July 8, 2020

FORM C-AR: Annual Report

20/20 GeneSystems, Inc.
9430 Key West Ave.
Rockville, MD 20850
(240) 453-6339; www.2020gene.com

ANNUAL REPORT FOR THE FISCAL YEAR ENDED DECEMBER 31, 2019

This Form C-AR (including the cover page and all exhibits attached hereto, the "Form C-AR") is being furnished by 20/20 GeneSystems, Inc., a Delaware corporation ("we," "us," "our" or "our company") for the sole purpose of providing certain information about the shares of Series A-2 Preferred Stock offered and sold by our company pursuant to Regulation Crowdfunding under the Securities Act of 1933, as amended (the "Securities Act"), for the fiscal year ended December 31, 2019. A copy of this report may be found on the company's website at www.2020gene.com.

On December 29, 2017, we completed an initial closing in which we raised $1,018,297 in gross proceeds through the sale of 312,361 shares of our Series A-2 Preferred Stock. On January 23, 2018, we completed a second and final closing in which we raised $48,988 in gross proceeds through the sale of 15,027 shares of our Series A-2 Preferred Stock.

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

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

Forward Looking Statement Disclosure

This Form C-AR and any documents incorporated by reference herein or therein contain forward-looking statements and are subject to risks and uncertainties. All statements other than statements of historical fact or relating to present facts or current conditions included in this Form C-AR are forward-looking statements. Forward-looking statements give our current reasonable expectations and projections relating to our financial condition, results of operations, plans, objectives, future performance and business. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as "anticipate," "estimate," "expect," "project," "plan," "intend," "believe," "may," "should," "can have," "likely" and other words and terms of similar meaning in connection with any discussion of the timing or nature of future operating or financial performance or other events.

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

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

About this Form C-AR

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

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

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BUSINESS DESCRIPTION

Overview

We are an early revenue stage digital diagnostics company with the core mission of developing and commercializing *in-vitro* diagnostic tests powered by machine learning to improve diagnostic accuracy and clinical usefulness. In response to the novel coronavirus pandemic that began in early 2020, we expanded upon our longstanding mission of reducing cancer mortality in the U.S. and around the world through early detection. More specifically, we acquired and commercialized several COVID-19 antibody tests, both rapid kits and laboratory-based tests.

For early cancer detection, we use 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. Our products include a multi-cancer test for screening at least five types of cancer from one blood sample known as OneTest (www.OneTestforCancer.com) and a blood test for early lung cancer known as PAULA's Test. In the coming months, we expect to integrate PAULA's Test into OneTest. Our 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 (www.BioCheckInfo.com). Our BioCheck kits for screening suspicious powders remains profitable, but with limited growth potential, at least in the U.S. absent a serial anthrax incident, or similar incident, like the one that occurred in the U.S. in 2001.

The Market for Early Detection of Cancer

The survival rate for the deadliest cancers is closely linked to stage at time of diagnosis. With lung cancer, for example, some studies show a five-year survival rate approaching 90% for screen detected Stage 1 cancers (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 five percent 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 studies by our collaborators in Taiwan demonstrate that these tests are useful for detecting even early stage cancers (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 the approach pioneered by us, this screening approach can be rendered significantly more accurate using machine learning algorithms that integrate clinical factors (e.g. age, gender, smoking history, etc.) with the biomarker levels. Evidence of our approach was published in a respected oncology journal in May 2020 co-authored by several 20/20 scientists. See Wang, et al. "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.

Our "East to West" business model is to use our algorithms to improve blood-based screening tests in regions where this testing is common (e.g. East Asia) while introducing this testing paradigm in regions where such testing is not yet widespread (e.g. North America).

East to West Model
Bringing Cancer Screening to the West

Typical Health Screening Center Menu of Cancer Marker Tests

Test Item	Price Required time	Explanatory Note
CEA	3,240yen	Tumor marker for cancers of the digestive tract (colon, rectum, stomach, pancreas), lungs, breasts and ovaries.
CA19-9	3,240yen	Tumor marker for cancer of the digestive tract (pancreas, gallbladder, bile duct).
PSA (for men)	3,240yen	Tumor marker for prostate cancer (Prostate-specific antigen test).
CA125 (for women)	3,240yen	Tumor marker for ovarian cancer.
SCC	3,240yen	Tumor maker for lung cancer (squamous cell carcinoma), esophageal cancer, head and neck carcinoma, cervical cancer, and skin cancer.
CYFRA	3,240yen	Tumor maker for lung cancer (squamous cell carcinoma).
Pro-GRP	3,780yen	Tumor marker for lung cancer (small cell carcinoma).
AFP, PIVKA-2	5,400yen	Tumor markers for liver cancer (hepatocellular carcinoma).
P53	4,320yen	Tumor marker potentially useful for early cancer detection, especially in combination with other markers.
CEA+CA19-9	4,860yen	Tumor marker panel for cancer of the digestive tract.
P53+CEA+CA19-9	8,640yen	Tumor marker panel (including P53) for cancer of the digestive tract.
SCC+CYFRA	5,400yen	Tumor marker panel for lung cancer.
P53+SCC+CYFRA	8,640yen	Tumor marker panel (including P53) for lung cancer.

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) 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 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. As of the date of this report, are unaware of any other companies that have adopted this approach.

Our solutions historically focused on lung cancer, which is the third most common cancer and the leading cause of cancer deaths among both men and women, according to the American Cancer Society. According to Grand View Research, the global lung cancer diagnostics market is forecasted to grow to $3.64 billion by 2024 from an estimated $1.63 billion in 2015. While the North American market generated the most revenue in 2015 (~$520 million), the Asia Pacific market has the largest projected growth rate at a CAGR of 9.5% from 2013 to 2024.

Our tests are built around the installed base of existing U.S. Food and Drug Administration, or FDA, approved tumor marker detection kits which run on automated instruments available from companies like Roche Diagnostics, Abbott Diagnostics, Siemens Diagnostics, and others. These tests and instruments are used in thousands of clinical testing labs worldwide, thereby permitting us to scale globally. To the best of our knowledge, no other company has yet commercialized a scalable lung or multi-cancer test utilizing the biomarker platforms and algorithm approach adopted by us.

In the second half of 2018, we transitioned our focus to the commercialization of a multi or "pan" cancer test (i.e. screening for several cancers from one blood sample) called OneTest. We believe that this test has a substantially larger market than any single cancer test. 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 market experience has shown that a large number of Americans are willing to pay up to an average of about $200 out-of-pocket for a blood test that can simultaneously screen for multiple cancers. There are about 115 million Americans between the ages 45-75, the optimal ages for cancer screening. Thus, we estimate that OneTest addresses a market of about $15 billion in the U.S. alone.

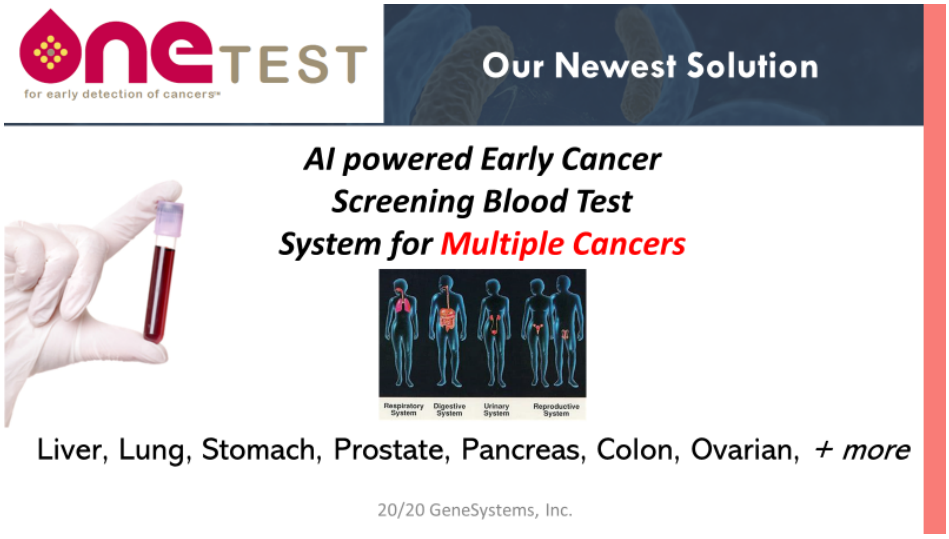
Artificial intelligence (AI) and machine learning are expected to transform healthcare by helping physicians diagnose and treat patients with greater accuracy and precision. According to Accenture, the U.S. can potentially save $150 billion annually by 2026, with key healthcare AI applications such as robot-assisted surgery, preliminary diagnosis, and virtual nursing assistants. 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 (e.g. Deep Learning Neural Networks) will increase.

We believe that we are the first company to incorporate the following four core elements in each of our cancer tests: (i) a panel of three to eight protein biomarkers, (ii) individual patient characteristics and health history (age, sex, smoking history, risk factors, and medical imaging results, etc.), (iii) data from hundreds to thousands of patients previously tested, and (iv) machine learning and artificial intelligence-based analytics. Additionally, we have added to our portal and test report forms a feature to easily show the biomarker trends from serial testing. Several studies have demonstrated that rising biomarkers levels over time is more useful than single time point testing.

Product Portfolio

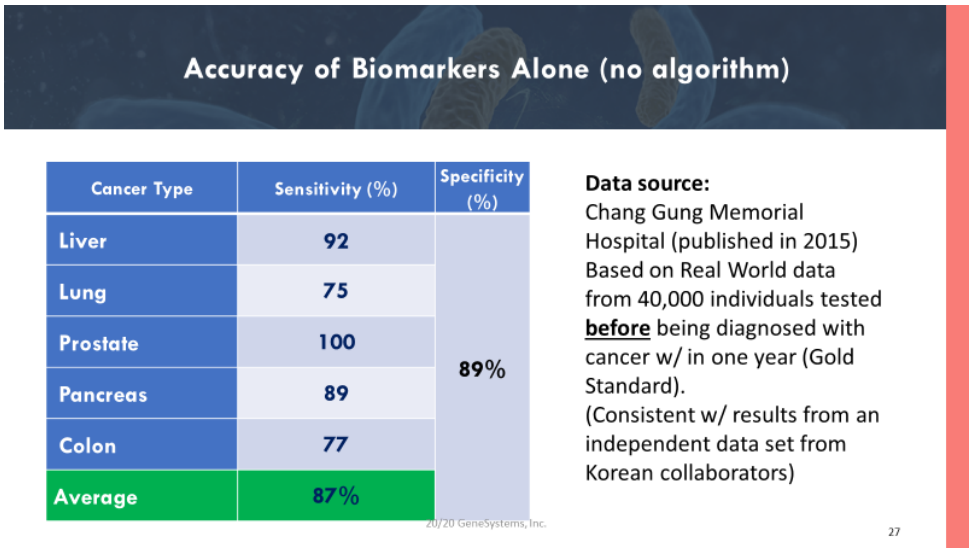
OneTest

In the second half of 2018, we began focusing on the commercialization of OneTest, a multi-cancer test and algorithm to screen for multiple cancer types from a single blood sample. OneTest is modeled on the testing approach common in East Asia where millions of healthy individuals receive cancer biomarker tests as part of yearly health check-ups. Real world data from over 40,000 individuals tested with the seven-biomarker panel over a 12-year period is the foundation of this test. Importantly, our algorithms and analytics substantially improve the accuracy of cancer tests currently used by physicians, hospitals, clinical labs, and health check centers in many parts of the world - without requiring new equipment or change in diagnostic testing practice. The algorithm combines the levels of protein biomarkers - like carcinoembryonic antigen, or CEA, alpha-fetoprotein, or AFP, prostate specific antigen, or PSA, and others, with patient information (e.g. age, gender, smoking history, etc.). We report patient risk of having five or more cancers (liver, lung, pancreas, and the like) and recommend follow-up testing with the objective of finding early tumors that can be surgically removed before they become fatal. We operate our own laboratory with a Certificate of Compliance (General Immunology) through June 2022. In May 2018, we acquired, installed, and validated the automated immunoassay analyzer manufactured by Roche Diagnostics needed to run OneTest (this same analyzer is also being used to run a COVID-19 antibody test as discussed below.) All of our standard operating procedures were in place per CLIA (Clinical Laboratory Improvement Amendments) requirements before the end of August 2018, after which we began several targeted sales and marketing campaigns.



Among the cancers for which OneTest accuracies are strongest are those of the lung, liver, pancreas and colon. 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.

The following demonstrates the accuracy of biomarkers, which is the first part of OneTest, without our algorithm.



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.

PAULA's Test

We previously introduced different versions of PAULA's (Protein Assays Using Lung Cancer Analytes) Test, the 2.0 version having been co-developed and validated by the Cleveland Clinic, in the U.S. in the second quarter of 2014. We believe that PAULA's Test was among the first combinatorial blood tests for the early detection of lung cancer that incorporates a machine learning algorithm that factors in clinical parameters (age, gender, smoking history) together with biomarker values. The algorithm analyzes biomarkers (also known as tumor antigens) associated with non-small cell lung cancer. PAULA's Test is designed for patients who are at high risk for lung cancer due to long-term smoking.

In the coming months, we expect to integrate PAULA's Test into OneTest. As most of the biomarkers measured in PAULA's Test (CEA, CA-125, Cyfra) are also part of OneTest, this integration mainly centers on using common testing instrumentation.

BioCheck Suspicious Powder Screening Kits

We have a longstanding business that makes and sells patented test kits for screening suspicious powders called BioCheck. These popular 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.

Our BioCheck business is small, but profitable, with gross profit margins of about 65%. Importantly, as discussed below, we are leveraging the network, sales channels, and positive brand identification we have built over many years from selling BioCheck to fire departments to introduce them to OneTest since firefighters have proven higher cancer incidence and mortality over the general population.

