malignant pulmonary nodules	WO 2017/173428	US and CN	2037
3	Algorithm for assessing the likelihood a patient has cancer	US 11,621,080	US and CN	2035-37
4	Cancer Classifier Models	PCT/US19/40075	US, CN and JP	2039
5	Methods and algorithms for identifying a patient for follow-up cancer diagnostic testing	WO 2021/247577	US	2041
6	Pan cancer universal algorithm	WO 2022/015700	US and CN	2041
7	Use of multiple tumor markers in a machine learning model for cancer detection	US 2018/0173847	US and TW	2036
Other - Biocheck				
8	Methods for processing dry powder for protein analysis and detection of bacterial spores	10,774,358	US	2036

No assurance is made that any pending patent applications within the portfolio will result in a granted patent.

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 and know-how. To further protect our intellectual property, we enter into confidentiality agreements with our employees, executive officers and directors.

Employees

As of December 31, 2023, we had a total of 21 employees of which 12 were full-time and 9 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, 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 2023 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.

On September 29, 2023, the FDA issued a proposed regulation under which they would begin to regulate LDTs starting in late 2027. The proposed rule, which will likely be finalized in April 2024, is expected to be challenged in court and may also be overridden by legislation in Congress. However, if the rules survive, they could significantly increase the cost and burden and affect our ability to market or improve existing LDTs and/or introduce new lab tests.

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 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 healthcare 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 ceased.

While we achieved profitability in 2021 and 2022, such profitability was mainly a result of COVID-19 testing, which ceased in the second quarter of 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.

Now that the pandemic emergency has ended, the bulk of our revenues depends 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.

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 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 and 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 this revenue growth is contingent upon individuals' willingness to pay out of pocket for our diagnostic tests.

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. 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.

Until our diagnostic tests are covered by Medicare or private insurance, we expect that self-pay will constitute a significant portion of our revenues for the foreseeable future. This revenue growth will be contingent on individuals' willingness to pay out of pocket for our diagnostic tests.

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 1,000 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 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.

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 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 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.

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 or 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 FCPA. 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 Federal Trade Commission, or 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. On September 29, 2023, FDA issued a proposed regulation under which they would begin to regulate LDTs starting in late 2027. The proposed rule, which will likely be finalized in April 2024, is expected to be challenged in court and may also be overridden by legislation in Congress. However, if the rules survive, they could significantly increase the cost and burden and affect our ability to market or improve existing LDTs and/or introduce new lab tests.

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 are 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 20,000,000 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 General 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 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 focus on 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, we believe our test 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 widely deployed technology (see "Carcinoembryonic Antigen, Carbohydrate Antigen 19-9, Cancer Antigen 125, Prostate-Specific Antigen and Other Cancer Markers: A Primer on Commonly Used Cancer Markers" World Journal of Oncology (2023) 14(1):4-14; "Clinically Meaningful Use of Blood Tumor Markers in Oncology" (2016) BioMed Research International, 2016:9795269, doi:10.1155/2016/9795269). Throughout East Asia, these biomarkers are used for screening as part of yearly health checkups. In the U.S. and other Western nations, tumor antigens are widely used to monitor therapy responses or disease recurrence in persons being treated for cancer. Furthermore, each of the biomarkers detected in the OneTest panel uses an existing *in vitro* diagnostic test platform that has been cleared or approved by the FDA for at least one disease indication and is automated, easy to use, and widely available. This proteomic approach permits significantly lower costs and easier access as compared to DNA-based testing with little if any 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 $60 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, Minomic, and helped it validate and launch its 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 expenses 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. However, following the expiration of the public health emergency in May 2023, all testing from both the State of Maryland and the Montgomery County Health Department has ceased, and we do not anticipate additional COVID-19 testing absent a new variant resulting in a significant increase in cases.

Our legacy business also includes a pioneering field test kit for screening suspicious powders for bioterror agents known as BioCheck, which hundreds of first responder organizations use regularly. Our BioCheck kits for screening suspicious powders remain profitable, but with limited growth potential.

Recent Developments

Option Agreement

On March 22, 2024, we entered into an option agreement with The Board of Regents, or the Board, of The University of Texas System, an agency of the State of Texas, on behalf of MD Anderson, pursuant to which MD Anderson has granted us an exclusive six-month option to enter into a royalty-bearing, exclusive license to certain patent rights and technology, which option may be exercised by us upon (i) our completion of an equity financing with proceeds of at least $23 million based on a pre-money valuation of at least $70 million (which such financing may not be obtained through a crowdfunding or Regulation A offering) and (ii) payment of a fee in the amount of $4,457,069.15. Upon exercise of the option, we will enter into a patent and technology license agreement with the Board and MD Anderson, in the form attached to the option agreement, pursuant to which MD Anderson will grant the license to us in exchange for certain royalties, fees and shares of common stock set forth in the patent and technology license agreement.

Convertible Bonds Subscription Agreement

On March 20, 2024, we entered into a convertible bonds subscription agreement with Cornerstone Investment Inc., or the Investor, pursuant to which we agreed to issue a convertible bond in the principal amount of $23 million to the Investor (or its designee) for a purchase price of $23 million. The issuance of the convertible bond is subject to customary closing conditions, as well as execution of the option agreement described above and a collaborative research agreement with MD Anderson. The convertible bond will have a term of five (5) years and will not bear interest; provided that (i) if any portion of the convertible bond has not been converted prior to the maturity date or the date on which an event of default (as defined in the convertible bond) occurs, as applicable, and (ii) the Investor desires to receive a cash payment with respect to such unconverted portion on the maturity date or the date on which an event of default occurs, as applicable, we shall be required to pay the Investor, in addition any other amounts required under the convertible bond, interest accrued on the aggregate principal sum of the convertible bond at a rate equal to 6% per annum from the date on which the convertible bond is issued up to the maturity date or the date on which an event of default occurs, as applicable. In addition, if the convertible bond is still outstanding after the maturity date or the date on which an event of default occurs, as applicable, then interest shall accrue beginning on the day after the maturity date on the outstanding principal balance and the default amount at a rate equal to 12% per annum. We may not prepay the convertible bond prior to the maturity date.

The convertible bond will be convertible at any time at the option of the holder into shares of our common stock, or, subject to stockholder approval, a new series of our preferred stock to be designated as series E preferred stock with the terms and conditions set forth in Annex A to the convertible bond. In addition, the convertible bond shall automatically be converted into series E preferred stock upon the earlier to occur of (i) an initial public offering of our common stock and concurrent listing on a national securities exchange, including without limitation the New York Stock Exchange, NYSE American or the Nasdaq Stock Market (any tier), (ii) a direct listing of our common stock on a national securities exchange, including without limitation the New York Stock Exchange, NYSE American or the Nasdaq Stock Market (any tier) or (iii) upon such stockholder approval. The number of shares to be issued upon conversion shall be equal (i) the outstanding principal amount of the convertible bond and all accrued and unpaid default interest, if any, divided by (ii) the conversion price then in effect. The initial conversion price will be $5.34 per share, subject to customary adjustments for stock dividends, stock splits, stock combinations, reclassifications, mergers, consolidations, sales of all assets, or similar events. In addition, subject to certain exceptions, if we issue any equity securities with an implied price per share of less than the conversion price then in effect, then the conversion price shall be adjusted, concurrently with such equity issuance, to the implied price per share received by us for such equity issuance. Finally, the conversion price will be subject to adjustment in the event that we complete an

initial public offering or a direct listing of our common stock on a national securities exchange that does not meet the requirements of a Q-IPO or a Direct Listing (each as defined below).

The convertible bond will be unsecured and will contain customary covenants and events of default for a loan of this type. We also agreed that the Investor will be entitled to nominate at least one (1) director to our board of directors as long as the convertible bond is outstanding. Subject to certain exceptions, we also agreed that the Investor will have the right to participate in any subsequent financing transactions involving the issuance of common stock or securities convertible into or exercisable or exchangeable for common stock for cash consideration in an amount required to maintain the Investor's fully diluted ownership in our company. We also agreed to use our best efforts to (i) close a firm commitment underwritten public offering and concurrent listing on a national securities exchange, including without limitation the New York Stock Exchange, NYSE American or the Nasdaq Stock Market (any tier), with a per share offering price of at least $5.34 plus interest accrued on $5.34 at a rate equal to 6% per annum from the issuance date of the convertible bond up to the date of listing, or the Target Price (which we refer to as a Q-IPO), or (ii) complete a direct listing of our common stock on a national securities exchange, including without limitation the New York Stock Exchange, NYSE American or the Nasdaq Stock Market (any tier), with the reference price of at least the Target Price (which we refer to as a Direct Listing), within three (3) years following the issuance date of the convertible bond, which period may be extended by one (1) year by mutual agreement between us and the Investor.

