DECISION DIAGNOSTICS CORP.

QUARTERLY REPORT FOR OTC PINK

MANAGEMENT'S DISCUSSION & ANALYSIS

Report for the Quarter Ended

September 30, 2020

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

Overview

Decision Diagnostics Corp. is a necessary services worldwide prescription and non-prescription diagnostics and home testing products distributor and the manufacturer of GenUltimate! glucose test strips, a Class II medical device for at-home use for the measurement of glucose, the PetSure! glucose test strip for the glucose testing of dogs and cats, a test strip designed to work with the Zoetis AlphaTrak and AlphaTrak II glucometers, a legacy meter, the GenUltimate! 4Pets Glucose system a proprietary glucose measuring system inclusive of the company's GenUltimate! 4Pets test strip and Avantage meter, for the testing of dogs, cats and horses. The company also has its GenUltimate! Sure and GenChoice! and GenUltimate! Precis test strips, products solely for off-shore sales (no domestic market), and our GenViro! Swift kits for Covid 19 testing now in front of the U.S. FDA for emergency (EUA) approval. We have also completed and are for sale in select international markets, our GenUltimate TBG product, a unique high precision product. In addition, the company has begun entered into a Definitive Agreement with a distributor for the sale of our GenUltimate! brand products and our GenViro Swift kits in Central and South Asian countries including India, Malaysia, Indonesia and Singapore. We are also finishing up contracting in the Russian Federation with a partner for our products and in the Russian Federation and aligned countries. This distributor has filed for approvals with Russian Federation regulators to represent our products in Eastern Europe and Russia. Our products will primarily be sold as an international private label market entry. Export Certificates for GenUltimate! Sure and GenUltimate! Precis have been received. With the exception of our GenUltimate and GenViro! Swift kits, we are concentrating new sales agreements of our brand in these international markets, to sell those products where there is no domestic or North American markets. We have also added distribution in the Caribbean and Africa.

In mid-February 2020 we were first advised of the large outbreak of Coronavirus in Korea, and in particular in the city of Daegu, Korea. Daegu is the Korean city where since 2016 the company's manufacturing facility and patient trials hospital are located. At first it was difficult to receive information as to the severity of the virus and how it was affecting the company's facility in Daegu, Korea. And, of course we have our own domestic coronavirus issues on a large scale in the U.S. As a result of the virus, now a pandemic, we have learned for the first time the use of words like "lock down" and "lock up." Our contract manufacturer The Bio Co., Ltd. ("The Bio") was eventually described to us as locked down and locked up and was unable to manufacture or ship to us our diabetic testing products from February 22 through March 27, 2020. We have subsequently recovered from these problems. It was explained in our 1Q and 2Q 2020 Quarterly Reports that even though The Bio had reopened for business in early March 2020, some of their suppliers, both locally, and in other parts of Korea, and outside of Korea, were still locked down. Our legacy product sales for 1Q 2020 as reported appeared to be strong, but had resulted from our shipping product from existing inventory. However, our performance in 2Q 2020 did not totally reflect the impact of the Covid-19 lock-downs both in the USA and Korea and sales were affected, not only by the inability to receive fresh inventory product from our Korean partner, but also from the economic impact in the U.S. where several of our distributors had major cash flow issues of their own and either curtailed ordering or were put on "cash in advance" terms, all of which affected our 2Q 2020 sales. In 3Q 2020 we are still dealing with slower payments, particularly from several distributors, and including one of our largest distributors.

As this Coronavirus spread, and with time on their hands during the lock down, we asked The Bio several days after their mid-February 2020 lock down, to look into whether some of our diabetic detection and management technologies could be put to use to perhaps develop a coronavirus diagnostic test. In particular our GenUltimate TBG product makes use of a technology known as Electrochemical Impedance Spectroscopy (impedance or EIS) to detect and quickly count red blood cells present in a human (or animal) sample. The EIS process employed by the company in its GenUltimate TBG product, counts the red blood cells in a sample in less than 4 seconds and then uses this "count" to statistically adjust the glucose test run by the GenUltimate product to correct for an over or under abundance of these red cells. We concluded, using a number of means, that we would use this same type of proprietary technology to "count" other particles in a human (or animal) sample -- including virus particles.

We had decided that if such a test methodology proved workable it was worthwhile from a humanitarian standpoint to use our limited resources at least to try to develop such a test ("count") method. Shortly thereafter we received three technical paper citations from our contract manufacturer, The Bio, regarding certain technical papers written from 2006 through 2015 where the researchers and scientists discussed their research in detail and their ability

to use a method called impedance (EIS) to identify and classify certain (now familiar) classes of virus. We also learned that although EIS was not a household name there were numerous applications both within and outside of healthcare where this concept was and is used. Regarding the references provided by our Korean partner, these papers described their impedance (EIS) methodologies for the identification of various influenza and influenza like virus in detail and the papers also included sample data sets. From these papers we became convinced that we could adapt our GenUltimate TBG impedance technology to work as a stand-alone diagnostic to identify Covid-19, and do so reliably.

https://duckduckgo.com/?q=electrical+impedance+spectroscopy+medical+products&t=newext&atb=v232-1&iax=images&ia=images

In all three papers it was described that researchers designed and built a bench level chemistry methodology and their version of an identification device, and then performed tests on live patients. In all cases the number of patients (subjects) tested was statistically significant. The importance of these publications indicated that a testing device and chemistry method, using EIS (better described as an energy pulse with traits somewhat similar to an electric current and a radio wave pulse), could be created in short order to measure the presence or absence of such a virus (of interest) such as influenza and H1N1 influenza, and of course SARS and MERS and through our own development methodology, Covid-19.