COVID-19 Antibody Tests

As the COVID-19 pandemic emergency manifested in the United States in March of 2020 our company, like many of our peers in the life sciences industry, considered potential opportunities to leverage our technical and business expertise, commercial relationships, and laboratory infrastructure. Beginning in late March, following new guidance from the FDA, we began to import, evaluate, market and distribute rapid COVID-19 IgM/IgG antibody detection kits manufactured by Innovita of China. This company was selected by us because they were one of the few manufacturers with approval from the Chinese FDA and because they presented a data set with specificity reported at 100% (specificity is especially important with antibody tests due to the need to negate false positives). Before selling the rapid test, we conducted external studies at six independent sites to verify that the tests performed as expected.

Sales of this product were brisk, especially during the month of April, when we sold over 70,000 tests. In May, a combination of negative news reports about the quality of rapid tests from China coupled with confusing guidance from the FDA dampened demand for this category of test. Accordingly, we have acquired laboratory-based antibody tests from Roche Diagnostics which has an Emergency Use Authorization, or EUA, from the FDA. According to the manufacturer, this test has a sensitivity of 100% and a specificity of 99.8%. Importantly, the test has been validated on nearly 5,000 samples so the low false positive rate—the most important criteria for antibody tests—is believed to be highly reliable. Conveniently, this test utilizes the same Roche Cobas testing instrument that we use to run OneTest, so we did not need to purchase any new instrumentation.

Demand for COVID-19 antibody tests during the second half of 2020 will depend heavily on the results of studies seeking to ascertain the extent and duration of immunity conferred by the presence of antibodies. New data emerges by the week, but as of late June 2020 studies out of the U.K. and China suggest at least 2-3 months of immunity. If these studies are confirmed with larger and more geographically diverse cohorts, this suggests that there will be significant demand for antibody tests by the fall of 2020.

Sales and Marketing Strategy

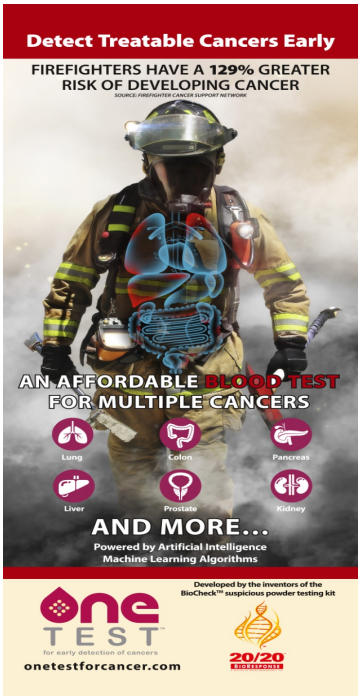
United States

Based on market research conducted in 2018 and sales in 2019, we believe that our best near-term market for our cancer tests in the U.S. is occupational health, and more specifically, 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. mesothelioma), the biomarkers that we measure have been shown to be elevated in numerous

published studies. Thus, we believe OneTest to be a useful tool for cancer screening of current and former firefighters. See www.OneTestforCancer/Firefighters.

There are an estimated one million active and retired firefighters (career and volunteer) in the U.S. between the ages of 45 to 75, the optimal ages for cancer screening. Thus, at an average selling price of $130 this represents a $130 million market in the U.S. alone.

As of the date of this report, we received OneTest orders from fire departments in more than a dozen states, as well as from individual firefighters, totaling over 1,200 test orders. Following the pandemic emergency in the U.S. beginning in March 2020, there was a significant drop in OneTest orders as routine medical examinations were deferred by most Americans. However, we are seeing increasing orders beginning in June and this occupational sector will likely remain a prime target for us at least through 2020 when we will expand to other occupations.



Studies have demonstrated that more than 60% of the genetic mutations that cause cancer come from random DNA copying errors over time (i.e. aging) rather than inherited genes or lifestyle (smoking, occupational exposure, etc.). Thus, we believe that all adults should be screened yearly for multiple cancers, beginning in middle age. To penetrate this exceptionally large market of healthy adults between the ages of 45 to 75 (about 115 million Americans alone) will require (i) a significant direct-to-consumer education and marketing campaign over many years and (ii) convenient access to phlebotomy services and medical 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 provide convenient "one-stop shopping" for OneTest.

As for COVID-19 related products which we are currently selling in the U.S. only, we have relied mainly on media outreach (i.e. press releases) to attract customers. Digital marketing is not available due to bans by Facebook and Google on advertisements related to COVID-19 related products. We have also engaged in cross-marketing our cancer and COVID-19 products by offering a complimentary antibody test for all blood specimens that arrive in our lab for OneTest.

International

Outside of the U.S., our commercialization models usually involve having blood samples tested locally with access to the OneTest algorithms over our cloud accessible portals. The target end-users are "Health Check Centers" of which there are thousands in Asia and parts of Europe and the Middle East. Heath Check Centers provide only screening examinations. They offer no treatment of injuries or illnesses. Invariably, these Health Check Centers offer routine testing of the biomarkers that are part of OneTest (albeit without any algorithms or analytics).

As of the date of this report, we have clinical users or marketing representatives in place in China, Taiwan, Japan, Israel, Jordan, Egypt, and the United Arab Emirates. These commercial engagements usually involved a month or two of free portal access followed by fee-based arrangements. Our largest global markets are likely in China and Japan due not only to their large populations, but to the fact that tens of millions of their citizens receive tumor biomarker testing each year as part health check-ups.

Lab Facility

We operate a CLIA approved laboratory facility, Genesys Biolabs, where testing can be performed. As part of our commercialization strategy, we established this CLIA certified lab facility to perform immunodiagnostic tests of the highest level of complexity. 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 CLIA.

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.

With regard to lung cancer, a longstanding focus of our company, key competitors include OncImmune, Ltd. and OncoCyte, Corp.

We are unaware of any widely utilized products on the market that currently compete with our proposed OneTest multi (pan) cancer test. In the U.S., we know of no pan-cancer blood test that large numbers of physicians routinely order on behalf of their patients. 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. Examples of companies working on pan-cancer tests include Grail, Thrive, and Freenome. We are aware of only one company actively marketing a "next-gen sequencing" test for pan-cancer screening in the U.S., the IvyGene test. Of note, IvyGene, like our pan-cancer test, is also being actively marketed to fire departments.

We believe we may be the first and only company to have a market ready pan-cancer blood test that meets each of the following criteria:

- Aids in the early detection of five or more cancers, especially deadly cancers such as those of the lung, liver, and pancreas for which there are no widely used screening tools in the U.S.;

- Includes machine learning algorithms powered by data from over 28,000 individuals, the majority of whom were tested **before** being diagnosed with cancer (it is very important to show that a test is useful to screen asymptomatic individuals vs. monitoring those who have confirmed cancer);

- Externally validated using an independent sample set; and

- Reasonably expected to be offered for under $200 over the next few years (this price point is important since these tests will not likely be covered by insurance for many years to come).

Our OneTest meets each of the above criteria whereas our known competitors are not expected to do so in the near future due to the need to run multi-year prospective clinical studies which are believed to be getting underway only this year. Data from a large cohort of individuals tested before being diagnosed with cancer is usually needed to assess the true efficacy of tests in a real-world screening population. Furthermore, most of our known competitors in the pan-cancer space are believed to rely heavily on next-generation sequencing of cell-free DNA, which is currently far more expensive than the immunoassays used by our company.

We currently intend, subject to a validation study, to incorporate our lung cancer assay (PAULA's Test) into OneTest, at least initially for those consumers with a history of smoking.

We believe that we are among the first companies to develop and bring to market in the U.S. and China machine learning algorithms developed from and used with standard biomarker tests run in thousands of Health Check Centers in East Asia and around the world. Accumulation of high-quality data to build these algorithms was a multi-year effort, thereby creating a substantial barrier to entry. As a first mover, serial data we collect from individuals who use our test will be fed back into the machine learning algorithm resulting in further accuracy improvement. Thus, we expect to remain ahead of emerging competitors in terms of continuously learning and improving test performance.

Customers

Over 3,500 individuals have been tested to date with PAULA's Test for the early detection of lung cancer. Approximately 1,500 of our newer OneTests have been ordered as of the date of this report with demand expected to substantially increase when the pandemic lockdown fully relaxes. We also have a legacy product, BioCheck, for screening suspicious powders that has been used by more than 1,000 fire departments and other emergency responder organizations worldwide. These customers are also targets for our lung and multi-cancer tests due to proven increase in lung cancer risk among firefighters.

Competitive Advantages

Based on our management's experience in the industry, we believe the following competitive strengths should enable us to compete effectively in and capitalize on the growing cancer diagnostic market.

- ***Our pan-cancer test and algorithm are based on data from a pre-symptomatic patient population and therefore should translate well into a real-world screening population***. 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 aforementioned competitors. However, unlike all of our known competitors, the data supporting our pan-cancer products were generated from tens of thousands of individuals undergoing yearly screenings in "real-world" patient settings where blood samples were taken and analyzed **before** the cancer diagnosis. In contrast, competing products were developed in a laboratory setting involving blood samples from individuals **after** they presented with symptoms of cancer when it has often advanced to a later stage. The accuracies of tests developed using this "case/control" model consistently fail to hold up in real-world screening practice.

- ***Our tests our designed to be compatible with existing 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 tens of thousands of individuals tested worldwide using standardized test kits and instruments.

- ***Our tests are expected to be more affordable compared to DNA based liquid biopsies***. We project that the average selling price of OneTest (blood test plus algorithm) will be about $165 (with bulk discounts provided to companies). For overseas users accessing the algorithm only (i.e. laboratory testing conducted in-country), the cost will average about $20 per use. In contrast, we estimate tests that incorporate next-gen sequencing of cell-free DNA will likely cost an average of $500 or more for at least the next several years.

- ***Cancer screening options in the U.S. are limited to only a few types of cancers***. Widespread cancer screening in the U.S. is limited to only colorectal, breast, prostate and cervical cancers. Our test offers additional early detection

options for other commonly diagnosed cancers such as lung, pancreatic and liver, malignancies where few if any low cost, easily accessible screening option exists today.

Growth Strategies

We will strive to be a leading cancer diagnostic company by pursuing the following growth strategies:

- ***Targeting of high-risk occupations***. Certain professions (e.g. 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.

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

- ***Direct-to-consumer outreach***. Our market research and pre-commercial pilots suggest that a substantial and growing segment of the wellness market is willing to pay an average of about $200 for early cancer screening blood tests if it helps to reduce the risk of advanced, lethal cancers. We believe that well educated consumers look to manage their own medical options when it comes to diagnostic testing, nutrition and preventative services. Even when it means going beyond what the medical establishment covers for general screening for the public, many people seek better understanding and management of their health. We have therefore adopted a consumer-initiated model where interested individuals request the test from a physician of their choice. We have no immediate plans for a pure direct-to-consumer model that avoids physicians entirely. Since our tests run on industry standard instruments which use very low-cost reagent kits, these low-cost consumable reagent kits allow running the cancer biomarker tests extremely affordable and profitable for the labs which run them. This low cost/high profit model means that our partner labs have a strong motivation to offer our tests to their medical providers.

Commercialization Milestones to Execute Our Growth Strategy

In order to achieve our ambitious growth strategies set forth above in a timely manner, we have established, and begun to execute the following goals and milestones with respect to OneTest:

COMMERCIALIZATION PHASES	UNITED STATES	OUTSIDE U.S. *(East Asia, Middle East, Russia)*
Pilot (Proof-of-Concept) Phase (Q3 2018 through Q2 2019)	Received first group orders from several fire departments. Demonstrated the ability to generate and fill on-line test orders using digital marketing. Generated nearly 200 paid test orders in the second quarter of 2019, a substantial increase over previous quarters.	Entered into software (algorithm) access subscription agreements with health check clinics or clinical laboratories in each of Taiwan, Japan, the UAE, Jordon, and Austria. Most provide for 2 or 3 months of free use before any royalty payments due. Average royalty per individual use about $20 USD.
Growth Phase (Q3 2019 through Q2 2020)	Doubled quarterly paid test volume to over 400 in the third quarter of 2019 and over 600 in the fourth quarter. Increased average test selling price from $110 to $130. Improved digital marketing to yield several on-line test orders each day. Cancer test demand fell in Q1 2020 due to pandemic as routine medical exams were deferred.	Entered into first software subscription agreement with a health check clinic in mainland China. Admitted to highly competitive Ping An Accelerator in Shenzhen China. Fewer than 3% of applicants worldwide are accepted into this program. This has given us access to various units within Ping An to pilot our software products.

		First peer-reviewed publication describing OneTest algorithm appeared in leading European oncology journal. Improved OneTest algorithm and portal to include "universal algorithm" permitting any number of biomarkers to be tested and "time to retest" feature.
Scale Up Phase (Q3 2020 and beyond)	Make test available at one or more retail pharmacy chains that operates in 50 states. Transition test from our CLIA lab to at least one national reference laboratory (e.g. LabCorp, Quest Diagnostics, BioReference Labs). Substantially expand sales and marketing. Increase average test volume to over 1,000 specimens per week.	Subscription agreements with 200 or more health check centers or clinics worldwide. Yearly run rate for royalties based on worldwide software subscriptions to exceed $1 million by 2021 with substantial growth.

The milestones above are generally sequential in nature, so delays in accomplishing one phase will likely delay subsequent phases. They also assume that our financing goals are accomplished in a timely manner. If our financing goals fall short or take longer than anticipated to complete, achievement of any or all of the aforementioned milestones and goals will be likely delayed.