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;
- the average price per test paid by consumers;
- the number of tests ordered per quarter;
- the costs of third-party laboratories to run our tests;
- the 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 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, 2023 and 2022, both in dollars and as a percentage of our revenues.

	December 31, 2023		December 31, 2022	
	Amount	% of Revenues	Amount	% of Revenues
Revenues	$ 1,424,304	100.00%	$ 11,059,145	100.00%
Cost of revenues	1,315,166	92.34%	5,937,398	53.69%

Gross profit	109,138	7.66%	5,121,747	46.31%
Operating expenses:				
Sales, general and administrative	5,061,450	355.36%	3,322,835	30.05%
Research and development	1,409,150	98.94%	120,043	1.09%
Loss on impairment of fixed assets	209,073	14.68%	-	-
Total operating expenses	6,679,673	468.98%	3,442,878	31.13%
Operating income (loss)	(6,570,535)	(461.32)%	1,678,869	15.18%
Other income (expense):				
Interest expense	(27,915)	(1.96)%	(15,685)	(0.14)%
Interest income	209,150	14.68%	68,421	0.62%
Gain on sale of asset	-	-	2,371	0.02%
Other expense	(2,009)	(0.14)%	-	-
Other income	-	-	452,899	4.10%
Total other (income) expense	179,226	12.58%	508,006	4.59%
Net income (loss)	$ (6,391,309)	(448.73)%	$ 2,186,875	19.77%

Revenues. We generated revenues from sales of COVID-19 tests, OneTest, BioCheck and from our CLIAx during the years ended December 31, 2023 and 2022. Our total revenues decreased by $9,634,841, or 87.12%, to $1,424,304 for the year ended December 31, 2023 from $11,059,145 for the year ended December 31, 2022. Such decrease was due to a significant decrease in revenues from sales of our COVID-19 tests and a decrease in revenues from our CLIAx, offset by increases in revenues from sales of OneTest and BioCheck. The following table summarizes our revenues by product:

	December 31, 2023		December 31, 2022	
	Amount	% of Revenues	Amount	% of Revenues
COVID-19 PCR Tests	$ 250,145	17.56%	$ 10,393,256	93.98%
COVID-19 Antibody/Antigen Tests	2,375	0.17%	97,452	0.88%
OneTest	921,502	64.70%	323,414	2.92%
BioCheck	187,926	13.19%	154,660	1.40%
CLIAx	62,356	4.38%	90,363	0.82
Total revenues	$ 1,424,304		$ 11,059,145	

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 decreased by $10,238,188, or 97.59%, to $252,520 for the year ended December 31, 2023 from $10,490,708 for the year ended December 31, 2022. Such decrease was due to the significant decrease in demand for COVID-19 testing as the pandemic has subsided. As of the date of this report, all testing has ceased at both the State of Maryland and Montgomery County Health Departments, and we do not anticipate additional COVID-19 testing absent a new variant resulting in a significant increase in cases.

Revenues from sales of OneTest increased by $598,088, or 184.93%, to $921,502 for the year ended December 31, 2023 from $323,414 for the year ended December 31, 2022. Such an increase was the result of adding additional sales leadership and personnel over the last year and increased digital advertising during the past twelve months.

Revenues from sales of BioCheck increased by $33,266, or 21.51%, to $187,926 for the year ended December 31, 2023 from $154,660 for the year ended December 31, 2022. Such an increase was due to our efforts to re-engage past customers to order the product again.

Revenues from our CLIAx decreased by $28,007, or 30.99%, to $62,356 for the year ended December 31, 2023 from $90,363 for the year ended December 31, 2022. Such decrease was due to the shift from tech transfer activities to ongoing laboratory activities for the processing of tests. The revenue for 2022 was predominantly for tech transfer of their lab developed test which yielded slightly higher revenue than for 2023, which was for ongoing laboratory activities both of which were billed to them monthly. The agreement with the CLIAx customer includes future revenue sharing and co-marketing of their test into the US market if we are involved in the selling of these tests.

Cost of revenues. Our cost of revenues includes materials, labor, and laboratory expenses. Our cost of revenues decreased by $4,622,232, or 77.85%, to $1,315,166 for the year ended December 31, 2023 from $5,937,398 for the year ended December

31, 2022. As a percentage of revenues, cost of revenues was 92.34% and 53.69% for the years ended December 31, 2023 and 2022, respectively. This significant decrease was due to the significant decrease in COVID-19 test revenue as detailed in the table below. The cost to provide COVID-19 testing in 2023 exceeded the revenue generated and as a result we assessed the viability of generating revenue on COVID-19-related equipment and remaining inventory as described further under loss on impairment of fixed assets below.

	December 31, 2023				December 31, 2022			
	Revenues	Cost of Revenues	Gross Profit	Gross Margin	Revenues	Cost of Revenues	Gross Profit	Gross Margin
COVID-19 Tests	$ 252,520	$ 260,556	$ (8,036)	(3.18%)	$10,490,708	$ 5,508,534	$ 4,982,174	47.49%
OneTest	921,502	939,924	(18,422)	(2.00%)	323,414	333,354	(9,940)	(3.07%)
BioCheck	187,926	100,335	87,591	46.61%	154,660	61,321	93,339	60.35%
CLIAx	62,356	14,351	48,005	76.99%	90,363	34,189	56,174	62.16%
	$ 1,424,304	$ 1,315,166	$ 109,138	7.66%	$11,059,145	$ 5,937,398	$ 5,121,747	46.31%

Gross profit and gross margin. Our gross profit decreased by $5,012,609, or 97.87%, to $109,138 for the year ended December 31, 2023 from $5,121,747 for the year ended December 31, 2022. Gross profit as a percentage of revenues (gross margin) was 7.66% and 46.31% for the years ended December 31, 2023 and 2022, respectively. From the table above, it is evident that the costs to provide COVID-19 testing exceeded the revenue earned during 2023. Fixed lab costs are allocated on a percent of revenue by product type basis thus putting downward pressure on all gross margins as COVID-19 revenue declined.

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 $1,738,615, or 52.32%, to $5,061,450 for the year ended December 31, 2023 from $3,322,835 for the year ended December 31, 2022. As a percentage of revenues, sales, general and administrative expenses were 355.36% and 30.05% for the years ended December 31, 2023 and 2022, respectively. Such increase was primarily due to the recognition of $892,780 in stock compensation expense recorded upon the granting of stock options in 2023 as compared to $176,082 in 2022. Other attributors to the increase include sales and marketing costs for hiring of additional salespeople and advertising activities in excess of the prior year by $341,219 and $397,859, respectively, as well as professional fees for accounting, legal, regulatory and business development activities in excess of 2022 by $169,242 related to increased regulatory filings and negotiation of license agreements for technology to enhance our product offerings.

Loss on impairment of fixed assets. In the year ended December 31, 2023, we performed an impairment analysis of laboratory equipment utilized in COVID-19 testing due to the significant material decrease in revenue and cash flow related to the COVID-19 testing and recorded an impairment charge of $209,073. It was determined after discussion with lab personnel that certain PCR laboratory equipment could be repurposed for potential future products and would be retained for research and development. The net book value of this equipment that remains in fixed assets equals $122,056 and will continue to be depreciated to research and development costs. As of December 31, 2023, we had no PCR testing inventory since the supplies were expensed to research and development.

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 increased by $1,289,107, or 1,073.87%, to $1,409,150 for the year ended December 31, 2023 from $120,043 for the year ended December 31, 2022. As a percentage of revenues, research and development expenses were 98.94% and 1.09% for the years ended December 31, 2023 and 2022, respectively. Approximately 53%, or $745,522, of the expenses in 2023 were due to a focus on the LDT validation of OneTest Premium (BioInfra I-Finder) technology with the remaining $663,628 distributed equally across the tech transfer of LungSPOT (lung cancer test), cardiovascular disease algorithms development and a capillary blood collection method study.