The company's GenUltimate TBG product makes use of impedance technology to measure the number of red blood cells in a patient blood sample, information relevant to a glucose measurement in that same patient. Mr. Berman, the company's CEO, became convinced that a similarly configured device could be built for the determination of Covid-19. During the development of the company's GenViro! Swift kit, our CEO Mr. Berman became further convinced that the GenUltimate TBG impedance "module" should be moved a new GenViro! Swift product, primarily because GenViro! appeared to need the same red blood cell (hematocrit) correction required and present in the company's GenUltimate! TBG product.

As quickly as it could the company engaged Matthew Musho, PhD (holder or collaborator in 33 patents published in parallel fields) to assist in the design of a testing method and device for the measurement of Covid-19.

https://patents.justia.com/inventor/matthew-k-musho

Dr. Musho a prolific inventor and a professional with a deserved reputation of making things work and in solving previously thought unsolvable problems, has spent a lengthy career in the area of bio-sensor design was a text-book definition of the skill level required by the company to design and bring to market a major advance in technology that defines the company's GenViro! Swift kit product. In addition to Dr. Musho, the company had previously engaged his wife Leslie to fill the company's needs for a QA and QA policies expert who also has major medical device product testing experience.

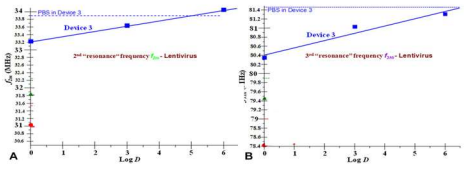
The company also engaged FDA practice counsel to prepare the company and its new product for submission for emergency use authorization (EUA) by the FDA. Counsel, already familiar with the company's diabetic products and technologies, understood almost immediately what the company was trying to achieve and during the last week in February counsel contacted the FDA. This contact was made a day or two prior to the FDA's eased guidance for EUA, published on February 27, 2020. A subsequent further easing of FDA past policy appeared in a March 16, 2020 guidance policy. Additional guidelines have been published by the FDA in May 2020 and July 2020, and in September and October 2020 the FDA added further guidance for products that identified Covid-19 through a direct antigen methodology. Several of these publications made the company's product development and testing tasks easier, some made it more difficult.

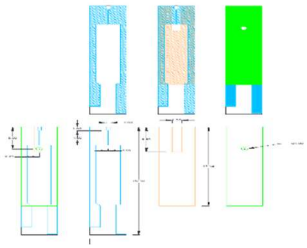
The specifications guidelines set down by Mr. Berman, for creating this Covid-19 testing device and its important chemistry, were that the test must be measured on a variation of the company's existing Precise or Avantage glucometer mold, along with changes to the electronics in the meter, and the differences in test strip size and configuration, to reflect the higher powered electrodes required for virus detection using small (fingertip) samples of whole blood. Subsequently, the company has also added testing using saliva to its kit configurations. In addition, the resulting chemistry would necessarily run using a patients (small sample of) whole blood taken from a finger prick, or saliva taken from a capture cylinder. It was established in advanced testing that 1-2 microliters of fluid (a small drop on a finger tip for blood, or a small amount in a saliva capture cylinder), to perform the test and provide a result

in one minute or less (later redefined in two iterations to its current 10.5 seconds or less), with at least a 95% accuracy (the newest FDA guidelines). It should be noted that the company's virus detection methodology for human saliva which makes use of all of the components in the original GenViro! chemistry (test strip) itself as well as the meter. Three alternative designs were provided and given to the company on March 2. Two of the designs were diagrammed by Mathew Musho, PhD (see below), the third design by a chemist and engineer from The Bio in Korea. The chosen of the three alternative product designs bears the trade name GenViro! Swift.

The company then set to work, along with Matthew Musho, PhD ("Musho"), to evaluate the designs, keeping in mind the desired specifications of the DECN CEO and product Program Director, which included availability of components without wait time, time to market (assuming FDA EUA), whether the chosen method was applicable to use in point of care and at-home environments, time of assay from commencement of test and until result, size of the blood and/or saliva samples, and finally cost to produce. Given the company's experience in working with biosensors and with electrode technology, the design review process took less time than originally expected. The last of the development period was used to determine which of the two Musho diagrammed specifications was to be chosen. The design provided by The Bio was set aside because it could not be used for reporting purposes by the company's existing meter technology, and therefore would require additional meter or instrumentation development. At the end of this process, the company chose to produce the product shown in the illustrations below but shortly thereafter asked its Korean partner to begin work on a second variation, which the company wished to use in a commercial setting as a confirmation tool, see Product Design 2 below).