Intellectual Property

We own or exclusively license 10 patent families related to cancer diagnostics and biowarfare detection. As of the date of this report, our patent portfolio included 16 granted patents and 13 pending applications in the U.S. and various other jurisdictions, including Canada. The earliest patent family (related to BioCheck) has a projected expiration date of 2020. Other family patents are expected to extend through 2039, based on priority date and projected expiration for pending applications or granted patents included in each family. No assurance is made that any pending patent applications within the portfolio will result in a granted patent.

Research and Development

Our research and development expenses include clinical data acquisitions, laboratory validation and bridging studies, data analysis algorithms and non-capitalizable machine learning software development. In the future, we may in-license and validate novel biomarker test kits that compliment or improve our current products. Our research and development expenses were $195,041 and $234,492 for the years ended December 31, 2019 and 2018, respectively.

Employees

As of the date of this report, we had a total of 15 full-time equivalent employees.

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.

Description of Real Property

We currently lease approximately 4,000 square feet of space at 9430 Key West Avenue, Rockville, Maryland comprised of general office and laboratory space.

In August 2011, we entered into a lease commencing in December 2011, which expired in November 2016. Under the lease agreement, we were to pay an annual rent of $134,975, plus additional operating expenses. The agreement included a 3%

annual increase and an option to expand office space. Upon expiration in November 2016, this lease has continued on a month-to-month basis. Total rent expense, including additional operating expenses related to this property, was $138,697 and $154,902 for the years ended December 31, 2019 and 2018, respectively.

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

Regulation

Based on advice of regulatory counsel, we believe that our products do not require pre-market approval from the FDA or its counterparts in most of the other countries that we plan to do business. In the U.S., our products likely fall into one of two categories: Laboratory Developed Tests, or LDTs, or 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. In general, LDTs are not regulated by the FDA but rather under a different regulatory regime called CLIA (Clinical Laboratory Improvement Amendments). Our laboratory is fully certified and compliant with CLIA. 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.

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 are doing 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."

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.

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 Generally

We are an early revenue stage company and have incurred operating losses since inception and we do not know when we will attain profitability. An investment in our securities is highly risky and could result in a complete loss of your investment if we are unsuccessful in our business plans.

We are an early stage company. Since inception, we have incurred operating losses and negative cash flow, and we expect to continue to incur losses and negative cash flow in the future. Our net losses for the years ended December 31, 2019 and 2018 were approximately $2.4 million and $1.5 million, respectively. 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.

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.

Our success depends heavily on our cancer screening tests.

For the foreseeable future, our ability to generate revenues will depend almost entirely on the commercial success of our cancer tests. The commercial success and our ability to generate revenues will depend on a variety of factors, including the following:

- 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; and
- maintaining and defending patent protection for the 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 would be adversely affected.

The success of our tests depends on the degree of market acceptance by physicians, patients, and others in the medical community.

Our 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:

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

If OneTest does not achieve an adequate level of acceptance, we may not generate the substantial revenues we need to generate to become profitable.

Our near-term revenues will be derived mainly from payment from consumers and employers rather than government or private health insurance.

Should we be able to successfully market our diagnostic tests and software we will, for at least the near-term, rely on self-pay from the consumers and employers but may not be able to receive reimbursement for them from payers, such as health insurance companies, health maintenance organizations and Medicare, or any reimbursement that we receive may be lower than we anticipate. We cannot guarantee that a sufficient number of consumers or their employers will willingly pay the amounts we require to sustain growth and profitability.

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.

The success of our business is substantially dependent upon the efforts of our senior management team.

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 development of 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 depends on our ability to retain our managerial personnel and to attract additional personnel.

Our success depends in large part on our ability to attract and retain managerial personnel. If we were to lose any of our senior management team, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. 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.

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 Rockville, Maryland. Our headquarters and manufacturing facilities are also located in Rockville, 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.

Failure of our internal controls over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the U.S. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Our growth and entry into new diagnostic tests, technologies and markets will place significant additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud.

Risks Related to Our Technology and Business Model

We will spend a substantial amount of our capital on data acquisition, 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 many not prove to be sufficiently efficacious or medically useful to gain widespread adoption or market share. The diagnostics tests and software that we have introduced to the market to date and have not yet generated significant revenues. Without diagnostic test sales or licensing fee revenues, we will not be able to operate at a profit, and we will not be able to cover our operating expenses without raising additional capital.

Physicians and hospitals 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 established companies, other small biotechnology 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.

Sales of any diagnostic tests that we develop and commercialize could be adversely impacted by the reluctance of physicians to adopt, promote or encourage the use of our tests and the availability of competing diagnostic tests.

The value of our diagnostic products is thus far proven mainly with real world evidence, rather than traditional clinical trials; 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.

If we fail to meet our obligations under various license 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 overseas research centers. These 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.

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

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.

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.

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 to detect cancer in a patient with a malignant tumor 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 Our Revenue Model

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

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

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

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

Risks Related to our COVID-19 Antibody Tests

We are relying on FDA policies and guidance provisions that have changed very recently and relate directly to the COVID-19 health crisis. If we misinterpret this guidance or the guidance changes unexpectedly and/or materially, potential sales of the COVID-19 antibody tests would be impacted.

The FDA issued non-binding guidance for manufacturers relating to the pathway to enable FDA approval for devices related to testing for COVID-19 under an EUA. On March 16, 2020, guidance specific to COVID-19 'serology tests' was issued that cover antibody tests like the ones we are distributing. In this guidance document and in subsequent communications with

FDA officials, the pathway to enable distribution of the COVID-19 test was further explained. If our interpretation of the newly revised guidance is incorrect or specifics around the guidance change, the sales of the COVID-19 test could be materially impacted.

If the COVID-19 antibody tests that we are distributing in the U.S. 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 COVID-19 diagnostic test. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our licensed COVID-19 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 the tests.

In the future, if our licensed COVID-19 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.

If we become subject to claims relating 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 confirmed to have been diagnosed with COVID-19. 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.

Our COVID-19 antibody tests are being manufactured on a high-volume scale, but the intense and growing worldwide demand could curtail available supply and increase our purchase prices.

While the manufacturers of the COVID-19 antibody tests have experience in manufacturing diagnostic tests, there can be no assurance that they can manufacture the COVID-19 antibody tests at a scale that is adequate for our current and future commercial needs. We may face significant or unforeseen difficulties in securing adequate supply of the COVID-19 antibody tests relating to the manufacturing of the tests. These risks include but are not limited to:

- competition from large purchasers worldwide, especially from Europe (in late March 2020, several European governments began to purchase millions of rapid COVID-19 antibody tests from Europe);
- technical issues relating to manufacturing components of the COVID-19 antibody tests on a high-volume commercial scale at reasonable cost, and in a reasonable time frame;
- difficulty meeting demand or timing requirements for orders due to excessive costs or lack of capacity for part or all of an operation or process;
- changes in Chinese government export controls, regulations or in quality or other requirements that lead to additional manufacturing costs or an inability to supply product in a timely manner, if at all; and

- increases in raw material or component supply cost or an inability to obtain supplies of certain critical supplies needed to complete our manufacturing processes.

These and other factors might limit our supply and increase our purchase price. In the event the tests cannot be manufactured in sufficient commercial quantities or manufacturing is delayed, our future prospects could be significantly impacted and our financial prospects could be materially harmed.

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 the COVID-19 antibody tests that could result in delays or shortfalls in our 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 the COVID-19 antibody 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.

We have relied and expect to continue to rely on third parties to conduct studies of the COVID-19 antibody tests that will be required by the FDA or other regulatory authorities and those third parties may not perform satisfactorily.

Although we intend to sell the COVID-19 antibody tests by virtue of recent FDA guidance allowing for reduced product clinical and analytical studies, we have relied on third parties, such as independent testing laboratories and hospitals, to conduct such studies. 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 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 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 will rely on third parties to manufacture the COVID-19 antibody tests that we distribute in the U.S., and if such third parties refuse or are unable to supply us with the COVID-19 tests, our business will be materially harmed.

We will rely on third parties to manufacture the COVID-19 antibody tests that we distribute in the U.S. If any issues arise with respect to the manufacturer's ability to manufacture and deliver to us the COVID-19 antibody tests, our business could be materially harmed.

While we have obtained options to procure exclusive distribution agreements for the exclusive rights to commercialize the rapid COVID-19 IgM/IgG antibody detection kits manufactured by Innovita in the United States, the manufacturer has no obligation to supply us with a minimum amount, or any, of these tests. The manufacturer may choose not to supply us with a sufficient quantity of such tests in order to supply such tests to other distributors, or for any reason. In addition, the manufacturers of all of our COVID-19 antibody tests may be unable to provide us with an adequate supply for various reasons, including, among others, if they become insolvent, if a United States regulatory authority or other governments block the import or sale of the COVID-19 tests, or if they fail to maintain their rights to manufacture the COVID-19 tests.

We face substantial competition.

The development and commercialization of blood tests to detect antibodies is highly competitive and subject to rapid technological advances. We may face future competition with respect to our current product candidates and any product candidates we may seek to develop or commercialize in the future. Our competitors may develop COVID-19 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 COVID-19 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.

Risks Related to Regulation

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;
- health information privacy and security, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or 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 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 regulatory approval of our diagnostic test products in one or more countries in which we do business.

Our diagnostic test products are classified as either Laboratory Developed Tests or Clinical Decision Support Software, 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.

As a result of required FDA pre-market review, our tests may not be cleared or approved on a timely basis, if at all.

The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission, or filing a pre-market approval application with the FDA.

We will have to maintain our CLIA certificate of registration license for our laboratory for the manufacture and use of diagnostic tests and as part of re-certification our laboratory will be inspected.

In addition to meeting federal regulatory requirements, each state has its own laboratory certification and inspection requirements for a CLIA laboratory that must be met in order to sell diagnostic tests in the state. CLIA licensed laboratories can lose their licenses if problems arise during a periodic inspection.

If the FDA regulates Laboratory Developed Tests and requires that we seek pre-market approval, there is no assurance that we will be able to comply with FDA requirements.

In 2020, legislation known as the VALID Act may be introduced in Congress that, if passed into law, could require pre-market FDA approval of most Laboratory Developed Tests. While this legislation would be expected to "grandfather" tests that were on the market at the time of passage, it could limit our ability to introduce new tests or substantial refinements to OneTest.

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

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

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

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

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

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

- The 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.

Risks Related to Our 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. 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.

The process of applying for and obtaining patents can be expensive and slow.

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.

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.

Risks Related to Our Dependence on Third Parties

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 the 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.

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.

The large laboratory testing chains in each of the countries in which we conduct business should be under contract with us before we can achieve widespread adoption of our cancer diagnostic tests so that consumers can easily obtain a blood draw. There is no assurance that we will be able to obtain the contractual obligations needed to achieve widespread use of our cancer diagnostic tests and commercial scale.

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.

Risks Related to Doing Business in China and Other Countries

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

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

including developing regions, could result in the disruption of commerce and negatively impact cash flows from our operations in those areas.

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

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 Ownership of our Securities

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 public offering 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 market maintained by OTC Markets Group Inc., subject to certain considerations, including, without limitation, the size and timing of our ongoing Regulation A offering, and whether we accomplish certain commercialization milestones. 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.

If we apply for quotation of our Common Stock on the OTCQB or OTCQX markets, it may have an unfavorable impact on our stock price and liquidity.

The OTCQB and OTCQX markets are significantly more limited markets than the New York Stock Exchange or The Nasdaq Stock Market. If we apply for quotation of our Common Stock on the OTCQB or OTCQX market, the quotation of our shares on such market may result in a less liquid market available for existing and potential stockholders to trade shares of our Common Stock, could depress the trading price of our Common Stock and could have a long-term adverse impact on our ability to raise capital in the future, Furthermore, we cannot assure you that we will be able to meet the initial listing standards of any stock exchange, or that we will be able to maintain any such listing.

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 stock and we do not intend to pay dividends for the foreseeable future.

We have paid no cash dividends on any class of our 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 shares after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our shares. 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.

Certain provisions of our second amended and restated certificate of incorporation may make it more difficult for a third party to effect a change-of-control.

Our second amended and restated certificate of incorporation authorizes our board of directors to issue up to 10,000,000 shares of Preferred Stock. The Preferred Stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by the stockholders. These terms may include voting rights including the right to vote as a series on particular matters, preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The issuance of any Preferred Stock could diminish the rights of holders of existing shares, and therefore could reduce the value of such shares. In addition, specific rights granted to future holders of Preferred Stock could be used to restrict our ability to merge with, or sell assets to, a third party. The ability of our board of directors to issue Preferred Stock could make it more difficult, delay, discourage, prevent or make it costlier to acquire or effect a change-in-control, which in turn could prevent our stockholders from recognizing a gain in the event that a favorable offer is extended and could materially and negatively affect the market price of our Common Stock.

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

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

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

the JOBS Act, under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not emerging growth companies, including but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

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

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

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

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not obtain and retain a listing or quotation of our Common Stock and if the price of our Common Stock is less than $5.00, our Common Stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our Common Stock, and therefore stockholders may have difficulty selling their shares.

If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our Common Stock could be negatively affected.

Any trading market for our Common Stock will be influenced in part by any research reports that securities industry analysts publish about us. We do not currently have and may never obtain research coverage by securities industry analysts. If no securities industry analysts commence coverage of us, the market price and market trading volume of our Common Stock could be negatively affected. In the event we are covered by analysts, and one or more of such analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage or us, the market price and market trading volume of our Common Stock could be negatively affected.

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

Overview

We are an early revenue stage digital diagnostics company with the core mission of developing and commercializing *in-vitro* diagnostic tests powered by machine learning to improve diagnostic accuracy and clinical usefulness. In response to the novel coronavirus pandemic that began in early 2020, we expanded upon our longstanding mission of reducing cancer mortality in the U.S. and around the world through early detection. More specifically, we acquired and commercialized several COVID-19 antibody tests, both rapid kits and laboratory-based tests.