Total other income (expense). We had total other income, net, of $179,226 for the year ended December 31, 2023, as compared to other income, net, of $508,006 for the year ended December 31, 2022. Total other income, net, for the year ended December 31, 2023 consisted of $209,150 of interest income offset by $27,915 of interest expense and other expenses of $2,009, while 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.

Net income (loss). As a result of the cumulative effect of the factors described above, we generated a net loss of $6,391,309 for the year ended December 31, 2023, as compared to a net income of $2,186,875 for the year ended December 31, 2022, a decrease of $8,578,184, or 392.26%.

Liquidity and Capital Resources

As of December 31, 2023, we had cash and cash equivalents of $4,089,461. 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

The following table provides detailed information about our net cash flow for the period indicated:

	Years Ended December 31,	
	2023	**2022**
Net cash provided by (used in) operating activities	$ (4,479,971)	$ 5,803,059
Net cash used in investing activities	(43,764)	(462,552)
Net cash provided by (used in) financing activities	(194,379)	112,599
Net increase (decrease) in cash and cash equivalents	(4,718,114)	5,453,106
Cash and cash equivalents at beginning of period	8,807,575	3,354,469
Cash and cash equivalent at end of period	$ 4,089,461	$ 8,807,575

Net cash used in operating activities was $4,479,971 for the year ended December 31, 2023, as compared to net cash provided by operating activities of $5,803,059 for the year ended December 31, 2022. Cash used in operating activities for the year ended December 31, 2023 was mainly attributed to the net loss of $6,391,309 and the addition of non-cash adjustments that positively impact operating cashflows which includes $1,303,952 of stock-based compensation and $209,073 of impairment of fixed assets. The remaining net decrease was primarily attributed to net positive cash from accounts receivable of $696,090 offset by a reduction to accounts payable and accrued expenses of $521,113. Cash provided by operating activities for the year ended December 31, 2022 was mainly attributed to our net income of $2,186,875 and the addition of non-cash adjustments that positively impact operating cashflows which includes $290,218 of depreciation and amortization expense and $176,082 of stock-based compensation. The remaining net increase was attributed to the following net positive changes in the asset accounts: net positive cash from accounts receivable of $3,484,807 and net decrease in inventory and prepaid expenses of $159,584, and the net negative impact to operating cashflows from reductions to accounts payable and accrued expenses of $720,299, offset from a net cash increase from deferred revenue of $163,524.

Net cash used in investing activities was $43,764 for the year ended December 31, 2023, as compared to $462,552 for the year ended December 31, 2022. The net cash used in investing activities for the year ended December 31, 2023 consisted of the acquisition of technology under a license agreement of $34,381 and purchases of capital equipment of $9,383, while the net cash used in investing activities for the year ended December 31, 2022 consisted of purchases of capital equipment of $261,793 and acquisition of technology under a license agreement and related validation costs of $206,509, offset by proceeds from sale of equipment of $5,750.

Net cash used in financing activities was $194,379 for the year ended December 31, 2023, as compared to net cash provided by financing activities was $112,599 for the year ended December 31, 2022. The net cash used in financing activities for the year ended December 31, 2023 consisted of deferred offering costs of $148,387 and principal payments on financing lease payments of $46,575, offset by net of proceeds from the exercise of warrants of $583, while the net cash provided by financing activities for the year ended December 31, 2022 consisted the 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.

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, 2023, 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, 2023, the outstanding balance of these notes is $229,164 consisting of principal of $213,010, net of unamortized debt issuance cost of $4,980 and an accrued interest balance of $21,134.

Contractual Obligations

Our principal commitments consist mostly of obligations under the convertible notes described above and the operating leases described under "*Description of Business—Facilities*." Other than indicated above, at December 31, 2023, we did not have other long-term debt obligations, capital (finance) lease obligations, operating lease obligations, purchase obligations or other long-term liabilities reflected on our balance sheet.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles 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 are recognized when returned serum specimens are analyzed in our CLIA laboratory and the results are reported to the customer. The specific transaction price is provided to the customer at the time of purchase either through the on-line portal or via a sales quote for commercial clients, which may be discounted from list price based on volume of tests ordered. Periodically, discounts are provided to individuals when purchased through our online portal. No estimates or adjustments are made to the transaction price for returns or refunds, since these events rarely occur. There are three customer groups: (i) individuals who purchase tests through our online portal; (ii) commercial clients that pay upfront for test kits and (iii) professional health organizations that purchase collection kits and are all billed upon completion of testing and when results are reported to the customer. Contracts with customers do not contain significant financing components based on the typical period between performance of services and collection of consideration. There are very little requests for returns or refunds.

- BioCheck – Revenues for kits are recognized when kits are shipped to the customer. The specific transaction price is provided to the customer at the time of purchase, which may be discounted from list price based on the volume of tests ordered. No estimates or adjustments are made to the transaction price for returns or refunds, since these events rarely occur. Customers' payment terms are due upon receipt and are not provided significant financing components based on the typical period between shipment of the product and collection of consideration. There are no requests for returns or refunds.

- 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 test kits are shipped to the customer based on negotiated prices per individual contracts. Customers' payment terms are due upon receipt of the invoice and are not provided significant financing components based on the typical period between shipment of the product and collection of consideration. There are no requests for returns or refunds.

    - COVID-19 Lab Tests (PCR) – Revenues from the sale of COVID-19 viral (PCR) tests are recognized when returned nasal swabs are analyzed in our CLIA laboratory and the results are reported to the customer.

        - For direct billing to customers, revenue is recorded based on the agreed contracted amount for each test completed. Customers' payment terms are net 30 days and are not provided significant financing components based on the typical period between completed tests and collection of consideration.

        - For insurance, we estimate the amount of consideration we expect to be entitled to receive from customer groups in exchange for providing services using the portfolio approach practical expedient. The use of the expedient is not expected to differ materially from applying the guidance to an individual contract. These estimates are based on utilizing the expected value method and include the impact of contractual allowances (including payer denials). The portfolios determined using the portfolio approach consist of the following groups of customers which are similar since they are all insurance providers with similar reimbursement practices: healthcare insurers and government payers (Medicare and Medicaid programs). The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation. We follow a standard process, which considers historical denial and collection experience and other factors (including the period of time that the receivables have been outstanding), to estimate contractual allowances and recording adjustments in the current period as changes in estimates. Further adjustments to the allowances, based on actual receipts, may be recorded upon settlement. We rely on a third part billing company to process all claims to be paid by insurance providers. As a result, the average days to receive payment on these types of claims exceeds ninety days in some cases. As of December 31, 2023, we were owed $2,078 from insurance companies. These claims are no longer billable directly to the customer and if not reimbursed by the insurance providers, the balance will be written off against the allowance for doubtful accounts.

- CLIAx – Contractually, we can earn revenue in two ways: (i) by providing laboratory services and (ii) through co-marketing activities of the CLIAx clients laboratory developed tests. Revenue for laboratory services is recognized monthly based on agreed laboratory activities for space, equipment use and contracted personnel. The revenue that can be earned through co-marketing activities would be recognized if we sell any of the customer's products. As of December 31, 2023, the CLIAx customer is working through its marketing plan and we have not yet performed any co-marketing activities and as a result have not sold any CLIAx products or recognized any related revenue.

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. The impairment losses for the year ended December 31, 2023 and 2022 were $209,073 and $0 for certain fixed assets, respectively. 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.

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.

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 $134,824 and $258,837 for the years ended December 31, 2023 and 2022, respectively.

Research and Development. We incur research and development costs during the process of researching and developing our laboratory tests, algorithms, information technologies, and other intellectual properties. Our research and development costs consist primarily of data acquisition and personnel costs of scientists and laboratory technicians. We expense these costs as incurred until the resulting product has been completed, tested, validated, 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 an expense over the employee's requisite vesting period and over the non-employee'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 any other recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on the accompanying consolidated financial statements.

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	61	From August 2000	N/A
Anne Shiflett	Acting Chief Financial Officer	58	From April 2023	30
Jiming Zhou, Ph.D.	Chief Operating Officer	57	From August 2020	N/A
Ron Baker	Chief Business Officer	73	From October 2019	N/A
Michael Lebowitz, Ph.D.	Chief Scientific Officer	56	From January 2020	24
John G. Compton, Ph.D.	Chairman of the Board	75	From July 2016	N/A
Richard M. Cohen	Director	73	From July 2016	N/A
Wei Lu	Director	40	From June 2023	N/A
Prasanth Reddy	Director	49	From November 2023	N/A
John W. Rollins	Director	79	From November 2017	N/A
Michael A. Ross, M.D.	Director	74	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. We believe that Mr. Cohen is qualified to serve on our board of directors due to his experience in our industry and knowledge of our company.