Product Design Chosen





The design above makes use of a virus antigen approach favored by some of the competitive companies in the Covid-19 testing field, but, as it turns out, not a favorite method at the FDA which favors PCR, a 35+ year old standard. The major difference (magic) is that the approach used by the company in its GenViro! product allows for swift (10.5 seconds or less) results using a minimum of blood from a finger prick, or an equally small amount of saliva from a human subject. All work commenced on the product specification chosen by Mr. Berman with components such as the platinum electrodes, platinum carbon paste, industrial films (several types) to make the biosensor, and perhaps a new impedance chip for the meter. Prototypes of the test strip and the metering device were employed and test strips for investigational testing were delivered to the company on August 2, 2020. Additional test strips in somewhat larger quantity were delivered in late August 2020.

For FDA EUA filing and the granting of a Pre-EUA by the FDA, the company first filed an application for its Professional use version of its GenViro! Covid-19 test kit on April 3. We received PEUA designation from the FDA on April 4. Conversations with FDA review staff began in earnest on April 14. This application was for the point of care testing of blood from human subjects. The company then filed a second EUA application with the FDA on May 1. This application was for our individual use GenViro! test kits. We received PEUA designation from the FDA on May 2. Further, the company plans to file a third EUA application for its GenViro! saliva based method, and plans to file this application, anticipated in late November 2020 or early in December 2020, as testing trials are completed. Testing has recently been streamlined at the request of the testing partner, an east coast based CLIA and FDA approved clinical laboratory that maintains a client (physician and clinic) client base throughout the USA (a company requirement). As of this writing our testing partner has completed all testing for the eventual EUA specificity level testing and anticipates turning over this data to the company as this quarterly report is filed. This partner has also begun testing for the EUA sensitivity level testing with first data expected to be turned over to the company in the next 10 days. Both testing regimens have been designed to meet with all FDA EUA requirements. Testing initially began in mid-October 2020.

The company has recently completed the packaging and package inserts for four versions of its GenViro! Product, GenViro! Point of Care, GenViro! At-Home use, GenViro! Saliva Point of Care, and GenViro! International in English, Spanish, French, German and Russian languages for Saliva. The company is in the process of having the UPC clearing house GS-1 assigning UPC identifiers to these four products, all of which will be produced for testing and registration purposes as "Investigational Use" products. An example is given below for illustrative purposes. The kit shown below will be used in the second of testing studies. The kit below will not be sold commercially. The company's (revised) retail kits will include a test strip, lancets (blood) or saliva cylinders (saliva) an interface sleeve to cut down human fluid contamination at the meter, and the meter itself.

GenViro! Swift kits are not yet available for sale in the USA or Puerto Rico. Emergency FDA Authorization is in process.

Late in 2Q 2020 the company filed two Provisional Patents with the U.S. Patent and Trademark Office for the protection of its impedance (EIS) based technologies employed in its GenViro! Swift and GenUltimate TBG prodcuts.

Regarding additional product development, the company has completed advanced development work and third party testing of its GenUltimate! TBG test strip and TGB Precise meter. Substantial testing for this product has been completed in Korea and parallel testing has been done by the company's U.S. consultants. In 2019, and in association with the company's advanced development engineers, company CEO Keith Berman asked for a change to the engineering foundation of the GenUltimate! TBG system to work in an identical manner with the company's GenUltimate test strip and with the Lifescan Ultra test strips that the company's GenUltimate product has become an alternative methodology to.

The TGB enhanced version of GenUltimate! is named GenUltimate! Premier and will go on sale commercially just as soon as the company's FDA registered contract manufacturer fully recovers from their experience with the Covid-19 virus that began in Korea in late January 2020 and reached critical proportions in February 2020, and now apparently has returned. At the moment our Korean partner is involved primarily with our GenViro! Swift kits. After the return of the virus passes in Korea we will turn our attention to begin manufacturing of this new version (Version 3) test strip is certain tooling needed to be added at the company's manufacturing facility. GenUltimate! Premier! owing to its near analyzer level precision (in a handheld device) will carry a substantially higher MSRP, Big Box, and wholesale pricing. The company will continue to sell its GenUltimate! product in existing markets.

As off-shore products GenUltimate! Sure and GenUltimate Precis are test strips that run on four existing Platinum/Lifescan legacy meters, and will only be sold in select international markets, primarily in the Russian Federation. There are no USA markets for either test strip. The International roll-out decisions were to choose those markets where the products will not encounter certain performance criteria issues created by the legacy metering platforms that the GenUltimate! Sure and GenUltimate! Precis test strips run on. The GenUltimate! Sure product in particular, although sharing many similarities with the company's GenUltimate! product, does not have the capability for future improvement or upgrade and as a result is viewed in the market and by DECN as a small niche product, where the niche grows smaller even in the near term. Thus, most of the company's attention for International markets will be focused on GenUltimate Precis. However, manufacturing of the GenUltimate! Sure product will allow the company to continue manufacturing the existing GenUltimate! test strip which uses the same manufacturing line. The GenUltimate! Precis product has more potential in that it is capable of having portions of the company's TGB technology added-on at a later date. Thus, the conclusion was that having two finished products is better than having no product at all, so the company will continue to perform compatibility testing with the family of legacy meters as we grow our relationship with the large Eastern European distributor.