For early cancer detection, we use 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. Our products include a multi-cancer test for screening at least five types of cancer from one blood sample known as OneTest and a blood test for early lung cancer known as PAULA's Test. In the coming months, we expect to integrate PAULA's Test into OneTest. As most of the biomarkers used in PAULA's Test are part of OneTest, this integration mainly centers on using common testing instrumentation.

Our 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. Our BioCheck kits for screening suspicious powders remains profitable, but with limited growth potential, at least in the U.S. absent a serial anthrax incident, or similar incident, like the one that occurred in the U.S. in 2001.

Recent Developments

Regulation A Offering

On January 8, 2020, we launched an offering under Regulation A of Section 3(6) of the Securities Act for Tier 2 offerings, pursuant to which we are offering 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. As of the date of this report, we have raised approximately $1.2 million in gross proceeds through the sale of 268,451 shares of our Series C Preferred Stock.

COVID-19 Antibody Tests

On April 5, 2020, we entered into a sales representative agreement with Mems Technologies Holdings Company Limited, or MEMS, a Hong Kong based company that has the rights to export COVID-19 rapid antibody test kits manufactured by Innovita (Tangshan) Biological Technology Co., Ltd., located in Hebei, China, or Innovita. Pursuant to this agreement, MEMS granted to us a non-exclusive right to solicit orders for the Innovita product from customers outside of China. We will receive a commission of ten percent (10%) of the price for Innovita products on orders solicited by us that are approved by MEMS, the terms of which shall be provided by MEMS. The term of the agreement with MEMS is two years.

In May 2020, we validated and began offering COVID-19 antibody tests manufactured by Roche Diagnostics.

PPP Loan

On May 19, 2020, we received a $144,000 Payroll Protection Program, or PPP, loan from the United States Small Business Administration, or SBA, under provisions of the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act. The PPP loan has a two-year term and bears interest at a rate of 1.0% per annum. Monthly principal and interest payments are deferred for six months after the date of disbursement. The PPP loan may be prepaid at any time prior to maturity with no prepayment penalties. The PPP loan contain events of default and other provisions customary for loans of this type. The PPP provides that the PPP loans may be partially or wholly forgiven if the funds are used for certain qualifying expenses as described in the CARES Act. We intend to use the proceeds from the PPP loan for qualifying expenses and to apply for forgiveness of the PPP loan in accordance with the terms of the CARES Act. We have classified the PPP loan as a current liability pending SBA clarification of the final loan terms.

Principal Factors Affecting our Financial Performance

Our operating results are primarily affected by the following factors:

- our ability to access additional capital and the size and timing of subsequent financings;

- the costs of acquiring additional data, technology, and/or intellectual property to successfully reach our goals and to remain competitive;
- personnel and facilities costs in any region in which we seek to introduce and market our products;
- the costs of sales, marketing, and customer acquisition;
- average price per test paid by consumers;
- the number of tests ordered per quarter;
- costs of third-party laboratories to run our tests;
- willingness of healthcare providers (including telemedicine providers) to prescribe and encourage our tests and the fees charged by them to do so;
- the costs of compliance with any unforeseen regulatory obstacles or governmental mandates in any states or countries in which we seek to operate; and
- the costs of any additional clinical studies which are deemed necessary for us to remain viable and competitive in any region of the world.

Going Concern Assessment

Our financial statements are prepared using U.S. generally accepted accounting principles, or U.S. GAAP, applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. Throughout the next 12 months from the date of this report, we intend to fund our operations through increased revenue from operations and the remaining capital raised through our recent Regulation A offerings. Based on our current capital, management believes the doubt regarding our ability to continue as a going concern has been alleviated.

Results of Operations

The following table sets forth key components of our results of operations during the years ended December 31, 2019 and 2018.

	Year Ended December 31,		Change	
	2019	2018	$	%
Revenues	$ 288,300	$ 277,047	$ 11,253	4.1%
Cost of revenues	263,917	217,595	46,322	21.3%
Gross profit	24,383	59,452	(35,069)	(59.0%)
Operating expenses				
Sales, general and administrative	2,296,632	1,299,174	997,458	76.8%
Research and development	195,041	234,492	(39,451)	(16.8)%
Total operating expenses	2,491,673	1,533,666	958,007	62.5%
Loss from operations	(2,467,290)	(1,474,214)	(993,076)	(67.4)%
Total other income (expense)	41,952	11,109	30,843	277.6%
Net loss	$ (2,425,338)	$ (1,463,105)	$ (962,233)	65.8%

Revenues. We generate revenues from sales of BioCheck and OneTest in 2019 and from BioCheck and PAULA's Test in 2018. Our total revenues were $288,300 for the year ended December 31, 2019, compared to $277,047 for the year ended December 31, 2018, an increase of $11,253, or 4.1%.

Revenues from sales of our cancer test (OneTest) for the year ended December 31, 2019 amount to $65,806, compared to revenues from sales of the prior year cancer test (PAULA's Test) of $8,024 for the year ended December 31, 2018, an increase of $57,782, or 720.1%. Revenues from our cancer test business increased compared to the prior year as we transitioned to OneTest and identified and engaged certain new addressable market segments, including firefighters, actively seeking novel cancer detection solutions. Revenues from sales of BioCheck decreased by $46,529, or 17.3%, from $269,023 in the year ended December 31, 2018 to $222,494 in the year ended December 31, 2019. The decrease in BioCheck sales is attributable to the reduced demand from State and Local governments in the current year.

Cost of revenues. Our cost of revenues includes materials, labor and laboratory costs. Our cost of revenues increased by $46,322, or 21.3%, to $263,917 for the year ended December 31, 2019 from $217,595 for the year ended December 31, 2018. This increase was mainly due to attributable an increase in base costs of maintaining a laboratory, amortization of license agreements attributable to the analyzation of OneTest orders and the required diagnostic reagent kits in connection with the OneTest sales increases.

Gross profit and gross margin. Our gross profit decreased by $35,069, or 59.0%, to $24,383 for the year ended December 31, 2019 from $59,452 for the year ended December 31, 2018. Gross profit as a percentage of revenues (gross margin) was 8.5% and 21.5% for the years ended December 31, 2019 and 2018, respectively. The decrease the in gross margin was primarily due to the decrease in sales of BioCheck, while at the same time the required labor and laboratory infrastructure cost established in the prior year was maintained.

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 $997,458, or 76.8%, to $2,296,632 for the year ended December 31, 2019, from $1,299,174 for the year ended December 31, 2018. Such increase was primarily due to an increase in sales and marketing related costs, primarily resulting from overseas business development initiatives in East Asia and the Middle East, as well as stock compensation expense for securities issued in 2019. As a percentage of revenues, sales, general and administrative expenses increased to 796.6% for the year ended December 31, 2019 from 468.9% for the year ended December 31, 2018.

Research and development expenses. Our research and development expenses include principally clinical data acquisitions, laboratory validation and bridging studies, data analysis algorithms and non-capitalizable machine learning software development. Our research and development expenses decreased by $39,451, or 16.8%, to $195,041 for the year ended December 31, 2019 from $234,492 for the year ended December 31, 2018. The decrease was due to the allocation of resources related to operations in 2019 compared to the prior year, as a result of increased sales. As a percentage of revenues, research and development expenses decreased to 67.7% for the year ended December 31, 2019 from 84.6% for the year ended December 31, 2018.

Net loss. As a result of the cumulative effect of the factors described above, our net loss increased by $962,233, or 65.8%, to $2,425,338 for the year ended December 31, 2019 from $1,463,105 for the year ended December 31, 2018.

Liquidity and Capital Resources

Historically, our sources of cash have included private placements of equity securities and cash generated from revenues. Our historical cash outflows have primarily been associated with cash used for operating activities such as research and development activities and other working capital needs; the acquisition of clinical data, patient samples (blood, tissue), intellectual property; and expenditures related to equipment and improvements used for our laboratory facility. We intend to fund our operations through increased revenue from operations and the remaining capital raised through our recent offerings.

Summary of Cash Flows

As of December 31, 2019, we had $636,018 in cash and cash equivalents. The following table presents a summary of our cash flows for the periods indicated:

	Year Ended December 31,	
	2019	**2018**
Net cash used in operating activities	$ (2,122,808)	$ (1,314,504)
Net cash used in investing activities	(1,664,152)	(436,173)
Net cash provided by financing activities	1,149,484	3,984,088
Net increase (decrease) in cash and cash equivalents	(2,637,476)	2,233,411
Cash and cash equivalents at beginning of year	3,273,494	1,040,083
Cash and cash equivalent at end of year	$ 636,018	$ 3,273,494

Net cash used in operating activities was $2,122,808 for the year ended December 31, 2019, as compared to $1,314,504 for the year ended December 31, 2018. The principal use of cash in operating activities was to fund our net loss. Cash flows from operations can vary significantly due to various factors, including changes in our operations, accounts receivable, prepaid expenses, accounts payable and accrued expenses.

Net cash used in investing activities was $1,664,152 for the year ended December 31, 2019, as compared to $436,173 for the year ended December 31, 2018. Net cash used in investing activities for the year ended December 31, 2019 consisted of investments in certificates of deposit of $2,216,284, purchases of property and equipment of $2,293 and investment in intangibles of $45,575, offset by a redemption of certificate of deposit of $600,000, while net cash used in investing activities for the year ended December 31, 2018 consisted of related party advances of $210,000, investments in license fee of $150,000, purchases of fixed assets in the amount of $64,074 and investments in intangibles of $12,099.

Net cash provided by financing activities was $1,149,484 for the year ended December 31, 2019, as compared to $3,984,088 for the year ended December 31, 2018. Net cash provided by financing activities for the year ended December 31, 2019 consisted entirely of net proceeds from the issuance of preferred stock, while net cash provided by financing activities consisted of net proceeds from issuance of preferred stock of $3,984,078 and proceeds from warrant exercises of $10.

On October 13, 2017, 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 shares of our Series A-2 Preferred Stock at a purchase price of $3.26 per share. On December 29, 2017, we completed an initial closing in which we raised $1,018,297 in gross proceeds through the sale of 312,361 shares of Series A-2 Preferred Stock. On January 23, 2018, we completed a second and final closing in which we raised $48,988 in gross proceeds through the sale of 15,027 shares of Series A-2 Preferred Stock.

On August 17, 2018, we launched an offering under Regulation A of Section 3(6) of the Securities Act for Tier 2 offerings, pursuant to which we offered shares of our Series B Preferred Stock at a purchase price of $3.53 per share. During 2018, we raised approximately $3,919,062 in gross proceeds through the sale of 1,110,216 shares of Series B Preferred Stock for net proceeds of $3,593,419. During 2019, we raised approximately $1,275,175 in gross proceeds through the sale of 361,271 shares of Series B Preferred Stock for net proceeds of $1,149,483.

From time to time, investors in our company are directed to deposit funds in a limited liability company, or an Investment LLC, set up by us for the purposes of managing investments seeking the advantages of the Maryland Biotechnology Investor Tax Credit program. On January 9, 2018 and March 16, 2018, we issued 11,380 and 94,785 shares of Series A-2 Preferred Stock at $3.26 per share for gross proceeds of $37,100 and $309,000 to an Investment LLC, respectively.

Capital Expenditures

In July of 2018, we purchased laboratory equipment to be used in our CLIA laboratory for approximately $59,000. We incurred nominal capital expenditures of $2,293 in the year ended December 31, 2019. We estimate that our total capital expenditures in fiscal year 2020 will reach approximately $150,000. Such funds will be used primarily to expand office and laboratory facilities in or around our location in Rockville, MD.

Contractual Obligations

In November 2000, we entered into a licensing agreement with the United States Public Health Service, or PHS, that gave us exclusive rights to use several patents owned by PHS. The agreement was subsequently amended in 2005 and 2011. Under the most current agreement, we were required to pay minimum annual royalty fees of $7,500 due and payable on January 1 of each calendar year from 2003 through 2011. Further payment of the minimum annual royalty has been deferred until January 1 of the calendar year following the first year we achieve annual net sales of the licensed product equal to or greater than $1,000,000. The minimum annual royalty will be due January 1 of each calendar year thereafter. The PHS agreement also calls for us to pay other royalties, including earned royalties, benchmark royalties, and sublicensing royalties. In addition, the agreement requires us to reimburse PHS for patent expenses incurred. Reimbursement is due on January 1 of each calendar year beginning in 2013. Minimum reimbursement of $10,000 is due until we have achieved $500,000 in net sales of licensed products, $20,000 once we have achieved between $500,000 and $1,000,000 in net sales of licensed products, and the balance of the remaining unreimbursed patent expenses due in full once we achieve net sales of licensed products of $1,000,000 or upon termination or expiration of the license, whichever comes first. In addition, PHS continues to submit annual requests for reimbursement of patent expenses incurred throughout the preceding year. Unreimbursed patent expenses are included in accrued expenses and were $195,794 at December 31, 2019 and 2018.

In July 2002, we entered into an award and royalty agreement with MdBio, Inc. Under this agreement, we received $150,000 in funding and are to make payments of 3% of gross sales revenues beginning in June 2003 and ending when a total of $450,000 has been repaid. Total royalty expenses incurred relating to this agreement were $8,641 for the years ended December 31, 2019 and 2018.

During 2010, we entered into a licensing agreement with Abbott Molecular, Inc., or Abbott. Under this agreement, we retained exclusive rights to use certain processes and know-how for which Abbott has a patent pending. Under this agreement, we are to pay royalties equal to 9% of the service revenue and net sales of each licensed product sold or otherwise disposed of prior to the issuance of the related patents and 18% of sales revenue or net sales of each licensed product sold or otherwise disposed of once the related patents are issued. Royalties will be deferred until either our lung cancer testing business is acquired by Abbott or another third party or the value of the royalties exceeds $1,000,000. The agreement also allows Abbott first right to acquire our lung cancer testing business at various intervals.