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.

Ron Baker. Mr. Baker has served as our Chief Business Officer since October 2019 and previously served as our Director of Sales from October 2019 to January 2023. Prior to joining us, he held executive management positions in clinical research, operations, technical, sales, marketing and business development with international, national and start-up companies, all related to specialized oncology laboratory services, including as executive director of U.S. sales for SGS Life Sciences (Belgium) from December 2006 to March 2018. He previously worked with Roche Diagnostics and Roche Clinical Labs, International Clinical Labs and Molecular Oncology (start-up sold to Dianon). Mr. Baker earned his BS in Biology from Loyola University.

Michael Lebowitz, Ph.D. Dr. Lebowitz has served as 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. We believe that Dr. Compton is qualified to serve on our board of directors due to his extensive experience in our industry.

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. We believe that Mr. Cohen is qualified to serve on our board of directors due to his extensive management and board experience.

Wei Lu. Ms. Lu has served as a member of our board of directors since June 2023. Ms. Lu has over 10 years of experience in private equity investment and post investment management. She has served as the Vice President of Ping An Ventures since January 2019, where she is mainly responsible for post investment management of medical investments, including biotechnology, medical devices, medical services, etc. Ms. Wei Lu holds Master's degree in Finance from Chongqing University.

Prasanth Reddy. Dr. Reddy has served as a member of our board of directors since November 2023. He is triple board-certified in internal medicine, medical oncology, and hematology, and practiced medicine and served in leadership positions for more than 14 years in various clinical settings including academia, private practice, managed care, and life sciences. Dr. Reddy was most recently senior vice president, global enterprise oncology head of Labcorp from January 2021 to July 2023. Previously he served as vice president of medical affairs at Foundation Medicine from February 2018 to December 2020. He currently serves in the Air Force Reserve as a Lt Colonel. Dr. Reddy earned a bachelor's degree in microbiology and psychology from Kansas State University, and a medical degree from the University of Kansas Medical Center, where he also completed his internal medicine residency and clinical hematology and oncology fellowship. Dr. Reddy has a master's degree in public health and is an alumnus of Harvard Business School. Additionally, he is a fellow of the American College of Physicians and is a Certified Physician Executive. We believe that Dr. Reddy is qualified to serve on our board of directors due to his extensive experience in our industry.

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. We believe that Mr. Rollins is qualified to serve on our board of directors due to his extensive board experience.

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. We believe that Dr. Ross is qualified to serve on our board of directors due to his extensive experience in our industry.

Our directors currently have terms which will end at our next annual meeting of the stockholders or until their successors are elected and qualify, subject to their prior death, resignation or removal. Officers serve at the discretion of the board of directors.

Wei Lu was elected by the holders of our series A-1 preferred stock and Mr. Rollins was elected by the holders of all series 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 W. 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 information concerning all cash and non-cash compensation awarded to, earned by or paid to the named persons for services rendered in all capacities during the noted periods. No other executive officers received total annual salary and bonus compensation in excess of $100,000.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Jonathan Cohen, Chief Executive Officer[2]	2023	250,000	200,000	481,120	45,364	976,484
	2022	250,000	150,000	-	44,936	444,936
Jiming Zhou, Chief Operating Officer	2023	215,000	160,000	436,480	-	811,480
	2022	200,004	180,726	-	-	380,730
Anne Shiflett, Acting Chief Financial Officer	2023	112,500	-	130,000	61,431	303,931
	2022	-	-	-	120,750	120,750

(1) The amount is equal to the aggregate grant-date fair value with respect to the awards, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718.

(2) Other compensation represents fringe benefits for insurance and employer 401(k) matches.

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 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 Anne Shiflett, our Acting Chief Financial Officer, an annual salary of $150,000 and she is also eligible for a bonus tied to financial raises prorated based on amount raised and for discretionary bonuses, as determined by our board of directors. Ms. Shiflett 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 her position.

Retirement Benefits

We have not maintained, and do not currently maintain, a defined benefit pension plan or nonqualified deferred compensation plan. We currently make available a retirement plan intended to provide benefits under Section 401(k) of the Internal Revenue Code of 1986, as amended, or the Code, pursuant to which employees, including the executive officers named above, can make voluntary pre-tax contributions. We match 3.5% of the first 6% of employee contributions.

Potential Payments Upon Termination or Change in Control

As described under "—*Employment Agreements*" above, Mr. Cohen is entitled to severance under certain circumstances described above.

Outstanding Equity Awards at Fiscal Year-End

The following table includes certain information with respect to the value of all unexercised options and unvested shares of restricted stock previously awarded to the executive officers named above at the fiscal year ended December 31, 2023.

	Option Awards				
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)**	**Option Exercise Price ($)**	**Option Expiration Date**
Jonathan Cohen	287,779	100,221	-	$1.74	01/01/2033
Jiming Zhou	256,667	95,333	-	$1.74	01/01/2033
Anne Shiflett	0	100,000	-	$1.74	01/01/2033

Director Compensation

The table below sets forth the compensation paid to our independent directors during the fiscal year ended December 31, 2023.

Name	**Fees Earned or Paid in Cash ($)**	**Option Awards ($)[(1)]**	**Total ($)**
John G. Compton	20,000	39,300	59,300
Richard M. Cohen	17,500	39,300	56,800
Ming Li[(2)]	-	-	-
Wei Lu[(2)]	-	-	-
Prasanth Reddy[(3)]	2,500	-	2,500
John W. Rollins	17,500	39,300	56,800
Michael A. Ross	15,000	39,300	54,300

(1) The amount is equal to the aggregate grant-date fair value with respect to the awards, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718.

(2) In June 2023, Ming Li resigned from the board and was replaced by Wei Lu.

(3) Prasanth Reddy was appointed to the board in November 2023.

Effective as of January 1, 2022, our independent directors, except for Ming Li and Wei Lu, 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.

On January 1, 2023, each independent director, except for Ming Li, was granted an option for the purchase of 30,000 shares of common stock that vests monthly over one year, each at an exercise price of $1.74 per share.

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 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 25, 2024 (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]	1,694,595	0	0	33.22%	*	*	17.44%
All directors and officers as a group[7]	3,054,005	13,029	21,535	60.34%	1.54%	4.87%	31.92%

*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 4,773,128 shares of our common stock outstanding as of April 25, 2024.

(3) Based on 846,368 shares of our Series A Preferred Stock outstanding as of April 25, 2024.

(4) Based on 442,402 shares of our Series A-2 Preferred Stock outstanding as of April 25, 2024.

(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 25, 2024, 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 328,195 shares of common stock exercisable within 60 days.

(7) Includes 1,384,177 shares of common stock, options for the purchase of 1,667,162 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

Since the beginning of our 2022 fiscal year, we have not entered into any transactions, nor is there 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 or 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*" above).

DESCRIPTION OF SECURITIES

Capitalization

We are authorized to issue 50,000,000 shares of common stock, par value $0.01 per share, and 20,000,000 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 4,773,128 shares of common stock held by 349 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 33 holders of record and 1,204,040 shares of series C preferred stock held by 2,514 holders of record.

Common Stock

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.

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. 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.

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 authorizes our board to issue up to 20,000,000 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 2,369,860 shares of common stock at a weighted average exercise price of $1.34 per share.

Warrants

As of the date of this report, we have issued warrants to purchase an aggregate of 47,093 shares of common stock at a weighted average exercise price of $1.56 per share.

Convertible Notes

We have 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) 90% 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.

Accordingly, the convertible promissory notes will automatically convert into shares of our common stock on the date on which our common stock begins trading on NYSE American 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 such date.

Anti-Takeover Effects of Delaware Law and Charter Provisions

Provisions of the General Corporation Law of the State of Delaware, or the DGCL, our certificate of incorporation and our bylaws could have the effect of delaying or preventing a third-party from acquiring us, even if the acquisition would benefit our stockholders. Such provisions of the DGCL, our certificate of incorporation and our bylaws are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board

of directors and to discourage certain types of transactions that may involve an actual or threatened change of control of our company. These provisions are designed to reduce our vulnerability to an unsolicited proposal for a takeover that does not contemplate the acquisition of all of our outstanding shares, or an unsolicited proposal for the restructuring or sale of all or part of our company.