Resources permitting, we intend to register the company's GenChoice! and GenUltimate! TBG products in the EU, because these products **do** meet ISO guidelines without further development. The GenUltimate! TBG meter, which will undergo 510K prosecution for its metering system, is next up of our diabetes related products for FDA clearance. The test strip, a close relative of the company's GenUltimate! test strip which is already FDA cleared. The company has contracted with the same expert organization that wrote the 510K document and a credentialed IRB who completed the GenChoice! clinical trial data and who will follow the same clearance path for the GenUltimate! TBG system. But as stated, both are resource depending products.

Our Current Business Foundation

Our subsidiaries, Pharma Tech Solutions, Inc., PDA Services, Inc. and PharmaTech Sensor Development Corp. operate in several healthcare products channels. In addition our subsidiary Decision IT Corp. engages in the acquisition and holding of Intellectual Property including Patents and Trademarks and specialty manufacturing equipment acquired for our Korean contract manufacturer of our GenUltimate! as well as our GenSure! and GenChoice! products. Our newest subsidiary Pharmatech Sensor Development Corp. manages our investment in specialty manufacturing machinery and testing laboratories, as well as an inventory credit line to finance inventory purchases of our GenUltimate! and PetSure! products. The company has endeavored to expand the credit line for the management of our GenChoice! and GenUltimate! TBG products. The company has discontinued its earlier GenStrip 50 product and ended the selling of the last of the inventory in November 2016. All of the GenStrip 50 test strips have subsequently reached expiration dates.

In March 2017 the company was approached by its Korean partner, The Bio Co., Ltd to design and fund a new product which the company calls GenUltimate! TBG. This product represents a major improvement in diabetic glucose monitoring. The GenUltimate! TBG system will be the first of its kind +/- 7% system. The latest ISO (2015) and FDA (2016) guidelines call for glucose monitoring systems to meet a +/- 15% standard, whereby the meter and strip must be within +/- 15% of a reference method in repeated testings 95% of the time. GenUltimate! and GenChoice! are +/- 15% test strips, with GenChoice! perhaps a little bit better, but in each case 97+% of the time in repeated samplings. GenUltimate! TBG is designed to meet the written standards of the ISO and FDA at +/- 7%, 97% of the time – effectively setting a new standard. The company has been funding the development of this system product since 2017, as well as a test strip only derivative version for use with a legacy meter sold overseas. In October 2018 the company implemented a strategic change to its development and manufacturing processes whereby we will standardize around two technology foundations, our GenUltimate! technology and our GenChoice! technology. Our PetSure! was the first marketable product to make use of the GenChoice! technology foundation, and is currently selling successfully in pet testing channels in the USA, Canada and the EU. GenUltimate! TBG will be the first enhancement of our GenUltimate! technology foundation. The company believes that these changes in our product development processes will lead to quicker to market products and streamlined and less costly manufacturing processes.

*Not for Sale in the US or Puerto Rico

As of this writing, GenUltimate! Precis and GenChoice! products are not available for sale in the U.S. or Puerto Rico.

Historical Construct

Shasta Technologies LLC, the original specifications provider of GenStrip, had an extremely difficult relationship with the US FDA and was the subject of a detailed and damning FDA (Enforcement) Warning Letter on April 8, 2014, and when they refused to respond to this Warning Letter in an expected fashion, the FDA then broadcast a worldwide Safety Notice on April 29, 2014, the FDA version of the Death Penalty. This second letter effectively ended Shasta's ability to be a product design specifier and manufacturer, due to a total lack of regulatory adherence in the highly regulated medical device industry. It is confusing to consider what Shasta could have possibly been thinking. The company's acquisition of Genstrip (now GenUltimate!) was fortuitous in its timing given the finality and outcome of Shasta Technologies' fatal troubles with the FDA. Shasta contested our acquisition and took other legal steps against their FDA lawyer and in retaliation against the company. During the efficacy of these litigations we had success in the courts. In December 2018 we received a grant of a judgment against Shasta for $3.6 million. We perfected this judgment in California, Pennsylvania, Oregon (Shasta's domicile) and Minnesota. As we began levy against Shasta we accepted their offer of Settlement. As a result of this Settlement we were able to value our acquisition of GenStrip under our 2014 Agreement. A substantial gain occurred and is fully described and carries over to this financial report.

The worldwide market for at-home blood glucose testing is an estimated $17.6 billion as of 2018, inclusive of the 2013 and 2016 changes to the Federal Medicare programs which gutted almost one-third of the U.S. market. The current GenUltimate! competes directly with one of the largest worldwide platform manufacturers the venerable Platinum (formerly Johnson & Johnson) Lifescan Inc. Ultra legacy product. J&J, which had owned Lifescan for more than 25 years, sold its Lifescan division and its venerable products to Platinum, a private equity firm. GenUltimate! (and the earlier GenStrip 50) were developed for use with the Lifescan OneTouch Ultra legacy system for at-home blood glucose testing, a system currently used daily by over 3 million diabetes afflicted Americans and 5.8 million diabetics world-wide. GenUltimate! competes in the overall at-home testing market by offering an economical solution to former users of the legacy platform provider's product. The company's GenUltimate! product is a much improved version. Our business model is unique to this market channel as our major business focus is directed toward diabetics who have attempted a change of their glucose monitoring platforms (systems) or those currently using the Lifescan legacy products but are dealing with escalating prices and lower (if any) insurance reimbursements. At the time of the introduction of GenStrip in March 2013, Lifescan controlled just under 40% of this market and 100% of its own Lifescan, Inc. OneTouch Ultra market. Their overall market share has since dropped below 30%. In October 2018 Lifescan, Inc. was sold to a large California based private equity firm in an asset sale arrangement. This event gave impetus to the changes we have made to our GenUltimate! TBG system, the first and only evolutionary enhancement to be offered to the Lifescan Ultra family of products still in use by over 4 million diabetics worldwide (see Litigation section).