In May 2011, we received a grant from the Maryland Biotechnology Center, or MBC. Under this grant agreement, we were to receive $200,000 in funding. Per the agreement, beginning January 31 of the year after the completion of the project, we are to repay MBC in payments equal to 3% of total sales revenues (excluding revenues relating to our BioCheck product). If the grant is not repaid in full by one year after the first payment date, the total repayment will equal 150% of the award, or $300,000. If the grant is not repaid in full by two years after the first payment date, the total repayment will equal 175% of the award, or $350,000. If the grant is not repaid in full by three years after the first payment date, the total repayment will equal 200% of the award, or $400,000.

In February 2016, we entered into a collaboration agreement with National Foundation for Cancer Research, Inc., or NFCR, a tax exempt 501(c)(3) organization, for the development of a cloud accessible algorithm to assist physicians in the Peoples Republic of China, or PRC, to interpret test results, and to support refinements of PAULA's Test. The NFCR will assist us in obtaining blood test data from the PRC. Upon execution of the agreement, we issued NFCR 19,157 shares of Common Stock. We issued an additional 19,157 shares of Common Stock in 2016 based on the first milestone of receiving data from the first 1,000 patients located in the PRC. Per the agreement, after we have analyzed data from the initial population, we may seek additional data from more patients which can trigger an additional 38,315 shares of Common Stock being issued. To date, this provision has not yet been triggered. If, upon seeking and receiving this additional patient data as set forth in the agreement, and immediately after issuing the requisite shares, for five (5) years we shall pay to NFCR two percent (2%) of gross sales we derive from the sale, licensing and other dispositions of the developed algorithm, payable quarterly.

Effective April 17, 2017, we entered into a six-month option agreement with Chang Gung Memorial Hospital of Taiwan to obtain and secure an exclusive license to certain technology, intellectual property, and data relating to our pan-cancer test. The option period was extended through February 28, 2018 through an amendment executed in November 2017. The option was exercised in a timely manner, payments were made, data was transferred to us and was verified by us and we entered an exclusive license to the technology until the last patent included in the specified technology expires, or 20 years. As consideration for this option, we paid an option fee of $75,000. Once the option was exercised in February 2018, we paid an additional license fee of $150,000 in cash and $300,000 in Common Stock (through the issuance of 92,025 shares of Common Stock), which were released from escrow upon verification of the viability of the data. We have amortized the license agreement over the term amounting to an accumulative amortization of $20,358 and $19,071 as of December 31, 2019 and 2018, respectively.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

Revenue Recognition. Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, using the modified retrospective method. We determined that the adoption of ASC 606 had no material impact to our financial statements. In accordance with ASC Topic 606, 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. We recognize revenue from the sale of BioCheck when purchase orders are processed, and kits are shipped to customers. Revenue from the sale of OneTest and PAULA's Test is recognized when returned testing kits are processed in the laboratory and the results

are reported. Due to the nature of OneTest and PAULA's Test, revenue per test is recorded based on historical average receipts from patients.

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, 2019 and 2018.

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

Impairment of Long-Lived Assets. The long-lived assets held and used by us are reviewed for impairment no less frequently than annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In the event that facts and circumstances indicate that the cost of any long-lived assets may be impaired, an evaluation of recoverability is performed. There were no impairment losses during the six months ended June 30, 2019 and 2018. There can be no assurance, however, that market conditions will not change or demand for our products and services will continue, which could result in impairment of long-lived assets in the future.

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

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

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

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

Recently Issued Accounting Pronouncements

In January 2017, the FASB issued ASU No. 2017-04, Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment. To simplify the subsequent measurement of goodwill, the update requires only a single-step quantitative test to identify and measure impairment based on the excess of a reporting unit's carrying amount over its fair value. A qualitative assessment may still be completed first for an entity to determine if a quantitative impairment test is necessary. The update is effective for fiscal year 2021 and is to be adopted on a prospective basis. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We are currently evaluating the impact of the adoption of this guidance on our financial condition, results of operations and cash flows.

In February 2016, the FASB issued ASU 2016-02, Leases. This ASU is a comprehensive new leases standard that amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. It will require

companies to recognize lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. Topic 842 retains a distinction between finance leases and operating leases. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous lease's guidance. The ASU is effective for annual periods beginning January 1, 2019 for public companies and January 1, 2022 for non-public companies, including interim periods within those fiscal years; earlier adoption is permitted. In the financial statements in which the ASU is first applied, leases shall be measured and recognized at the beginning of the earliest comparative period presented with an adjustment to equity. Practical expedients are available for election as a package and if applied consistently to all leases. We are currently evaluating the impact of the adoption of this guidance on our financial condition, results of operations and cash flows.

In June 2016, the FASB issued ASU 2016-13 Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. ASU 2016-13 is effective for annual reporting periods, and interim periods within those years beginning January 1, 2020 for public companies and January 1, 2023 for non-public companies. We are currently in the process of evaluating the impact of the adoption of ASU 2016-13 on our financial statements.

DIRECTORS AND OFFICERS

Directors, Executive Officers and Significant Employees

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	57	From August 2000	N/A
John G. Compton	Chairman of the Board	71	From July 2016	N/A
Richard M. Cohen	Director	69	From July 2016	N/A
Jayson Lee	Director	37	From July 2016	N/A
John W. Rollins	Director	75	From November 2017	N/A
Michael A. Ross	Director	69	From July 2016	N/A

Jonathan 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 the company's most successful products, OneTest and BioCheck, and has led the commercial launch and sales of both. Mr. Cohen has become a successful healthcare entrepreneur in the U.S., particularly with respect to equity crowdfunding, since it was implemented by the JOBS Act. 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 companies. He is the architect of the Maryland Biotechnology Investor Tax Credit, the most aggressive investor incentive in the U.S. He also led the legislative effort that resulted in the first increase in funding under the federal Small Business Innovative Research in over 30 years. Mr. Cohen is currently leading a coalition of small, emerging diagnostics companies to advocate against overly burdensome FDA regulations that limit patient access to innovative tests. 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 18 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.

John Compton has served as Chairman of the Board since July 2016. Mr. Compton 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. Mr. Compton served as Vice-President of BioReference Laboratories from 2007 to 2013. Previously, Mr. 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. GeneDx is a world leader in diagnostic genetic testing with an acknowledged expertise in rare

and ultra-rare genetic disorders, as well as one of the broadest menus of sequencing services available among commercial laboratories. Mr. Compton holds B.S. degrees in Physics and Biology from MIT, received his Ph.D. from the University of California, Berkeley in Biophysics, and did his post-doctoral training in protein-DNA interactions at the Baylor College of Medicine. He was a Staff Scientist at the National Institutes of Health, Bethesda, from 1991-2000. In 2003, he was awarded the Entrepreneur of the Year award by the Technology Council of Maryland.

Richard M. Cohen has served as a member of our board of directors since July 2016. Mr. Cohen 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. From 2013 to present, Mr. Cohen has been President of Richard M. Cohen Consultants. He was the CEO, CFO, and Board Member of CorMedix Inc., Bridgewater, NJ, a publicly traded (NYSE) 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 as Audit Committee Chair of 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, Stanford University, B.S. with honors, Wharton School, University of Pennsylvania. Mr. Cohen has no relation to CEO Jonathan Cohen.

Jayson Lee has served as a member of our board of directors since July 2016. Mr. Lee has served as an Executive Director at Ping An Ventures, a 10% stockholder of our company, since 2016. Ping An Ventures is the investment arm of Ping An, one of the largest health and life insurance companies in China. At Ping An Ventures, Mr. Lee focuses on direct investment in the healthcare sector with an emphasis on Series B to pre-IPO companies. Previously, Mr. Lee was Executive Director at BE Capital (Beijing China) from 2014 to 2016, where he also focused on healthcare investments and he served at the China Development Investment Bank from 2009 to 2014. Mr. Lee has his M.B.A. degree from National Chengchi University in Taiwan and studied in Norges Handelshøyskole.

John W. Rollins has served as a member of our board of directors since November 2017. He is an active investor with the Keiretsu Forum and other angel investor organizations. Since 2014, Mr. Rollins 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 CEO from 2008 to 2010. Prior to 2001, he founded and served for three decades as the CEO and chairman of AZTECH Software Corporation (Bethesda, MD), the nation's first specialized provider of information technology services to non-profit organizations. Mr. Rollins's board experience has included serving as Trustee of the National Park Trust (Vice Chair and Treasurer) (1990 to present), Director of the MedStar Georgetown University Hospital (Vice Chair) (2002 to 2013), the Washington Hospital Center (Vice Chair and Treasurer) (1977 to 2002), and the U.S. Association for Small Business & Entrepreneurship (2004 to 2006). Mr. Rollins earned his A.B. in Mathematics from Dartmouth and his M.B.A. in Finance from the Stanford University Graduate School of Business.

Michael A. Ross has served as a member of our board of directors since July 2016. Dr. Ross has served as the Chairman and CEO of Euclid Systems Corporation (Herndon, VA) 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 Michael visits 4-5 times per year. Prior to joining Euclid, he was CEO 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 a OB-GYN-Infertility practice in Northern Virginia from 1980 to 2007. Dr. Ross has been a Clinical Professor of Obstetrics and Gynecology, George Washington University Medical Center since 1979, and has served on the Boards of Directors of several biotech and medical device companies. He has a B.S. in Chemistry and Biology from Dickinson College and an M.D. from George Washington University.

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

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

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

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

- been convicted in a criminal proceeding (excluding traffic violations and other minor offences); or

- had any petition under the federal bankruptcy laws or any state insolvency law was filed by or against, or a receiver, fiscal agent or similar officer was appointed by a court for the business or property of such person, or any partnership in which he was general partner at or within two years before the time of such filing, or any corporation or business association of which he was an executive officer at or within two years before the time of such filing.

Corporate Governance

Our board of directors currently has two standing committees, an audit committee and a compensation 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

Our board of directors plays an active role, as a whole and also at the committee level, in overseeing management of our risks and strategic direction. Our board of directors regularly reviews information regarding our liquidity and operations, as well as the risks associated with each. Our audit committee oversees the process by which our senior management and relevant employees assess and manage our exposure to, and management of, financial risks. Our compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed about such risks.

Audit Committee

Our audit committee currently consists of Messrs. Richard Cohen and Michael A. Ross, with Mr. Cohen serving as chairman. The primary purposes of our audit committee are to assist our board of directors in fulfilling its responsibility to oversee the accounting and financial reporting processes of our company and audits of our financial statements, including: (i) responsibility for the appointment, termination, compensation, retention and oversight of the work of the independent auditor; (ii) pre-approving all auditing services and permissible non-audit services to be performed by the independent auditor; (iii) reviewing the independent auditor's audit plans procedures, including the general audit approach, scope, staffing, fees and timing of the audit; (iv) reviewing all accounting policies and practices; (v) reviewing the year-end audited financial statements, the unaudited quarterly or interim financial statements, and the management discussion and analysis in the reports filed with the SEC; (vi) reviewing major financial risk exposures and the steps management has taken to monitor and control such exposures; (vii) reviewing and approving related-party transactions; (viii) reviewing the adequacy and effectiveness of our internal controls, internal audit procedures, and the adequacy and effectiveness of our disclosure controls and procedures; (ix) reviewing matters related to the corporate compliance activities; and (x) reviewing and assessing annually the audit committee's performance and the adequacy of its charter.

Compensation Committee

Our compensation committee currently consists of Messrs. Richard M. Cohen, John G. Compton and John Rollins, with Mr. Rollins serving as chairman. The primary purposes of our compensation committee are to assist our board of directors in fulfilling its responsibility to determine the compensation of our executive officers and directors and to approve and evaluate the compensation policies and programs of our company, including: (i) reviewing the structure and competitiveness of our executive compensation programs; (ii) reviewing trends in management compensation, overseeing the development of new compensation plans, and, when necessary, approving the revision of existing plans; (iii) reviewing and approving the compensation structure for corporate officers at the level of corporate vice president and above; (iv) overseeing an evaluation of the performance of our executive officers and approving the annual compensation, including salary, bonus, incentive and equity compensation, for the executive officers; (v) reviewing and approving corporate goals and objectives relevant to the compensation of our chief executive officer, evaluate the performance of the chief executive officer in light of those goals and objectives, and setting the compensation level of chief executive officer based on this evaluation; (vi) reviewing and approving the compensation of our directors, including, without limitation, equity and equity-based compensation; (vii) reviewing and making recommendations concerning long-term incentive compensation plans; and (viii) reviewing and assessing annually the compensation committee's performance and the adequacy of its charter.

Compensation of Directors and Executive Officers

Summary Compensation Table

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

Name	Capacities in which compensation was received	Cash Compensation ($)	Other Compensation ($)	Total Compensation ($)
Jonathan Cohen	Chief Executive Officer and President	$307,895	$9,020	$316,915

Other compensation represents fringe benefits for insurance in the amount of $9,020.

Employment Agreement

On May 6, 2019, we entered into an employment agreement with Jonathan Cohen, our Chief Executive Officer and President, with an initial term commencing as of January 1, 2019 and ending on December 31, 2019, which will automatically renew 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. In the event that the employment agreement is renewed, the compensation committee shall approve, prior to the commencement of the renewal period, the criteria for the cash bonus for such renewal period. We also agreed to, as soon as practicable following execution of the employment agreement, but no later than September 30, 2019, grant Mr. Cohen a customary number of stock options, as agreed between us and Mr. Cohen, with a strike price equal to the then fair market value of a share of Common Stock and with a customary vesting schedule. In addition, we are required to pay or reimburse Mr. Cohen for all reasonable and necessary expenses actually incurred or paid by Mr. Cohen in the performance of his duties under the employment agreement, upon submission and approval of expense statements, vouchers or other supporting information in accordance with our then customary practices. 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.