Our authorized but unissued shares of common stock are available for our board of directors to issue without stockholder approval, subject to NYSE American s rules. 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 20,000,000 shares of preferred stock. Our board acting alone and without approval of our stockholders, subject to NYSE American's rules, 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 may be adopted, amended or repealed by our board of directors. Our bylaws also 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 vote 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.

We are subject to Section 203 of the DGCL, which regulates corporate acquisitions. Section 203 prevents an "interested stockholder," which is defined generally as a person owning 15% or more of a corporation's voting stock, or any affiliate or associate of that person, from engaging in a broad range of "business combinations" with the corporation for the three years after becoming an interested stockholder unless:

- the board of directors of the corporation had previously approved either the business combination or the transaction that resulted in the stockholder's becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder's becoming an interested stockholder, that person owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, other than statutorily excluded shares; or
- following the transaction in which that person became an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Under Section 203, the restrictions described above also do not apply to specific business combinations proposed by an interested stockholder following the announcement or notification of designated extraordinary transactions involving the corporation and a person who had not been an interested stockholder during the previous three years or who became an interested stockholder with the approval of a majority of the corporation's directors, if such extraordinary transaction is approved or not opposed by a majority of the directors who were directors prior to any person becoming an interested

stockholder during the previous three years or were recommended for election or elected to succeed such directors by a majority of such directors.

Section 203 may make it more difficult for a person who would be an interested stockholder to effect various business combinations with our company for a three-year period. Section 203 also may have the effect of preventing changes in our management and could make it more difficult to accomplish transactions which our stockholders may otherwise deem to be in their best interests.

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: April 29, 2024

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)	April 29, 2024
/s/ Anne Shiflett Anne Shiflett	Acting Chief Financial Officer (principal financial and accounting officer)	April 29, 2024
/s/ John G. Compton John G. Compton	Chairman of the Board	April 29, 2024
/s/ Richard M. Cohen Richard M. Cohen	Director	April 29, 2024
/s/ Wei Lu Wei Lu	Director	April 29, 2024
/s/ Prasanth Reddy Prasanth Reddy	Director	April 29, 2024
/s/ John W. Rollins John W. Rollins	Director	April 29, 2024
/s/ Michael A. Ross Michael A. Ross	Director	April 29, 2024

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, 2023 and 2022, 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, 2023 and 2022, 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*
San Diego, California
April 26, 2024
We have been the Company's auditor since 2018.

20/20 GENESYSTEMS, INC.
BALANCE SHEETS
DECEMBER 31, 2023 AND 2022

	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 4,089,461	$ 8,807,575
Accounts receivable, net	68,834	764,924
Inventory	60,668	87,074
Prepaid expenses	81,469	72,270
Total current assets	4,300,432	9,731,843
License agreement, net	316,143	340,929
Property and equipment, net	244,203	580,911
Intangible assets, net	210,386	179,403
Right of use assets	933,394	1,088,783
Due from affiliated entities	-	2,699
Deferred offering costs	148,387	-
Other assets	214,883	290,453
Total assets	$ 6,367,828	$ 12,215,021
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 360,279	$ 464,282
Accrued liabilities	232,685	649,795
Deferred revenue	254,871	316,222
Financing lease liabilities – current	-	46,575
Lease liability – current	163,788	153,297
Total current liabilities	1,011,623	1,630,171
Long-term liabilities:		
Convertible note payable, net of unamortized debt discount	229,164	207,246
Lease liability – long term	839,549	1,003,338
Total long-term liabilities	1,068,713	1,210,584
Total liabilities	2,080,336	2,840,755
Commitments and contingencies (Note 8)	-	-
Stockholders' equity:		
Preferred stock, $0.01 par value; 20,000,000 authorized; 15,384,238 and 5,384,238 undesignated as of December 31, 2023 and 2022, respectively	-	-
Series C preferred stock, $0.01 par value; 3,340,909 authorized; 1,204,040 shares issued and outstanding as of December 31, 2023 and 2022; liquidation preference of $5,297,776	12,043	12,043
Series B preferred stock, $0.01 par value; 3,569,405 authorized; 1,471,487 shares issued and outstanding as of December 31, 2023 and 2022; liquidation 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, 2023 and 2022; liquidation 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, 2023 and 2022; liquidation 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, 2023 and 2022; liquidation preference of $2,598,350	8,464	8,464
Common stock, $0.01 par value; 50,000,000 authorized; 4,773,128 and 4,764,811	47,731	47,648

shares issued and outstanding as of December 31, 2023 and 2022, respectively		
Additional paid-in capital	28,150,331	26,845,879
Accumulated deficit	(23,956,731)	(17,565,422)
Total stockholders' equity	4,287,492	9,374,266
Total liabilities and stockholders' equity	$ 6,367,828	$ 12,215,021

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	2023	2022
Revenues	$ 1,424,304	$ 11,059,145
Cost of revenues (including stock-based compensation $82,941 and $0, respectively)	1,315,166	5,937,398
Gross profit	109,138	5,121,747
Operating expenses:		
Sales, general and administrative (including stock-based compensation $892,332 and $176,081, respectively)	5,061,450	3,322,835
Research and development (including stock-based compensation $328,679 and $0, respectively)	1,409,150	120,043
Loss on impairment of fixed assets	209,073	-
Total operating expenses	6,679,673	3,442,878
Operating income (loss)	(6,570,535)	1,678,869
Other income (expense):		
Interest expense	(27,915)	(15,685)
Interest income	209,150	68,421
Gain on sale of asset	-	2,371
Other expense	(2,009)	-
Other income	-	452,899
Total other income (expense)	179,226	508,006
Provision for income taxes	-	-
Net income (loss)	$ (6,391,309)	$ 2,186,875
Basic net income (loss) per common share	$ (1.34)	$ 0.46
Diluted net income (loss) per common share	$ (1.34)	$ 0.23
Weighted-average common shares outstanding, basic	4,768,799	4,763,561
Weighted-average common shares outstanding, diluted	4,768,799	9,487,385

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	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, 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
Stock based compensation	-	-	-	-	-	-	-	-	-	-	-	-	1,303,952	-	1,303,952
Exercise of warrants	-	-	-	-	-	-	-	-	-	-	8,317	83	500	-	583
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	-	(6,391,309)	(6,391,309)
Balance, December 31, 2023	1,204,040	$ 12,043	1,471,487	$ 14,715	442,402	$ 4,424	651,465	$ 6,515	846,368	$ 8,464	4,773,128	$ 47,731	$ 28,150,331	$ (23,956,731)	$ 4,287,492

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ (6,391,309)	$ 2,186,875
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	140,416	194,053
Stock based compensation	1,303,952	176,082
Amortization of license fees	24,786	26,784
Amortization of ROU assets, net of liabilities	2,091	67,852
Amortization of debt discount	5,208	1,529
Gain on sale of asset	-	3,379
Impairment of intangibles	-	24,091
Loss on impairment of fixed assets	209,073	-
Changes in operating assets and liabilities:		
Accounts receivable	696,090	1,937,689
Other receivables	-	1,547,118
Inventory	26,406	159,584
Prepaid expenses and other assets	66,371	34,798
Accounts payable	(104,003)	(248,487)
Related party payable	2,699	-
Interest payable	16,710	-
Accrued liabilities	(417,110)	(471,812)
Deferred revenue	(61,351)	163,524
Net cash (used in) provided by operating activities	(4,479,971)	5,803,059
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(9,383)	(261,793)
Proceeds from the sales of equipment	-	5,750
Acquisition of license agreement and patent cost	(34,381)	(206,509)
Net cash used in investing activities	(43,764)	(462,552)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from convertible notes payable	-	183,166
Convertible notes payable financing costs	-	(11,715)
Deferred offering costs	(148,387)	-
Principal payments on financing lease liabilities	(46,575)	(58,864)
Proceeds from exercise of warrant	583	12
Net cash provided by (used in) financing activities	(194,379)	112,599
Increase (decrease) in cash and cash equivalents	(4,718,114)	5,453,106
Cash and cash equivalents, beginning of year	8,807,575	3,354,469
Cash and cash equivalents, end of year	$ 4,089,461	$ 8,807,575
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
Escrow of convertible notes payable principal	$ -	$ 29,843
Accrued liability reclassed to equity	$ -	121,500
Operating lease, ROU assets and liabilities	$ -	$ 103,276

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2023 AND 2022

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.