Until our receipt of the March 2016 ruling from the FDA, two years (and growing) was a standard development to market timeline for in-vitro diagnostic products similar to Genstrip / GenUltimate! In fact the long review periods and stifling performance standards established have contributed to a large decline in new products offerings in the USA and the industry since 2014.

In 2019 we again improved GenUltimate!. GenUltimate! has become the only version of the original Genstrip line that will be packaged to conform with the FDA UDI standards, and was released as UDI compliant as

of September 24, 2016. Manufacturing of Genstrip 50 ended and on-going sales continued under the GenUltimate! brand, and includes the FDA UDI packaging.

Lifescan Inc., until October 2018, then the diabetes testing division of Johnson & Johnson, sued the company in three separate suits, all in Federal court, beginning in September 2011. These suits proved costly in that their intended purpose was to keep the Genstrip product off of retail market shelves. Until these suits were settled in May 2016, the company's marketing abilities were severely limited. In fact, even as of this writing, the company faces market obstacles brought about by the original litigation with Lifescan, Inc. However, it should be noted that Johnson & Johnson announced in January 2018 that their entire diabetic business (three divisions, multiple products) had been put up for sale, and offers for some or all of their businesses had been received. The sale closed in October 2018 with the completion of an asset sale to a large California based private equity firm, Platinum Private Equity.

The settlements we did achieve with J&J provided a hard-fought victory for the company, particularly since in 2015 Shasta had admitted to patent infringements of all three J&J diabetic medical device patents that were being adjudicated. We settled these lawsuits in a novel manner, where Johnson & Johnson paid the company a settlement amount in cash, in those lawsuits where the company was a defendant, a rarity in matters where the Plaintiff (J&J) had initiated the strike suit in the first place. J&J, as a part of the settlement, also granted the company licenses to three J&J patents (including one patent that J&J subsequently lost as a result of 3rd party prosecution by the company, through final action by the US Supreme Court), the larger value gained from this 5-year legal battle. In March 2016, prior to its settlement, the company's Pharma Tech Solutions, Inc. and Decision IT Corp. subsidiaries brought suit against Johnson & Johnson and Lifescan, Inc. in Nevada Federal court for patent infringement, the company alleging that Lifescan, Inc.'s OneTouch Ultra product was and had been infringing both of the company's patents. In March 2017, after a protracted battle with J&J where they tried to invalidate the company's lawsuit, the court in a major ruling agreed that the company will be allowed to move forward (a major victory so early in the suit) and will also be allowed to allege the Doctrine of Equivalents, a legal doctrine that would preclude J&J from twisting words through its pleadings and expert reports to escape justice. In April 2016 the company amended its original suit to include allegations under the Doctrine of Equivalents.

Further, in January 2016 the US Supreme Court ruled that the Doctrine of Laches, a defense used by many Defendants in patent infringement suits could no longer be used. This ruling further deprived J&J of one of its most important defenses against the company's current patent infringement claims. All of this action did not dissuade the Nevada District Court trial judge from granting J&J a Motion for Summary Judgment in October 2018. As a result of this ruling, the company filed an appeal to the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit court") in Washington, DC (the patent court). The company's appeal was ruled against by the Federal Circuit court in 4Q 2019. The company, with many other irons in the fire, decided not to avail ourselves of further expensive and resource depleting appeal, thus ending this litigation.

The Current Business

On September 26, 2020 the company entered the international Covid-19 testing market by launching its GenViro! Swift kits in select international settings. Just prior to this product launch the company entered into a distribution agreement with a distributor with access to Asian markets, including India, Malaysia and Indonesia. An initial order was placed, the order having a book value of over $4 million. In the next 120 days the company anticipates entering the Covid-19 test kit market with unique, cost effective, accurate and wholly proprietary products for the testing of Covid-19 in the USA, pending, of course, U.S. FDA authorization. The first of the company's GenViro! Swift products will be its saliva based test kits. Almost all available resources are being directed to the Covid-19 products (see Business Introduction). It is unknown how big this market will eventually grow to encompass, but given the severity of the Covid-19 pandemic, the fact that the company is developing screening tests, we expect to make a big market entry as we finish our product, manufacture it, and achieve FDA initial and then complete clearance. One recent study shows anecdotal worldwide revenue currently at $15 billion and, of course, growing dramatically.

The company continues to anticipate substantial and worldwide demand for its GenViro! Swift kits even in an environment where Covid-19 vaccines are available. We stand by our initial forecasts.