Director Compensation

Our non-executive directors are paid a cash fee of $750 for each board meeting attended, with the Chairman receiving a cash fee of $1,000 for each board meeting attended. During 2019, our non-executive directors received total cash compensation of $19,250 for serving as directors. The total number of directors in the group was seven.

In addition, on August 1, 2019, we issued options for the purchase of an aggregate of 292,680 shares to six non-executive directors who served on the board during 2018. These options have an exercise price of $0.82 per share and vested in full on the date of grant.

Stock Incentive Plan

On July 16, 2019, our board of directors adopted the 20/20 GeneSystems, Inc. 2019 Stock Incentive Plan, or the Plan. The following is a summary of certain significant features of the Plan.

Awards that may be granted include incentive stock options as described in section 422(b) of the 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. 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 2,000,000, 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 July 2, 2020 (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 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 9430 Key West Avenue, Suite 100, Rockville MD 20850.

	Amount of Beneficial Ownership Acquirable[1]								
Name and Address of Beneficial Owner	Total Common Stock	Series A Preferred Stock	Series A-1 Preferred Stock	Series A-2 Preferred Stock	Percent of Common Stock[2]	Percent of Series A Preferred Stock[3]	Percent of Series A-1 Preferred Stock[4]	Percent of Series A-2 Preferred Stock[5]	Percent of Total Voting Stock[6]
Jonathan Cohen[7]	1,471,262	0	0	0	30.46%	*	*	*	17.29%
All directors and officers as a group[8]	1,735,605	13,029	651,465	21,535	35.99%	1.54%	100.00%	4.87%	28.53%
Joel Kanter[9]	537,272	143,750	0	0	11.37%	16.98%	*	*	8.10%

*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 4,725,633 shares of our Common Stock outstanding as of July 2, 2020.

(3) Based on 846,368 shares of our Series A Preferred Stock outstanding as of July 2, 2020.

(4) Based on 651,465 shares of our Series A-1 Preferred Stock outstanding as of July 2, 2020.

(5) Based on 442,402 shares of our Series A-2 Preferred Stock outstanding as of July 2, 2020.

(6) 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 July 2, 2020, there were 1,471,487 shares of Series B Preferred Stock and 268,451 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.

(7) Includes 1,366,400 shares of Common Stock and options for the purchase of 104,862 shares of Common Stock exercisable within 60 days.

(8) Includes 1,384,177 shares of Common Stock and options for the purchase of 348,762 shares of Common Stock and warrants for the purchase of 2,666 shares of Common Stock exercisable within 60 days.

(9) Includes (i) 28,597 shares of Common Stock held by Kanter Family Foundation; (ii) 223,500 shares of Common Stock held by Chicago Investors VI, LLC; (iii) 13,500 shares of Common Stock held by Equity Investments, LP; (iv) 209,494 shares of Common Stock and 143,750 shares of Series A Preferred Stock held by Outside Investors, LLC; and (v) 62,181 shares of Common Stock held by Windy City, Inc.

From time to time, investors in our company are directed to deposit funds in Investment LLCs set up by us for the purposes of managing investments seeking the advantages of the Maryland Biotechnology Investor Tax Credit program. All matters submitted to a vote of our stockholders must be submitted to the members of the Investment LLCs for their approval. Therefore, the members have voting control over the securities held by these Investments LLC's in proportion to their interests and the proportional share of our securities is included in the table above.

INTEREST OF MANAGEMENT AND OTHERS IN CERTAIN TRANSACTIONS

The following includes a summary of transactions since the beginning of our 2018 fiscal year, or any currently proposed transaction, in which we were or are to be a participant and the amount involved exceeded or exceeds the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any related person had or will have a direct or indirect material interest (other than compensation described under "Item 3. Directors and Officers—Compensation of Directors and Executive Officers"). We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

We utilize the services of Barry Cohen, the brother of our Chief Executive Officer, to assist with marketing, business development and software product development. During the years ended December 31, 2019 and 2018, consulting expenses and salary of approximately $51,588 and $51,256 respectively, were incurred to this related party, with approximately $21,707 included within accrued liabilities as of December 31, 2018.

From time to time, investors in our company are directed to deposit funds in an Investment LLC set up by us for the purposes of managing investments seeking the advantages of the Maryland Biotechnology Investor Tax Credit program. Funds from those Investment LLCs either have been or will be transferred to our company pursuant to the rules and procedures of the tax credit program. Our shares will be issued to investors in those Investment LLCs in the same manner as if they invested directly in our company. While we perform the administrative tasks for the Investment LLCs when they are active, we have no ownership, requirements to fund, or voting privileges within these entities.

As of December 31, 2019 and 2018, we had approximately $2,700 and $57,000, respectively, due from various Investment LLCs controlled by certain stockholders of our company as a result of funds advanced to them by us as it relates to the expected tax refunds under the Maryland Biotechnology Investor Tax Credit program.

During 2017, an Investment LLC received approximately $240,000 in funds for investment in our company, pending application of the Maryland Biotechnology Investor Tax Credit. In November and December 2017, the Investment LLC lent $210,000 to us, which we subsequently repaid in 2018 upon the investment LLC receiving the requisite initial tax credit certificate. Furthermore, the $240,000 investment was made by the Investment LLC as part of a total investment of $309,000 for shares of stock in 2018.

DESCRIPTION OF SECURITIES

Capitalization

We are authorized to issue 25,000,000 shares of Common Stock, par value $0.01 per share, and 10,000,000 shares of Preferred Stock, $0.01 par value per share, of which 1,303,000 have been designated as Series A Preferred Stock, 978,000 have been designated as Series A-1 Preferred Stock, 800,000 have been designated as Series A-2 Preferred Stock, 3,569,405 have been designated as Series B Preferred Stock and 3,340,909 have been designated as Series C Preferred Stock. Our certificate of incorporation authorizes our board to designate the relative rights and preferences of the undesignated shares of our Preferred Stock, which is known as blank check Preferred Stock.

As of the date of this report, we have 4,725,633 shares of Common Stock, 846,368 shares of Series A Preferred Stock, 651,465 shares of Series A-1 Preferred Stock, 442,402 shares of Series A-2 Preferred Stock, 1,471,487 shares of Series B Preferred Stock and 268,451 shares of Series C Preferred Stock outstanding.

Common Stock

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

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

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

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

Preferred Stock

We are authorized to issue up to 10,000,000 shares of Preferred Stock. Our certificate of incorporation authorizes our board to issue these shares 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.

Subject to the rights of the holders of any series of Preferred Stock, the number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by resolution adopted by our board of directors and approved by the affirmative vote of the holders of a majority of the voting power of all outstanding shares of capital stock entitled to vote on the matter, voting together as a single class.

We are authorized to issue up 1,303,000 shares of Series A Preferred Stock, 978,000 shares of Series A-1 Preferred Stock, 800,000 shares of Series A-2 Preferred Stock, 3,569,405 shares of Series B Preferred Stock and 3,340,909 shares of Series C Preferred Stock. We collectively refer to the Series A Preferred Stock, Series A-1 Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock and Series C Preferred Stock as 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 our 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 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 our 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 our 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 our assets to a non-affiliate of our company, (b) a merger, acquisition, change of control, consolidation or other transactions or series of transactions in which our 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 of our company.

Dividends. The Designated Preferred Stock will not be entitled to dividends or distributions unless and until our 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 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 the certificate of incorporation. 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 our company or (g) in connection with a stock split, stock division, reclassification, stock dividend or other recapitalization.

Redemption. 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 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 Series A Preferred Stock, Series A-1 Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock and Series C Preferred Stock, as applicable.

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, the certificate of designation, 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 our 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 outstanding options for the purchase of 495,597 shares of Common Stock.

Warrants

As of the date of this report, we have outstanding warrants for the purchase of 111,206 shares of Common Stock.

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.

Prior Offerings

We have conducted the following securities offerings in the past three years:

Security Type	Number Sold	Money Raised	Use of Proceeds	Offering Date	Exemption from Registration Used or Public Offering
Series A-2 Preferred Stock	327,388	$1,067,285	General marketing, research and development and working capital	October 13, 2017	Section 4(a)(6) of the Securities Act and Regulation CF
Series B Preferred Stock	1,398,995	$4,938,484	Sales and marketing, research and development, intellectual property development and protection, cybersecurity and patient privacy protections and working capital	August 17, 2018	Regulation A of Section 3(b) of the Securities Act
Series C Preferred Stock	268,451	$1,181,000	Sales and marketing, research and development, intellectual property development and protection, cybersecurity and patient privacy protections, and working capital and other general corporate purposes	January 8, 2020	Regulation A of Section 3(b) of the Securities Act

OTHER INFORMATION

The Company has 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: July 8, 2020

20/20 GENESYSTEMS, INC.

/s/ Jonathan Cohen
Name: Jonathan Cohen
Title: Chief Executive 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	CEO, President and Director (principal executive officer and principal financial and accounting officer)	July 8, 2020
/s/ Richard M. Cohen Richard M. Cohen	Director	July 8, 2020
/s/ John W. Rollins John W. Rollins	Director	July 8, 2020
/s/ Michael A. Ross Michael A. Ross	Director	July 8, 2020

EXHIBIT A
FINANCIAL STATEMENTS

20/20 GENESYSTEMS, INC.

AUDITED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2019 AND 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of 2020 GeneSystems, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of 2020 GeneSystems, Inc. (the "Company") as of December 31, 2019 and 2018, the related statements of operations, stockholders' equity and cash flows, for 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, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ dbb*mckennon*

We have served as the Company's auditor since 2017.
Newport Beach, California
July 6, 2020

20/20 GENESYSTEMS, INC.
BALANCE SHEETS
DECEMBER 31, 2019 AND 2018

	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 636,018	$ 3,273,494
Accounts receivable, net	32,498	15,488
Inventory	35,477	26,298
Short-term investment (certificates of deposit)	1,647,806	-
Prepaid expenses	51,567	16,478
Total current assets	2,403,366	3,331,758
License agreement, net	410,571	430,929
Property and equipment, net	48,924	60,994
Intangible assets, net	247,453	211,066
Due from affiliated entities	2,699	57,667
Other assets	12,873	12,795
Total assets	$ 3,125,886	$ 4,105,209
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 382,722	$ 327,668
Accrued liabilities	516,063	492,874
Deferred revenue	77,775	-
Total current liabilities	976,560	820,542
Commitments and contingencies (Note 5)	-	-
Stockholders' equity:		
Series B preferred stock, $0.01 par value; 3,569,405 authorized; 1,471,487 and 1,110,216 shares issued and outstanding, respectively	14,715	11,102
Series A-2 preferred stock, $0.01 par value; 800,000 authorized; 442,402 shares issued and outstanding	4,424	4,424
Series A-1 preferred stock, $0.01 par value; 978,000 authorized; 651,465 shares issued and outstanding	6,515	6,515
Series A preferred stock, $0.01 par value; 1,303,000 authorized; 846,368 shares issued and outstanding	8,464	8,464
Common stock, $0.01 par value; 25,000,000 authorized; 4,725,633 shares issued and outstanding	47,256	47,256
Additional paid-in capital	21,870,200	20,583,816
Accumulated deficit	(19,802,248)	(17,376,910)
Total stockholders' equity	2,149,326	3,284,667
Total liabilities and stockholders' equity	$ 3,125,886	$ 4,105,209

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	2019	2018
Revenues	$ 288,300	$ 277,047
Cost of revenues	263,917	217,595
Gross profit	24,383	59,452
Operating expenses:		
Sales, general and administrative	2,296,632	1,299,174
Research and development	195,041	234,492
Total operating expenses	2,491,673	1,533,666
Operating loss	(2,467,290)	(1,474,214)
Other income (expense):		
Interest income	58,852	11,193
Other expense	(16,900)	(1,834)
Other income	-	1,750
Total other (income) expense	41,952	11,109
Net loss	$ (2,425,338)	$ (1,463,105)
Basic and diluted net loss per common share	$ (0.51)	$ (0.31)
Weighted-average common shares outstanding, basic and diluted	4,725,633	4,713,339

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	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			
Balance, December 31, 2017	-	$ -	312,361	$ 3,124	651,465	$ 6,515	846,368	$ 8,464	4,632,608	$ 46,326	$ 16,305,560	$ (15,913,805)	$ 456,184
Stock compensation			2,301	23							7,477		7,500
Exercise of warrants	-	-	-	-	-	-	-	-	1,000	10	-	-	10
Issuance of shares for license agreement	-	-	-	-	-	-	-	-	92,025	920	299,080	--	300,000
Issuance of preferred stock, net of issuance costs	1,110,216	11,102	127,740	1,277	-	-	-	-	-	-	3,971,699	-	3,984,078
Net loss	-	-	-	-	-	-	-	-	-	-	-	(1,463,105)	(1,463,105)
Balance, December 31, 2018	1,110,216	$ 11,102	442,402	$ 4,424	651,465	$ 6,515	846,368	$ 8,464	4,725,633	$ 47,256	$ 20,583,816	$ (17,376,910)	$ 3,284,667
Stock compensation	-	-	-	-	-	-	-	-	-	-	140,514	-	140,514
Issuance of preferred stock, net of offering costs	361,271	3,613	-	-	-	-	-	-	-	-	1,145,870	-	1,149,483
Net loss	-	-	-	-	-	-	-	-	-	-	-	(2,425,338)	(2,425,338)
Balance, December 31, 2019	1,471,487	$ 14,715	442,402	$ 4,424	651,465	$ 6,515	846,368	$ 8,464	4,725,633	$ 47,256	$ 21,870,200	$ (19,802,248)	$ 2,149,326

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,425,338)	$ (1,463,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	23,550	11,689
Stock compensation	140,514	7,500
Amortization of license fees	20,358	19,071
Changes in operating assets and liabilities:		
Accounts receivable	(17,010)	37,618
Inventory	(9,179)	11,494
Prepaid expenses and other	(66,689)	(2,863)
Accounts payable	55,054	73,229
Accrued liabilities	23,189	(7,124)
Receipt (payment) of funds - affiliated entities	54,968	(513)
Deferred revenue	77,775	-
Other liabilities	-	(1,500)
Net cash used in operating activities	(2,122,808)	(1,314,504)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(2,293)	(64,074)
Related party advances	-	(210,000)
Investments in certificates of deposit	(2,216,284)	-
Redemption of certificate of deposit	600,000	-
Investment in license fee	-	(150,000)
Investment in intangibles	(45,575)	(12,099)
Net cash used in investing activities	(1,664,152)	(436,173)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	-	10
Proceeds from sale of preferred stock, net of offering costs	1,149,484	3,984,078
Net cash provided by financing activities	1,149,484	3,984,088
Increase (decrease) in cash and cash equivalents	(2,637,476)	2,233,411
Cash and cash equivalents, beginning of year	3,273,494	1,040,083
Cash and cash equivalents, end of year	$ 636,018	$ 3,273,494
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
Non-cash disclosures of cash flow information:		
Common stock issued for license agreement	$ -	$ 300,000

See accompanying notes to the financial statements

20/20 GENESYSTEMS, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018

NOTE 1 – BUSINESS AND NATURE OF OPERATIONS

20/20 GeneSystems, Inc. (the "Company"), founded in May 2000, is a digital diagnostics company with the core mission of reducing cancer mortality in the U.S. and around the world through early detection. To do so, the Company uses machine learning and big data analytics approaches to substantially improve the accuracy of tumor biomarkers that are currently tested in millions of individuals around the world.