Management Plans

The Company had incurred operating losses since its inception up to December 31, 2020; however, the Company experienced profitability from January 1, 2021 through December 31, 2022 from revenue generated from COVID-19 testing. With the winding down and lifting of the government funding of COVID-19 testing reimbursement, the Company incurred operating losses for 2023. Historically during the years of losses, the Company has relied on debt and equity financing for working capital. The Company expects to fund its operations through cash on hand, increased revenue from operations, planned reductions in spending, and the remaining capital raised through its planned Regulation CF offering and institutional financing in the form of a convertible bond.

Based on the Company's plans, management believes the doubt regarding the Company's ability to continue as a going concern has been alleviated.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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 and stock-based compensation.

Business Segments

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

Reclassifications

The Company has reclassified, combined or separately disclosed certain amounts in the prior years' financial statements and accompanying footnotes to conform with the current year's presentation. On the Balance Sheet, prior period presentation of $206,509 of "License Agreements, net" is now contained within "Other Assets".

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, 2023 and 2022. 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, 2023, 2022 and 2021, customer accounts receivable totaled $68,834, $764,924 and $4,215,465, respectively. Receivables through a third-party provider for insurance claims of $0 and $547,438 are included in this balance at December 31, 2023 and 2022, 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 $29,346 and $62,460 is included in accounts receivable at December 31, 2023 and 2022, 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, 2023 and 2022.

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.

Intangible Assets - License Agreements

In accordance with ASC 730-10-25-2.c, Topic 350-30 paragraph 805-50-30-2, license fees incurred through license agreements for technology supporting specific products to be sold are either expensed or recognized as intangible assets. The Company recognizes intangible assets when the following criteria are met: (1) the asset is identifiable, (2) the Company has control over the asset, (3) the cost of the asset can be measured reliably, and (4) it is probable that economic benefits will flow to the Company. In accordance with Topic 350-30 paragraph 805-50-30-2, the costs that are capitalized are measured by the cash paid to the licensor for the licensing of their technology in accordance with the license agreement. Any costs incurred during the validation of the technology are expensed once incurred. The license fees are amortized either beginning when the technology is validated internally and is ready to be included within the Company's product offerings over the period covered by the agreement which might include extensions or based on other terms specific to the agreement.

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, 2023 and 2022 were $209,073 and $24,091 for certain equipment and 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. The total deferred offering costs at December 31, 2023 and 2022 was $148,387 and $0, respectively.

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, 2023 and 2022.

	2023	2022
Weighted average common shares outstanding used in calculating basic earnings per share	4,768,799	4,763,561
Warrants to purchase Common Stock	47,093	54,751
Options to purchase Common Stock	2,394,415	53,311
Convertible notes	47,302	-
Series C Preferred Stock	1,204,040	1,204,040
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
Dilutive effect excluded from earnings per share	(7,104,572)	-
Weighted average common shares outstanding used in calculating diluted earnings per share	4,768,799	9,487,385

The Company excluded all Preferred Stock, warrants and options from the computation of diluted net loss per share the year ended December 31, 2023.

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. 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,	
	2023	**2022**
Revenues		
BioCheck	$ 187,926	$ 154,660
OneTest	921,502	323,414
COVID-19 PCR Tests	250,145	10,393,256
COVID-19 Antibody/Antigen Tests	2,375	97,452
CLIAx	62,356	90,363
Total revenues	$ 1,424,304	$ 11,059,145

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

- OneTest – Revenues from the sale of OneTest are recognized when returned serum specimens are analyzed in the Company's CLIA laboratory and the results are reported to the customer. The specific transaction price is provided to the customer at the time of purchase either through the on-line portal or via a sales quote for commercial clients, which may be discounted from list price based on volume of tests ordered. Periodically, discounts are provided to individuals when purchased through the Company's online portal. No estimates or adjustments are made to the transaction price for returns or refunds, since these events rarely occur. There are three customer groups: (i) individuals who purchase tests through the Company's online portal; (ii) commercial clients that pay upfront for test kits and (iii) professional health organizations that purchase collection kits and are all billed upon completion of testing and when results are reported to the customer. Contracts with customers do not contain significant financing components based on the typical period between performance of services and collection of consideration. There are very little requests for returns or refunds.

- BioCheck – Revenues for kits are recognized when kits are shipped to the customer. The specific transaction price is provided to the customer at the time of purchase, which may be discounted from list price based on the volume of tests ordered. No estimates or adjustments are made to the transaction price for returns or refunds, since these events rarely occur. Customers' payment terms are due upon receipt and are not provided significant financing components based on the typical period between shipment of the product and collection of consideration. There are no requests for returns or refunds.

- 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 test kits are shipped to the customer based on negotiated prices per individual contracts. Customers' payment terms are due upon receipt of the invoice and are not provided significant financing components based on the typical period between shipment of the product and collection of consideration. There are no requests for returns or refunds.

- COVID-19 Lab Tests (PCR) – Revenues from the sale of COVID-19 viral (PCR) tests are recognized when returned nasal swabs are analyzed in the Company's CLIA laboratory and the results are reported to the customer.

    - For direct billing to customers, revenue is recorded based on the agreed contracted amount for each test completed. Customers' payment terms are net 30 days and are not provided significant financing components based on the typical period between completed tests and collection of consideration.

    - For insurance, the Company estimates the amount of consideration it expects to be entitled to receive from customer groups in exchange for providing services using the portfolio approach practical expedient. The use of the expedient is not expected to differ materially from applying the guidance to an individual contract. These estimates are based on utilizing the expected value method and include the impact of contractual allowances (including payer denials). The portfolios determined using the portfolio approach consist of the following groups of customers which are similar since they are all insurance providers with similar reimbursement practices: healthcare insurers and government payers (Medicare and Medicaid programs). The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation. The Company follows a standard process, which considers historical denial and collection experience and other factors (including the period of time that the receivables have been outstanding), to estimate contractual allowances and recording adjustments in the current period as changes in estimates. Further adjustments to the allowances, based on actual receipts, may be recorded upon settlement. The Company relies on a third part billing company to process all claims to be paid by insurance providers. As a result, the average days to receive payment on these types of claims exceeds ninety days in some cases. As of December 31, 2023, the Company was owed $2,078 from insurance companies. These claims are no longer billable directly to the customer and if not reimbursed by the insurance providers, the balance will be written off against the allowance for doubtful accounts.

- CLIAx – Contractually, the Company can earn revenue in two ways: (i) by providing laboratory services and (ii) through co-marketing activities of the CLIAx clients laboratory developed tests. Revenue for laboratory services is recognized monthly based on agreed laboratory activities for space, equipment use and contracted personnel. The revenue that can be earned through co-marketing activities would be recognized if the Company sells any of the customer's products. As of December 31, 2023, the CLIAx customer is working through its marketing plan and the Company has not yet performed any co-marketing activities and as a result has not sold any CLIAx products or recognized any related revenue.

Deferred revenue represents contract liabilities that are recorded when cash payments are received or are due in advance of the Company's satisfaction of performance obligations. The deferred revenue for the years ended December 31, 2023, 2022 and 2021 were $254,871, $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 $134,824 and $258,837 for the years ended December 31, 2023 and 2022, 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 $780,127 and $358,337 for the years ended December 31, 2023 and 2022, 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. As of December 31, 2023, and 2022, the Company has a valuation allowance on the net deferred assets due to the continued likelihood that realization of any future benefit from deductible temporary differences and net operating loss carryforwards cannot be sufficiently assumed.

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, 2023, approximately 51% of total accounts receivable were due from two sources. As of December 31, 2022, approximately 51% of total accounts receivable were due from one source. During the year ended December 31, 2023, approximately 37% of total revenues were received from one source. During the year ended December 31, 2022, approximately 94% of total revenues were received from two sources. With the decline in COVID-19 incidences and the US Government no longer funding this testing, the Company's customers no longer require COVID-19 testing services' and the Company's revenue in this area is now zero.

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. The revenues in these areas have ceased entirely due to the end of the pandemic and emergency funding by the US Government.