The current foundation business is focused on the diabetes testing market, a market still dominated by four large pharmaceutical manufacturers who provide very similar and equally focused products, selling at essentially equal prices. Our Genstrip's original introduction, even with the fits and starts, employed a business model different than those models employed by the major market players. Recent successes in the on-line marketplace, particularly on the Walmart and Amazon on-line markets has allowed the company to alter the market dynamics, lowering average price (which has occurred) or allowing for increased testing by diabetics for a lesser price, thereby affecting all market segments. In addition, and recently, both Amazon and Walmart have discontinued sales of certain competing products on their worldwide marketplaces due to product discontinuance or product shortcoming.

The company's major current market focus is to pharmacy chains, grocery chains with in-store pharmacies, large all-purpose retailers with in-store pharmacies, and group buying and chain pharmacy organizations, and for its pet testing products, on-line sales and chain pet supply stores and retail pet outlets.

The company has also implemented a successful "direct to diabetic" business model and has (independently or along with our distributors) executed on-line agreements with several of the largest retail chains, diabetic supply co-operatives, group purchasing organizations, as well as on-line mass merchandisers such as Amazon.com, EBay, Walmart, Sears, and approximately 1050 other on-line cooperatives and product aggregators. The company considers this rapid adoption to be a success gained in a very short period of time.

The efforts being expended in the "big-box" arena are greatly aided by the company's recent success with the explosively growing on-line Marketplaces, many sponsored by the large retail pharmacies and retail stores. We expect the same type of response, perhaps even greater for our upcoming Covid-19 test kits. If not for the big blip in sales caused by the 2Q 2020 Covid-19 issues and lock-downs, these Marketplaces and their fast growing sister organizations to these retailers have in some cases eclipsed traditional industry marketing plans. The company's recent successes in the on-line Marketplaces has given the company a beachhead in this market as the uncertainty brought on by the J&J lawsuits has (finally) waned.

Alltara *choice and Altara ultimate are* not yet available for sale or distribution in the United States or Puerto Rico.

Since March 2015 when we first we acquired special intellectual property and specialty manufacturing equipment which will shall serve our business interests now and into the future. We have increasingly turned to Alpha Capital Anstalt ("Alpha"), Navesink Device Initiatives, Sovereign Partners and Licgo Partners, whereby these organizations either purchased an 18-month 15% OID derivative instruments or Preferred C and Preferred D stock units, to facilitate the acquisition of intellectual property or manufacturing equipment, or to finance our growth. In 1Q, 2Q and 4Q 2016 and 2Q, 3Q and 4Q 2017, 2Q and 3Q 2018, and 1Q and 2Q 2019 and finally in 2Q and 3Q 2020 we completed additional financing transactions with both Alpha and/or, Sovereign, and Licgo. In 2020, to help us fund our Covid-19 product endeavors, Alpha loaned us an additional $2.1 million to carry on and complete our GenViro! Swift development and testing. From time to time we drop below this $300,000 threshold, primarily at the end of fiscal quarters. Alpha also financed our acquisition of new specialty manufacturing equipment to facilitate our contract manufacturer in Korea as they develop our new GenChoice! product.

In late July 2019 the company was contacted by a large Eastern European distributor of J&J/Lifescan, now (Platinum Equity) products. To begin, this distributor wishes to distribute the company's GenUltimate! Precis product, a product that has no USA market, does not require FDA clearance to be sold overseas but appears to be a natural for Eastern European markets, particularly in CIS states and the Ukraine. The company completed an "accuracy" test for the GenPrecis! product to allow for its registration which is in process. We also plan to sell our GenViro! Swift kits to this distributor.

Additional Background and Foundation

On April 30, 2014 we first implemented our FDA mandated Quality Plan and are now operating as the manufacturer (operator) of the GenUltimate! test strip. We have implemented subsequent Quality Plans with our Korean contract manufacturer for our GenUltimate! product. Similar Quality Plans and FDA registrations will be in place for the company's GenChoice! and GenUltimate! TBG products in the near term, and for our GenAccord and GenCambre products later in the coming months. Our overall Quality Plan, a living document, is in its fifth re-write.

The company brought suit against Shasta and the former contract manufacturer in Pennsylvania in November 2018. On December 31, 2018 the Pennsylvania court awarded the company with a $3.6 million judgment against Shasta. We were pursuing collection of this judgment in Minnesota, California, Oregon and Pennsylvania. To that end we filed for a Writ of Attachment against Shasta for the $3,600,000. This Writ will allow the company to bring an end to the litigation against Shasta in California and Minnesota (in an action stat that includes our FDA lawyer). On June 29, 2019 Settlement documents were executed by Shasta and the company to bring an end to the litigation in the four states. Shasta agreed to drop all claims against the company, and we agreed not to further pursue Shasta (but not Conductive Technologies, Inc. and not the former DECN shareholders). After five years, the company can now value its acquisition of the GenStrip technology and Marks, and any knowhow. We have done so as of the period ended September 30, 2019 (see financials) and have realized a gain in the period.

We continue to litigate in Pennsylvania against the former contract manufacturer and anticipate a handsome settlement in the coming months, who apparently while working for us, was also working against us and for Johnson & Johnson. The company is also pursuing those persons who owned stock in the company who may have traded stock in the market based on information and documents provided by Shasta, or who were given confidential documents by Shasta, gained through the litigation discovery and provided to these shareholders, who then posted the information on public message boards.