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 products include a multi-cancer test for screening at least five types of cancer from one blood sample known as OneTest and, until 2019, we also sold a blood test for early lung cancer known as PAULA's Test.

In the company months, the Company expects to integrate PAULA's Test into OneTest. 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.

Going Concern

We have incurred operating losses since inception and historically relied on debt and equity financing for working capital. Throughout the next 12 months, the Company intends to fund its operations through increased revenue from operations and the remaining capital raised through its recent Regulation A offering. 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, through the date of these financial statements, the Company has raised approximately $1.2 million in gross proceeds through the sale of 268,451 shares of Series C Preferred Stock. In addition, in March 2020 the Company began distributing Covid-19 test kits and in May 2020 received funds from the Payroll Protection Program (see Note 9). Based on the Company's current capital, 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

Use of Estimates

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

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, 2019 and 2018. 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, 2019 and 2018, customer accounts receivable totaled $32,498 and $15,488, respectively. 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 $17,000 and $1,479 is included in accounts receivable at December 31, 2019 and 2018, 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, 2019 and 2018.

Certificates of Deposit

The Company uses certificates of deposit for short-term investments. No more than $250,000 is invested in any single certificate of deposit so that all balances are covered by federally insured limits. As of December 31, 2019 and 2018, $1,647,806 and $0, respectively, of the Company's certificates of deposit had original maturities greater than three months and therefore were not included in cash and cash equivalents.

Internal Use Software

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

Property and Equipment

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

Intangible Assets - Patents

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

Impairment of Long-Lived Assets

The long-lived assets held and used by the Company are reviewed for impairment no less frequently than annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In the event that facts and circumstances indicate that the cost of any long-lived assets may be impaired, an evaluation of recoverability is performed. There were no impairment losses during 2019 and 2018. 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 Financial Accounting Standards Board ("FASB") ASC 340 with regards to offering costs. Prior to the completion of an offering, offering costs will be capitalized as deferred offering costs on the balance sheet. The deferred offering costs will be charged to stockholders' equity upon the completion of an offering or to expense if the offering is not completed.

Preferred Stock

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

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

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

Per Share Information

Basic per share information is computed based upon the weighted average number of shares of Common Stock outstanding during the period. Diluted per share information consists of the weighted average number of shares of Common Stock outstanding, plus the dilutive effects of potential shares of Common Stock, including convertible Preferred Stock, and options and warrants calculated using the treasury stock method. In loss periods, dilutive common equivalent shares are excluded as the effect would be anti-dilutive. During the years ended December 31, 2019 and 2018, the Company excluded the outstanding securities summarized below from its calculation of diluted loss per share, as their effects would have been anti-dilutive.

	2019	2018
Warrants to purchase Common Stock	113,106	117,823
Options to purchase Common Stock	-	-
Series B Preferred Stock	1,471,487	1,110,216
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
	3,524,828	3,168,274

Revenue Recognition

Effective January 1, 2018, the Company adopted ASC Topic 606, Revenue from Contracts with Customers, using the modified retrospective method. The Company determined that the adoption of ASC 606 had no material impact to the Company's financial statements. In accordance with ASC Topic 606, 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,	
	2019	**2018**
Revenues		
BioCheck	$ 222,494	$ 269,023
Cancer Test (OneTest/PAULA's Test)	65,806	8,024
Total revenues	$ 288,300	$ 277,047

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

- BioCheck – Revenues for kits is recognized when purchase orders are processed and kits are shipped to customers.
- OneTest/PAULA's Test – Revenue from the sale of OneTest and PAULA's Test is recognized when returned testing kits are processed in the laboratory and the results are reported. Due to the nature of OneTest and PAULA's Test, revenue per test is recorded based on historical average receipts from patients and insurance companies.

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 $15,775 and $7,244 for the years ended December 31, 2019 and 2018, respectively.

Research and Development

The Company incurs research and development costs during the process of researching and developing the Company's technologies and future manufacturing processes. The Company's research and development costs consist primarily of materials and services. The Company expenses these costs as incurred until the resulting product has been completed, tested, and made ready for commercial use.

Advertising

The Company expenses advertising costs as incurred. Advertising expenses were $41,282 and $46,635 for the years ended December 31, 2019 and 2018, respectively.

Stock-Based Compensation

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

Income Taxes

The Company applies ASC 740, Income Taxes. Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial statement reported amounts at each period end, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The provision for income taxes represents the tax expense for the period, if any and the change during the period in deferred tax assets and liabilities. At December 31, 2019 and 2018, the Company has established a full allowance against all deferred tax assets.

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

Concentrations

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

As of December 31, 2019, approximately 42% of total accounts receivable were due from two sources. As of December 31, 2018, approximately 34% of total accounts receivable were due from two sources. During the year ended December 31, 2019, approximately 11% of total revenues were received from one source. During the year ended December 31, 2018, approximately 35% of total revenues were received from two sources. Management believes the loss of one or more of these customers would not have a significant effect on the Company's financial condition.

Recent Accounting Pronouncements

In January 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-04, Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment. To simplify the subsequent measurement of goodwill, the update requires only a single-step quantitative test to identify and measure impairment based on the excess of a reporting unit's carrying amount over its fair value. A qualitative assessment may still be completed first for an entity to determine if a quantitative impairment test is necessary. The update is effective for fiscal year 2021 and is to be adopted on a prospective basis. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the impact of the adoption of this guidance on its financial condition, results of operations and cash flows.

In February 2016, the FASB issued ASU 2016-02, Leases. This ASU is a comprehensive new leases standard that amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. It will require companies to recognize lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. Topic 842 retains a distinction between finance leases and operating leases. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous lease's guidance. The ASU is effective for annual periods beginning January 1, 2019 for public companies and January 1, 2022 for non-public companies, including interim periods within those fiscal years; earlier adoption is permitted. In the financial statements in which the ASU is first applied, leases shall be measured and recognized at the beginning of the earliest comparative period presented with an adjustment to equity. Practical expedients are available for election as a package and if applied consistently to all leases. The Company is currently evaluating the impact of the adoption of this guidance on its financial condition, results of operations and cash flows.

In June 2016, the FASB issued ASU 2016-13 Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. ASU 2016-13 is effective for annual reporting periods, and interim periods within those years beginning January 1, 2020 for public companies and January 1, 2023 for non-public companies. The Company is currently in the process of evaluating the impact of the adoption of ASU 2016-13 on its financial statements.

NOTE 3 – PROPERTY AND EQUIPMENT

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

	2019	2018
Office equipment	$ 81,681	$ 79,661
Furniture and fixtures	17,132	17,132
Laboratory equipment	383,516	383,516
Leasehold improvements	5,973	5,700
Total property and equipment	488,302	486,009
Less accumulated depreciation	(439,378)	(425,015)
	$ 48,924	$ 60,994

Depreciation expense was $14,363 and $10,097 for the years ended December 31, 2019 and 2018, respectively.

NOTE 4 – INTANGIBLE ASSETS

Intangible assets consisted of the following at December 31, 2019 and 2018:

	2019	2018
Issued patents (amortized)	$ 31,840	$ 31,840
Unissued patents (unamortized)	201,514	201,514
Software development costs	45,575	-
Total patents	278,929	233,354
Less accumulated amortization	(31,476)	(22,288)
	$ 247,453	$ 211,066

Amortization expense for intangible assets for the years ended December 31, 2019 and 2018 was $9,188 and $1,592. Estimated amortization expense on issued patents and software development costs for the years ending December 31 are as follows:

2020	16,784
2021	16,784
2022	9,187
2023	1,592
2024	1,592
	$ 45,939

NOTE 5 – COMMITMENTS AND CONTINGENCIES

Leases

In August 2011, the Company entered into a lease commencing in December 2011 which expired in November 2016. Under the lease agreement, the Company was to pay an annual rent of $134,975, plus additional operating expenses. The agreement included a 3% annual increase and an option to expand office space. Upon expiration, this lease has continued on a month-to-month basis. Total rent expense, including additional operating expenses related to this property, was $138,697 and $154,902 for the years ended December 31, 2019 and 2018, respectively.

Royalties and License Agreements

The Company has entered into various agreements related to fundraising and other consulting services that commits the Company to paying certain additional fees contingent upon certain milestones and/or events. The amount of liability, if any, cannot be reasonably estimated. Hence, no liability has been recorded in the accompanying financial statements.

In 2008, the Company entered into three deferred bonus agreements and agreed to pay deferred bonus payments of approximately $500,000 if certain events related to stock options were triggered. The related stock options expired in February 2018. Upon expiration of these options, the contingency related to this deferred bonus also expired.

In November 2000, the Company entered into a licensing agreement with the United States Public Health Service ("PHS") that gave the Company exclusive rights to use several patents owned by PHS. The agreement was subsequently amended in 2005 and 2011. Under the most current agreement, the Company was required to pay minimum annual royalty fees of $7,500 due and payable on January 1 of each calendar year from 2003 through 2011. Further payment of the minimum annual royalty has been deferred until January 1 of the calendar year following the first year the Company achieves annual net sales of the licensed product equal to or greater than $1,000,000. The minimum annual royalty will be due January 1 of each calendar year thereafter. The PHS agreement also calls for the Company to pay other royalties, including earned royalties, benchmark royalties, and sublicensing royalties. In addition, the agreement requires the Company to reimburse PHS for patent expenses incurred. Reimbursement is due on January 1 of each calendar year beginning in 2013. Minimum reimbursement of $10,000 is due until the Company has achieved $500,000 in net sales of licensed products, $20,000 once the Company has achieved between $500,000 and $1,000,000 in net sales of licensed products, and the balance of the remaining unreimbursed patent expenses due in full once the Company achieves net sales of licensed products of $1,000,000 or upon termination or expiration of the license, whichever comes first. In addition, PHS continues to submit annual requests for reimbursement of patent expenses incurred throughout the preceding year. Unreimbursed patent expenses are included in accrued expenses and were $195,794 at December 31, 2019 and 2018.

In July 2002, the Company entered into an award and royalty agreement with MdBio, Inc. Under this agreement, the Company received $150,000 in funding and is to make payments of 3% of gross sales revenues beginning in June 2003 and ending when a total of $450,000 has been repaid. Total royalty expenses incurred relating to this agreement were $8,641 for the years ended December 31, 2019 and 2018.

During 2010, the Company entered into a licensing agreement with Abbott Molecular, Inc. ("Abbott"). Under this agreement, the Company retained exclusive rights to use certain processes and know-how for which Abbott has a patent pending. Under this agreement, the Company is to pay royalties equal to 9% of the service revenue and net sales of each licensed product sold or otherwise disposed of prior to the issuance of the related patents and 18% of sales revenue or net sales of each licensed product sold or otherwise disposed of once the related patents are issued. Royalties will be deferred until either the Company's lung cancer testing business is acquired by Abbott or another third party or the value of the royalties exceeds $1,000,000. The agreement also allows Abbott first right to acquire the Company's lung cancer testing business at various intervals.

In May 2011, the Company received a grant from the Maryland Biotechnology Center ("MBC"). Under this grant agreement, the Company was to receive $200,000 in funding. Per the agreement, beginning January 31 of the year after the completion of the project, the Company is to repay MBC in payments equal to 3% of total sales revenues (excluding revenues relating to the Company's BioCheck suspicious powder screening kit). If the grant is not repaid in full by one year after the first payment date, the total repayment will equal 150% of the award, or $300,000. If the grant is not repaid in full by two years after the first payment date, the total repayment will equal 175% of the award, or $350,000. If the grant is not repaid in full by three years after the first payment date, the total repayment will equal 200% of the award, or $400,000.