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, 2023	December 31, 2022
Office equipment	$ 147,259	$ 160,669
Furniture and fixtures	57,691	54,112
Laboratory equipment	463,719	896,636
Vehicles	40,555	40,555
Leasehold improvements	12,221	12,221
Total property and equipment	721,445	1,164,193
Less accumulated depreciation	(477,242)	(583,282)
	$ 244,203	$ 580,911

In the year ended December 31, 2023, the Company performed an impairment analysis of laboratory equipment utilized in COVID-19 testing due to the significant material decrease in revenue and cash flow related to the COVID-19 testing and recorded an impairment charge of $209,073. It was determined after discussion with lab personnel that certain PCR laboratory equipment could be repurposed for potential future products and would be retained for research and development. The net book value of this equipment that remains in fixed assets equals $122,056 and will continue to be depreciated to research and development costs.

Depreciation expense was $137,018 and $183,662 for the years ended December 31, 2023 and 2022, respectively.

NOTE 4 – INTANGIBLE ASSETS

Intangible assets consisted of the following:

	December 31, 2023	December 31, 2022
Issued patents (amortized)	$ 31,840	$ 31,840
Unissued patents (unamortized)	207,150	177,423
Software development costs	4,654	45,575
Total	243,644	254,838
Less accumulated amortization	(33,258)	(75,435)
	$ 210,386	$ 179,403

Amortization expense for intangible assets was $3,398 and $10,391 for the years ended December 31, 2023 and 2022, respectively. Unissued patents represent the legal fees incurred to file and prosecute patents prior to issuance. The unissued patents are for active pending patents only. Any accumulated legal fees associated with abandoned unissued patents are expensed in the period they are abandoned.

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. The lease was paid off in 2023.

NOTE 6 – OPERATING LEASES

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, 2023
Operating lease right-of-use lease asset	$ 1,242,936
Accumulated amortization	(309,542)
Net balance	$ 933,394
Lease liability, current portion	163,788
Lease liability, long term	839,549
Total operating lease liabilities	$ 1,003,337
Weighted Average Remaining Lease Term – operating leases	63 months
Weighted Average Discount Rate – operating leases	3.8%

Future minimum lease payments under this operating lease as of December 31, 2023, were as follows:

2024	$ 199,629
2025	204,632
2026	209,767
2027	215,036
2028	220,460
Thereafter	68,293
Total lease payments	1,117,817
Less imputed interest	(114,480)
Maturities of lease liabilities	$ 1,003,337

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 $0 and $22,720 for the years ended December 31, 2023 and 2022, respectively. In early 2022, the Company vacated the property and entered into an agreement to settle any remaining obligations due.

Lease expense for the year ended December 31, 2023 was comprised of the following:

	December 31, 2023	December 31, 2022
Operating lease expense	$ 196,851	$ 177,041

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, 2023, 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) 90% 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, 2023 and 2022, the outstanding balance of these notes is $229,164 and $207,246, respectively, consisting of principal of $213,010, net of unamortized debt issuance cost of $4,980 and $10,187, respectively, and an accrued interest balance of $21,134 and $4,423, respectively.

Interest expense on the notes totaled $16,711 and $4,423 for the year ended December 31, 2023 and 2022, respectively, and the Company recorded amortization of debt discount in the amount of $5,207 and $1,529 during the year ended December 31, 2023 and 2022, respectively.

NOTE 8 – COMMITMENTS AND CONTINGENCIES

Royalties and License Agreements

License agreements:

	December 31, 2023	December 31, 2022
International license agreement	450,008	450,008
Total license agreements	450,008	450,008
Less accumulated amortization	(133,865)	(109,079)
	$ 316,143	$ 340,929

The Company is amortizing the license agreement over the term amounting to an amortization expense of $24,786 and $26,784 for the years ended December 31, 2023 and 2022, respectively.

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 $150,000 of certain up-front fees and $300,008 in Common Stock and ongoing royalty fees. In accordance with ASC 720-10-25-2.c, Topic 350-30-25-1, the Company recognized the $150,000 in up-front fees paid and the $300,000 in Common Stock as an Intangible Asset – License fee since the technology is deemed to provide a future benefit in its use to the Company by way of its sales of OneTest. The Company entered an exclusive license to the technology until the last patent included in the specified technology expires, or 20 years. The Company has amortized the license agreement over the term amounting to an accumulative amortization of $133,865 and $109,079 as of December 31, 2023 and 2022, respectively.

In August 2022, the Company entered into a three-year agreement to obtain and secure an exclusive license to certain multi-cancer diagnostic testing technology that incorporates additional biomarkers not currently part of the Company's OneTest. This product once validated will be marketed as OneTest Premium. In addition to OneTest Premium, the license agreement provides access to other technology for tests that assess various chronic diseases such as immune function, cardiovascular function and diabetic propensity that utilizes measurement of additional biomarkers. As of December 31, 2022, in accordance with ASC 720-10-25-2.c, Topic 350-30-25-1, the Company recognized the $150,000 in up-front fees paid along with an additional $56,509 in equipment validation materials in other asset and was recognized as research and development costs upon completion of the validation study as of December 31, 2023. The initial up-front license fee of $150,000 will be amortized through the recognition of royalty fees incurred on each sale and is included within the other assets on the accompanying balance sheet. Upon validation, the Company will recognize future per-test royalty fees in the range of $12-$25 per test.

On January 6, 2023, the Company entered into an option agreement to license certain proprietary technology from a leading cancer research institute for their in vitro diagnostics in the field of lung cancer blood-based predisposition evaluation tool. 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 up to three one-month extensions if needed upon mutual consent and additional option fees of $10,000 for each month extended. In accordance with ASC 720-10-25-2.c, Topic 350-30-25-1, the Company recognized the $70,000 in up-front option fee paid as an Intangible Asset – License fee since the technology once licensed will be deemed to provide a future benefit in its use to the Company by way of potential sales of LungSpot-lung cancer test. The initial up-front license fee of $70,000 will be amortized over the life of the final license agreement once finalized or expensed if a final agreement is not consummated. The agreement was not extended on July 6, 2023 and as a result, the $70,000 upfront fee was expensed to research and development costs as there was not alterative use for the license fee paid.

NOTE 9 – STOCKHOLDERS' EQUITY

On July 18, 2023, the Company filed a Certificate of Amendment of Second Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, pursuant to which the authorized Common Stock was increased from 25,000,000 shares to 50,000,000 shares and the authorized Preferred Stock was increased from 10,000,000 shares to 20,000,000 shares.

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, 2023 and 2022, 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, 2023 and 2022.

Series A-1 Preferred Stock

As of December 31, 2023 and 2022, 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, 2023 and 2022.

Series A-2 Preferred Stock

As of December 31, 2023 and 2022, 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, 2023 and 2022.

Series B Preferred Stock

As of December 31, 2023 and 2022, 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, 2023 and 2022.

Series C Preferred Stock

As of December 31, 2023 and 2022, there were 1,204,040 shares of Series C Preferred Stock issued and outstanding.

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, 2023 and 2022, there were 4,773,128 and 4,764,811 shares of Common Stock and outstanding, respectively.

During the year ended December 31, 2023, the Company issued 8,317 shares of Common Stock upon the exercise of warrants for proceeds of $583.

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.

Stock Options

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 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, which represented the fair market value of the Company's Common Stock on date of grant, 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 for a total fair market value of $183,708.

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, which represented the fair market value of the Company's Common Stock on date of grant, under the 2022 Plan, which 1,155,000 options issued to certain employees and officers vest 50% upon the date of grant and the remainder vest over 24 months, 210,000 options issued to certain employees and officers vest 25% on the first anniversary of the date of grant and monthly thereafter for remaining 36 months, and 120,000 options to certain directors that vest over a term of 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 2023 was determined using the Black Scholes option pricing model with the following assumptions: dividend yield: 0%; volatility: 79.7% to 92.7%; risk free rate: 3.99% to 4.73%; estimated term of five and ½ to seven years for a total fair market value of $1,862,400.

On April 1, 2023, the Company issued a non-qualified stock option for the purchase of 50,000 shares at an exercise price of $1.74 per share to an officer under the 2022 Plan which vests 25% on the first anniversary of the date of grant and monthly thereafter for remaining 36 months. 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 2023 was determined using the Black Scholes option pricing model with the following assumptions: dividend yield: 0%; volatility: 82.8%; risk free rate 3.6%; estimated term seven years for a total fair market value of $66,000.

With the assistance of third parties, the Company determined the fair market value of its Common Stock underlying the stock options comparing a market approach through analysis of comparable public companies and a venture funding approach taking into account the senior terms of the Company's Preferred Stock as compared to the Common Stock to arrive at a fair market value per share estimate for a common share. Once calculated, the Company applied a discount of 27% to account for the lack of marketability.