We currently employ eight professionals at or locally managed through our executive business office located at 2660 Townsgate Road, Suite 300, Westlake Village, California 91361. In addition, we maintain two full-time and seven part-time positions located throughout the United States. We also maintain a Quality Assurance office through our exclusive agent in Seoul, Korea as a means to fulfill our quality commitments to the FDA. Our telephone number is (805) 446-1973 and our website addresses are and www.pharmatechsolutionsinc.com and www.genultimate.com. and www.decisiondiagnostics.com. Additional web sites will be added for our GenChoice! product, our GenUltimate! TBG product and our GenViro! Covid-19 testing products.

As a part of the company's strategic plans, we have applied (to register) for fourteen Trademarks with the USPTO. The company's Genstrip product is a registered Trademark of Shasta Technologies LLC. Now that we own this Mark, we do not intend to renew it. Our applications were filed with the USPTO in 1Q and 2Q 2015 and throughout 2016, 2017, 2018, 2019 and 2020. The company intends to use these Marks, as granted, to brand new products, rebranding of existing products, and the establishment of a family of Marks associated with our company and its place in our industry.

As of September 30, 2020, the company has received registration confirmation from the USPTO for the following Marks:

"Alltara!"
"GenUltimate!"
"GenSure!"
"GenChoice!"
"GenAccord!"
"GenCambre!"
"GenUltimate! TBG"
"Firefly!"
"ConsumerValue!"
"Infatig"
"Medicius!"

Our marks for Alltara!, ConsumerValue!, Infatig!, and Medicius! will be used for product families as an integral part of our relationships with the "big-box" entities. We have several Marks that were filed to further enhance our GenUltimate! TBG product and technology. These Marks were first filed in 2Q 2019. Subsequently we have filed for trademarks for GenUltimate! TBG, GenViro! and Genviro! Swift.

The company is also in discussions with prospective partners for our GenUltimate! TBG and GenViro! Products. While we are much further along with our GenUltimate! TBG product, a competitive mainline, legacy products company. The interest expressed in out GenViro! product has been unprecedented, at least for us, both from large USA based manufacturers and distributors, as well as those overseas. We recently brought on a distributor who will sell all of our products (but particularly GenViro! Swift kits) in central and southern Asia and India. We have also decided to take on our Russian Federation partner to distribute our GenViro! test kits in the Russian Federation and elsewhere in Eastern Europe despite a similar "knock off" product having some publicity in Eastern Europe. We believe this group is at least two years away from any commercial viability, if ever.

The company's stock currently trades on the OTCMarkets OTC Expert Market tier. The company's shares are DTC and DWAC eligible. On April 22, 2020 the company's shares were suspended from trading by the U.S. SEC. This suspension ended on May 8, 2020. On May 8, 2020 with the lifting of the SEC imposed suspension, our shares began trading again on the OTC Expert market. Certain brokers/marketmakers are in the process of filing a Form 15c2-11 to revive the company's trading on the OTC Pink market where we traded prior to April 22, 2020. The company, as an issuer, has almost no contact with these brokers/marketmakers and relies on information provided to us by our larger investors.

In mid-2018 the company chose to file a Regulation A offering in an effort to improve its disclosure to the SEC. The company had planned to use this filing, reviewed by the SEC without comment on August 23, 2018, to move toward uplist on the OTCMarkets exchange in 2019. In February 2019 the company, after completing all of the ancillary tasks required of a Reg. A filer, amended its registration with the SEC, a necessary requirement. Subsequently, the company's stock price improved so that the registration offering price was much lower than the stock trading price. In early March, during the stock price rise, the company was informed that a certain party, who at that point claimed to own approximately 4% of the company's outstanding shares, wished to buy the entire Reg. A offering on the date said offering became qualified. That would allow this certain party to gain control of the company for approximately $5.3 million, a value much lower than the trading price of the company's common stock. This was/is a common predatory M&A strategy often used by private equity funds. On March 18, 2019, acting on a resolution by the company's Board of Directors, the Reg. A registration was withdrawn.

In February 2019 the company was approved for Deposit/Withdrawal at Custodian (DWAC) a method of electronically transferring new shares or paper share certificates to and from the Depository Trust Company (DTC) using a Fast Automated Securities Transfer (FAST) service transfer agent as the distribution point. DWAC transfer is a method employed by most funds and large investors.

Business activities throughout the next twelve months:

The company's business on a day-to-day basis includes the distribution of our GenUltimate! products, (50 count and 100 count versions), International distribution of our GenUltimate! Sure and GenUltimate! Precis products (25 count and 50 count versions), and our PetSure! products (30 count and 60 count versions), and throughout 2020 our GenChoice! (25 count, 50 count and 100 count versions), at least in international markets, and the GenUltimate! TBG (25 count, 50 count, 100 count versions and a meter), also in 2020. The company's GenUltimate! TBG product will be sold worldwide and will, require a strategic partner, unless a settlement of our litigation with Johnson & Johnson allows us to sell GenUltimate! TGB independently. The company has chosen one prospective partner looking to pay for the license rights to the GenUltimate! TBG product, a long term royalty for their continuing sales, and the settlement of other matters. The company has just completed a redesign of its GenUltimate! TBG test strip, building a technology foundation around its GenUltimate! technology.