In February 2016, the Company entered into a collaboration agreement with National Foundation for Cancer Research, Inc. ("NFCR"), a tax exempt 501(c)(3) organization, for the development of a cloud accessible algorithm to assist physicians in the Peoples Republic of China ("PRC") to interpret test results, and to support refinements of the Company's PAULAs test. The NFCR assisted the Company in obtaining blood test data from the PRC. Upon execution of the agreement, the Company issued NFCR 19,157 shares of Common Stock. The Company issued an additional 19,157 shares of Common Stock in 2016 based on the first milestone of receiving data from the first 1,000 patients located in the PRC. Per the agreement, after the Company has analyzed data from the initial population, it may seek additional data from more patients which can trigger an additional 38,315 shares of Common Stock being issued. To date, this provision has not yet been triggered. If upon seeking and receiving this additional patient data as set forth in the agreement, and immediately after issuing the requisite shares, the Company for five (5) years shall pay to NFCR two percent (2%) of gross sales the Company derives from the sale, licensing and other dispositions of the developed algorithm, payable quarterly.

Effective April 17, 2017, the Company entered into a six-month option agreement with Chang Gung Memorial Hospital (CGMH) of Taiwan to obtain and secure an exclusive license to certain technology, intellectual property, and data relating to our pan-cancer test. The option period was extended through February 28, 2018 through an amendment executed in November 2017. The option was exercised in a timely manner, payments were made, data was transferred to the Company and was verified by it and the Company entered an exclusive license to the technology until the last patent included in the specified technology expires, or 20 years. As consideration for this option, the Company paid an option fee of $75,000. Once the option was exercised in February 2018, the Company paid an additional license fee of $150,000 in cash and $300,000 in Common Stock (through the issuance of 92,025 shares of Common Stock), which were released from escrow upon verification of the viability of the data. The Company has amortized the license agreement over the term amounting to an amortization expense of $20,358 and $19,071 as of December 31, 2019 and 2018, respectively.

NOTE 6 – STOCKHOLDERS' EQUITY

Preferred Stock

The Company has authorized the issuance of 10,000,000 shares of Preferred Stock with par value of $0.01, of which 1,303,000 have been designated as Series A Preferred Stock, 978,000 have been designated as Series A-1 Preferred Stock, 800,000 shares have been designated as Series A-2 Preferred Stock and 3,569,405 shares have been designated as Series B 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 and Series B Preferred Stock have a liquidation preference of $3.07, $3.07, $3.26 and $3.53, 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 Series A Preferred Stock, Series A-1 Preferred Stock, Series A-2 Preferred Stock and Series B 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 Series A Preferred Stock, Series A-1 Preferred Stock, Series A-2 Preferred Stock and Series B Preferred Stock, as applicable.

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, 2019 and 2018, 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, 2019 and 2018.

Series A-1 Preferred Stock

As of December 31, 2019 and 2018, 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, 2019 and 2018.

Series A-2 Preferred Stock

On December 29, 2017, the Company issued 312,361 shares of Series A-2 Preferred Stock at $3.26 per share for proceeds of $936,017, net of $82,280 of offering cost fees, to investors an equity crowdfunding offering under Section 4(a)(6) of the Securities Act and Regulation Crowdfunding promulgated thereunder. On January 23, 2018, the Company completed a second and final closing of this equity crowdfunding offering and issued 15,027 shares of Series A-2 Preferred Stock for gross proceeds of $48,988. In connection with this offering, the Company also issued 6,548 shares of Series A-2 Preferred Stock to First Democracy VC, the platform for the offering, as partial consideration for their services.

On January 9, 2018 and March 16, 2018, the Company issued 106,165 and 94,785 shares, respectively, of Series A-2 Preferred Stock at $3.26 per share for gross proceeds of $346,100 to an Investment LLC (as defined below).

On February 15, 2018, the Company issued 2,301 shares of Series A-2 Preferred Stock to a consultant as partial compensation for services provide by such consultant.

As of December 31, 2019 and 2018, there were 442,402 shares of Series A-2 Preferred Stock issued and outstanding.

Series B Preferred Stock

On August 17, 2018, the Company launched its offering under Regulation A of Section 3(6) of the Securities Act for Tier 2 offerings, pursuant to which the Company offered a minimum of 127,479 shares of Series B Preferred Stock and a maximum of 3,399,433 shares of Series B Preferred Stock at an offering price of $3.53 per share, or a minimum of $450,000 of shares and a maximum of $12,000,000 of shares, on a "best efforts" basis.

In the year ended December 31, 2018, the Company raised $3,919,062 in gross proceeds through the sale of 1,110,216 shares of Series B Preferred Stock for net proceeds of approximately $3,593,419.

In the year ended December 31, 2019, the Company raised $1,275,175 in gross proceeds through the sale of 361,271 shares of Series B Preferred Stock for net proceeds of approximately $1,149,483.

As of December 31, 2019 and 2018, there were 1,471,487 and 1,110,216 shares of Series B Preferred Stock issued and outstanding, respectively.

Common Stock

The Company is authorized to issue 25,000,000 shares of Common Stock.

In February 2018, the Company issued 92,025 shares of Common Stock with a value of $300,000 in conjunction with a license agreement. The shares were valued based on the selling price of the A-2 Preferred Stock to third parties, as the common stock has relatively consistent rights with preferred stock.

In November 2018, the Company issued 1,000 shares of Common Stock upon the exercise of $0.01 warrants for proceeds of $10.

As of December 31, 2019 and 2018, there were 4,725,633 shares of Common Stock and outstanding.

Stock Options

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

On July 16, 2019, the board of directors adopted the 20/20 GeneSystems, Inc. 2019 Stock Incentive Plan (the "2019 Plan"). The 2019 Plan provides for the grant of equity awards to employees, consultants, advisors and outside directors of the Company and its subsidiaries, including incentive stock options as described in section 422(b) of the Internal Revenue Code of 1986 ("ISOs"), non-qualified stock options (i.e., options that are not incentive stock options) ("NSOs") and awards of restricted stock. Up to 2,000,000 shares of Common Stock may be issued pursuant to awards granted under the 2019 Plan. The 2019 Plan is administered by compensation committee of the board of directors and expires ten years after adoption.

On August 1, 2019, the Company granted NSOs for the purchase of 292,680 shares of Common Stock at an exercise price of $0.82 per share, all of which vested in full on the date of grant. No stock options were granted during the year ended December 31, 2018. 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 2019 was determined using the Black Scholes option pricing model with the following assumptions: dividend yield: 0%; volatility: 70.2%; risk free rate: 1.68%; term 10 years.

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

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

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

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

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

At times, the Company granted stock options under the 2007 Plan in excess of the authorized shares under the plan. However, as of December 31, 2019 and 2018, due to forfeitures the number of options outstanding under the 2007 Plan are less than the authorized shares. The Company does not believe that such non-compliance with the 2007 Plan limits causes significant exposure to the Company as any options in excess have been forfeited and any such compensation expense has been recognized in historical financial information in compliance with applicable accounting standards. In 2017, the 2007 Plan expired.

A summary of the ISO activity is as follows:

	Total Options	Weighted Average Exercise Price Per Share	Total Weighted Average Remaining Contractual Life
Options outstanding, December 31, 2017	233,763	$ 4.33	3.3
Granted	-	-	-
Exercised	-	-	-
Expired	(80,401)	4.00	-
Options outstanding, December 31, 2018	153,362	4.50	4.0
Granted	-	-	-
Exercised	-	-	-
Expired	-	-	-
Options outstanding, December 31, 2019	153,362	$ 4.50	3.0
Options exercisable, December 31, 2019	153,362	$ 4.50	3.0

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

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

	Total Options	Weighted Average Exercise Price Per Share	Total Weighted Average Remaining Contractual Life
Options outstanding, December 31, 2017	145,761	$ 4.50	1.8
Granted	-	-	-
Exercised	-	-	-
Forfeited/Expired	(96,206)	4.50	-
Options outstanding, December 31, 2018	49,555	4.50	4.15
Granted	292,680	0.82	10.0
Exercised	-	-	-
Expired	-	-	-
Options outstanding, December 31, 2019	342,235	$ 1.35	8.65
Options exercisable, December 31, 2019	342,235	$ 1.35	8.65

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

Warrants

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, 2017	117,906	$ 0.01	4.98
Granted	-	-	-
Exercised	(1,000)	0.01	0.59
Forfeited/Expired	-	-	-
Warrants outstanding, December 31, 2018	116,906	0.01	4.00
Granted	-	-	-
Exercised	-	-	-
Forfeited/Expired	(5,700)	-	-
Warrants outstanding, December 31, 2019	111,206	$ 0.01	3.17
Warrants exercisable, December 31, 2019	111,206	$ 0.01	3.17

NOTE 7 – RELATED PARTY TRANSACTIONS

The Company has historically employed or contracted with immediate family members of the Chief Executive Officer. Such arrangements are under compensation arrangements for services provided in the normal course of business. As of December 31, 2019 and 2018, the Company has an outstanding balance due to Barry Cohen, the Chief Executive Officer's brother, in the amount of $0 and $27,832 for professional services, respectively.

From time-to-time, investors in the Company are directed to deposit funds in a Limited Liability Company ("Investment LLC") set up by the Company for the purposes of managing investments seeking the advantages of the Maryland Biotechnology Investor Tax Credit program. Funds from those Investment LLCs either have been or will be transferred to the Company pursuant to the rules and procedures of the tax credit program. Shares of the Company will be issued to investors in those Investment LLCs in the same manner as if they invested directly in the Company. While the Company performs the administrative tasks for the Investment LLC when they are active, the Company has no ownership, requirement to fund, or voting privileges within these entities.

As of December 31, 2019 and 2018, the Company has approximately $2,700 and $57,000 due from various Investment LLCs controlled by certain stockholders of the Company as a result of funds advanced to them by the Company as it relates to the expected tax refunds under the Maryland Biotechnology Investor Tax Credit program.

During 2017, an Investment LLC received approximately $240,000 in funds for investment in the Company, pending application of the Maryland Biotechnology Investor Tax Credit. In November and December 2017, the Investment LLC lent the Company $210,000 which the Company subsequently repaid in 2018 upon the investment LLC receiving the requisite initial tax credit certificate. Furthermore, the $240,000 investment was made by the Investment LLC as part of a total investment of $309,000 for shares of Series A-2 Preferred Stock in 2018.

NOTE 8 – 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, 2019 and 2018:

	2019	2018
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:

	2019	2018
Expected federal tax benefit	$ (509,900)	$ (307,300)
Expected state tax benefit	(200,300)	(120,700)
Nondeductible expenses and other	(308,500)	3,400
Increase (decrease) in valuation allowance	1,018,700	424,600
Total provision for income taxes	$ -	$ -

The major components of the deferred taxes are as follows at December 31, 2019 and 2018:

	2019	2018
Account receivable, net	$ 5,000	$ 400
Accumulated depreciation	(1,500)	(1,500)
Deferred rent	-	-
Intangible assets, net	(64,800)	(61,700)
Accrued expenses	42,900	27,600
Net operating loss	5,449,000	4,447,100
Deferred tax asset value allowance	(5,430,600)	(4,411,900)
	$ -	$ -

On December 22, 2017 the Tax Cuts and Jobs Act (“TCJA”) was signed into law. The TCJA reduces the corporate income tax rate from 34% to 21% effective January 1, 2018. All deferred income tax assets and liabilities, including NOL’s have been remeasured using the new rate under the TCJA.

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, 2019, the Company had available approximately $18,678,000 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, 2019 are approximately $18,504,000 and begin to expire in 2020. The valuation allowance for deferred tax assets increased by approximately $1,018,700 and $424,600 during the years ended December 31, 2019 and 2018, respectively.

The United States Federal and applicable state returns from 2015 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 9 – SUBSEQUENT EVENTS

Regulation A Offering and Establishment of Series C Preferred Stock

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 is offering 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. As of the date of these financial statements, the Company has raised approximately $1,181,000 in gross proceeds through the sale of 268,451 shares of Series C Preferred Stock.

On March 9, 2020, the Company filed a Certificate of Designation with the Secretary of State of the State of Delaware to establish the terms of the Series C Preferred Stock. Pursuant to the terms of the of the Certificate of Designation, the Company designated 3,340,909 shares of its Preferred Stock as Series C Preferred Stock. The terms of the Series C Preferred Stock are identical to the Designated Preferred Stock described under Note 6, except that the liquidation preference for the Series C Preferred Stock is $4.40 per share.

COVID-19 Antibody Tests

On April 5, 2020, the Company entered into a sales representative agreement with Mems Technologies Holdings Company Limited ("MEMS"), a Hong Kong based company that has the rights to export COVID-19 rapid antibody test kits manufactured by Innovita (Tangshan) Biological Technology Co., Ltd., located in Hebei, China ("Innovita"). Pursuant to this agreement, MEMS granted to the Company a non-exclusive right to solicit orders for the Innovita product from customers outside of China. The Company will receive a commission of ten percent (10%) of the price for Innovita products on orders solicited by the Company that are approved by MEMS, the terms of which shall be provided by MEMS. The term of the agreement with MEMS is two years.

In May 2020, the Company validated and began offering COVID-19 antibody tests manufactured by Roche Diagnostics.

PPP Loan

On May 19, 2020, the Company received a $144,000 Payroll Protection Program ("PPP") loan from the United States Small Business Administration ("SBA") under provisions of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). The PPP loan has a two-year term and bears interest at a rate of 1.0% per annum. Monthly principal and interest payments are deferred for six months after the date of disbursement. The PPP loan may be prepaid at any time prior to maturity with no prepayment penalties. The PPP loan contain events of default and other provisions customary for loans of this type. The PPP provides that the PPP loans may be partially or wholly forgiven if the funds are used for certain qualifying expenses as described in the CARES Act. The Company intends to use the proceeds from the PPP loan for qualifying expenses and to apply for forgiveness of the PPP loan in accordance with the terms of the CARES Act. The Company has classified the PPP loan as a current liability pending SBA clarification of the final loan terms.

The Company has evaluated subsequent events that occurred after December 31, 2019 through July 6, 2020, the issuance date of these financial statements. There have been no other events or transactions during this time which would have a material effect on these financial statements.