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 because it has insufficient history upon which to base an assumption about the terms, 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.

During the years ended December 31, 2023 and 2022, the Company recorded stock-based compensation of $1,303,952 and $297,582, respectively, which is an expense of $82,941 and $0 in cost of revenues, $892,332 and $297,582 in the sales, general and administrative expenses, $328,679 and $0 in research and development, respectively. As of December 31, 2023, there was approximately $569,675 of total unrecognized share-based compensation related to unvested stock options, which the Company expects to recognize over approximately three years.

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, 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
Granted	-	-	-
Exercised	-	-	-
Expired	(21,362)	4.50	-
Options outstanding, December 31, 2023	-	$ -	-
Options exercisable, December 31, 2023	-	$ -	-

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, 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
Granted	1,535,000	1.74	10.0
Exercised	-	-	-
Forfeited	(68,000)	1.66	-
Expired	-	-	-
Options outstanding, December 31, 2023	2,394,415	$ 1.48	8.14
Options exercisable, December 31, 2023	1,891,915	$ 1.41	7.90

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period. The following assumptions were used to calculate share-based compensation expense for years ended December 31, 2023 and 2022:

	2023	2022
Exercise price	$1.735	$1.0643
Share price	$1.740	$1.0643
Volatility	79.7% -92.7%	68.5%
Risk-free interest rate	3.6% - 4.73%	1.63%
Dividend yield	0.0%	0.0%
Expected term	5.5 to 7.0 years	5.0 years

Warrants

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, 2021	103,637	$ .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
Granted	-	-	-
Exercised	(8,317)	0.01	-
Forfeited/Expired	(17,083)	0.01	-
Warrants outstanding, December 31, 2023	47,093	$ 1.56	2.70
Warrants exercisable, December 31, 2023	47,093	$ 1.56	2.70

NOTE 10 – 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, 2023 and 2022, the Company paid $101,978 and $58,078, 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 $31,050 and $75,000 in 2023 and 2022 to this organization, respectively.

NOTE 11 – 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, 2023 and 2022:

	2023	2022
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:

	2023	2022
Expected federal tax (expense) benefit	$ 1,342,200	$ (459,200)
Expected state tax (expense) benefit	527,300	(180,400)
Nondeductible expenses and other	(416,700)	(126,900)
(Increase) decrease in valuation allowance	(1,452,800)	766,500
Total provision for income taxes	$ -	$ -

The major components of the deferred taxes are as follows at December 31, 2023 and 2022:

	2023	2022
Account receivable, net	$ 7,400	$ 18,300
Accumulated depreciation	(1,500)	(1,500)
Intangible assets, net	(69,300)	(78,000)
Accrued expenses	62,100	39,400
Net operating loss	6,077,100	4,644,800
Deferred tax asset valuation allowance	(6,075,800)	(4,623,000)
	$ -	$ -

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, 2023, the Company had available approximately $20.8 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, 2023 are approximately $20.7 million and have begun to expire in 2020. There is a full valuation allowance as of December 31, 2023 and 2022 which may be reversed in future periods at a point when the Company can make the determination that recoverability will be probable. The valuation allowance for deferred tax assets increased and decreased by approximately $1,452,800 and $766,500 during the years ended December 31, 2023 and 2022, 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 12 – SUBSEQUENT EVENTS

The Company has evaluated subsequent events that occurred after December 31, 2022 through April 26, 2024, 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.

Option Agreement

On March 22, 2024, the Company entered into an option agreement with The Board of Regents (the "Board") of The University of Texas System, an agency of the State of Texas, on behalf of by The University of Texas M.D. Anderson Cancer Center ("MD Anderson"), pursuant to which MD Anderson has granted the Company an exclusive six-month option to enter into a royalty-bearing, exclusive license to certain patent rights and technology, which option may be exercised by the Company upon (i) the Company's completion of an equity financing with proceeds of at least $23 million based on a pre-money valuation of at least $70 million (which such financing may not be obtained through a crowdfunding or Regulation A offering) and (ii) payment of a fee in the amount of $4,457,069.15. Upon exercise of the option, the Company will enter into a patent and technology license agreement with the Board and MD Anderson, in the form attached to the option agreement, pursuant to which MD Anderson will grant the license to the Company in exchange for certain royalties, fees and shares of Common Stock set forth in the patent and technology license agreement.

Convertible Bonds Subscription Agreement

On March 20, 2024, the Company entered into a convertible bonds subscription agreement with Cornerstone Investment Inc. (the "Investor"), pursuant to which the Company agreed to issue a convertible bond in the principal amount of $23 million to the Investor (or its designee) for a purchase price of $23 million. The issuance of the convertible bond is subject to customary closing conditions, as well as execution of the option agreement described above and a collaborative research agreement with MD Anderson. The convertible bond will have a term of five (5) years and will not bear interest; provided that (i) if any portion of the convertible bond has not been converted prior to the maturity date or the date on which an event of default (as defined in the convertible bond) occurs, as applicable, and (ii) the Investor desires to receive a cash payment with respect to such unconverted portion on the maturity date or the date on which an event of default occurs, as applicable, the Company shall be required to pay the Investor, in addition any other amounts required under the convertible bond, interest accrued on the aggregate principal sum of the convertible bond at a rate equal to 6% per annum from the date on which the convertible bond is issued up to the maturity date or the date on which an event of default occurs, as applicable. In addition, if the convertible bond is still outstanding after the maturity date or the date on which an event of default occurs, as applicable, then interest shall accrue beginning on the day after the maturity date on the outstanding principal balance and the default amount at a rate equal to 12% per annum. The Company may not prepay the convertible bond prior to the maturity date.

The convertible bond will be convertible at any time at the option of the holder into shares of Common Stock, or, subject to stockholder approval, a new series of Preferred Stock to be designated as Series E Preferred Stock with the terms and conditions set forth in Annex A to the convertible bond. In addition, the convertible bond shall automatically be converted into Series E Preferred Stock upon the earlier to occur of (i) an initial public offering of the Company's Common Stock and concurrent listing on a national securities exchange, including without limitation the New York Stock Exchange, NYSE American or the Nasdaq Stock Market (any tier), (ii) a direct listing of the Company's Common Stock on a national securities exchange, including without limitation the New York Stock Exchange, NYSE American or the Nasdaq Stock Market (any tier) or (iii) upon such stockholder approval. The number of shares to be issued upon conversion shall be equal (i) the outstanding principal amount of the convertible bond and all accrued and unpaid default interest, if any, divided by (ii) the conversion price then in effect. The initial conversion price will be $5.34 per share, subject to customary adjustments for stock dividends, stock splits, stock combinations, reclassifications, mergers, consolidations, sales of all assets, or similar events. In addition, subject to certain exceptions, if the Company issues any equity securities with an implied price per share of less than the conversion price then in effect, then the conversion price shall be adjusted, concurrently with such equity issuance, to the implied price per share received by the Company for such equity issuance. Finally, the conversion price will be subject to adjustment in the event that the Company completes an initial public offering or a direct listing of its Common Stock on a national securities exchange that does not meet the requirements of a Q-IPO or a Direct Listing (each as defined below).

The convertible bond will be unsecured and will contain customary covenants and events of default for a loan of this type. The Company also agreed that the Investor will be entitled to nominate at least one (1) director to the board of directors as long as the convertible bond is outstanding. Subject to certain exceptions, the Company also agreed that the Investor will have the right to participate in any subsequent financing transactions involving the issuance of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock for cash consideration in an amount required to maintain the Investor's fully diluted ownership in the Company. The Company also agreed to use its best efforts to (i) close a firm commitment underwritten public offering and concurrent listing on a national securities exchange, including without limitation the New York Stock Exchange, NYSE American or the Nasdaq Stock Market (any tier), with a per share offering price of at least $5.34 plus interest accrued on $5.34 at a rate equal to 6% per annum from the issuance date of the convertible bond up to the date of listing (the "Target Price" and such offering, a "Q-IPO"), or (ii) complete a direct listing of Common Stock on a national securities exchange, including without limitation the New York Stock Exchange, NYSE American or the Nasdaq Stock Market (any tier), with the reference price of at least the Target Price (a "Direct Listing"), within three (3) years following the issuance date of the convertible bond, which period may be extended by one (1) year by mutual agreement between the Company and the Investor.

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.