In 1Q and 2Q 2020 we began the development of our GenViro! test kits, two different proprietary and unique technologies. During the month of March 2020 virtually all available company resources have been directed to GenViro!. We plan to begin sales overseas in select markets in late 3Q 2020 or early 4Q 2020. We still have hope to sell our GenViro! Swift saliva kits in the U.S. in the next 120 days.

Companies in the manufacturing and marketing channels in the industry all employ packaging processes, including Korean, Chinese and Taiwanese manufacturers. In truth, the manufacturer operations collectively decided **not** to pay an extra $10,000 for each of the packaging machines, or the $0.10 for a slightly larger test strip vial (holder). The company believes this "me-tooism" to be a form of mental blinders. In implementing the company's new private label strategy, Decision Diagnostics decided not to bow to the packaging machine or "me-too" limitations. Instead the new packaging to be employed by the company will take into account diabetic testing patterns and the average number of testing days in a month. Private label versions of the company's products will be packaged in sizes of 30 count, 60 count and 120 count packages. This concept has been readily accepted by the company's private label target list in a detailed survey, and it is believed that this new packaging concept will be a marketing coup. Diabetics test every day of the month, not just 1.67 times a day. So a vial of 30 of the company's test strips (and 60 and 120) will accommodate the testing needs of the user, not the limitations of a particular type of packaging machine. Sales to the private label industry will be through private label product groups where every private label partner will own a private label group, each group containing all of the company's products in selective private label packaging.

The company currently has three major private label targets, the largest drug store chain, another top-5 drug store chain, and the second largest grocery store chain. In addition, the private label packaging is being offered to the largest drug store chains in Mexico and Canada. The Mexican chain, who also has numerous stores in Chile and Argentina has moved quickly. However, in all cases the sales process is in the closing stages. Closes of this nature, do however, take time. The company has Trademarked four product label groups for exclusive sales of products to the private label concerns: Alltara!, Advant!, Infatig!, and Medicius!.

Other 12-month business objectives include:

1. The practice of specializing in the distribution of GenUltimate! and PetSure! and GenUltimate! 4Pets products, and the completion of the GenViro!, and GenUltimate! TBG products.

2. Combining our wholesale and retail diagnostics distribution with the major successes we have had in the on-line retail markets, and adding legacy retail organizations (already some legacy retailers of note). See discussion above concerning private label opportunities and our private label lines.

3. Continue to implement the plans provided by our agent MWK LLC, and PARAGON Sales and Marketing in efforts to secure big-box pharmacy chains, chain grocers and nationwide retailers in addition to the private label groups previously discussed.

Recent Business Milestones:

In 1Q 2019, 2Q 2019, 3Q and 4Q 2019 and 1Q, 2Q, and 3Q 2020 the company has accomplished the following milestones.

1. In March 2020 we completed design of two Covid-19 test kits for commercial sale as soon as FDA Pre-EUA and EUA approval is gained (see Business Section Introduction).

2. We have prepared for introduction a premier version of our popular GenUltimate! test strip for launch. This type of product differentiation is common for mature product lines.

3. We completed the design and manufacture of PetSure! glucose test strips for the international markets, and completed development of our GenChoice!, GenUltimate! 4Pets and GenUltimate! TBG products.

4. The company initiated a marketing program to the on-line Marketplaces sponsored by pharmacy chain, department store and grocery store retailers, as well as mass merchandisers, and including the largest retailers. This program has so far been the most successful endeavor since our inception.

5. The company has retained patent counsel to file patents for our GenUltimate! TBG and Precise meters and test strips, and for our newest adaptation, our two GenViro! Covid-19 test kits. Provisional patents have been filed with the USPTO.

Financing Requirements

At September 30, 2020, we had cash and equivalents of $615,500 and negative working capital of $3,545,710. We anticipate that we will require up to $250 million in **trade debt financing** to finance our expected sales of our GenViro!, (especially GenViro! Swift kits) GenUltimate!, GenUltimate! Premier (for big box) GenUltimate! TBG, and GenChoice!. Trade debt financing is traditional debt where the borrower borrows cash, usually from a revolving line of credit used to finance pre-payment for inventory. The company anticipates drawing down the trade debt in installments of first $1 million, then $2 million, and finally $5 million. Money for this type of debt is readily available from wealthy individuals, finance companies or a bank or other financial institution and at the term of the loan pays the lender back in cash. The company has noted substantial disinformation in public forums regarding trade debt financing. The above paragraph is the company's final position regarding its trade debt posture. We will borrow money, finance manufacturing of our product purchases, and then pay the money back to the lender. **Complicated derivative and/or toxic equity financing is NOT expected to be used.** We will operate our business like a business. Most financing is hard to get for a small company, nonetheless we will aspire to endure. Without the financing our sales will be curtailed.

In March 2020 the company entered into six Notes (loans) with its main investor, Alpha Capital Anstalt, for a total of $2.10 million. As of September 30, 2020, Alpha has rendered $2,100,000 in loans, based on Alpha's funding and fulfillment of six of these Notes.

In March 2012 we renewed our agreement with Alpha Credit Resources ("ACR") for a third time in order to obtain this debt financing. After the expiration of that agreement, in November 2013 we executed a new line of credit with Alpha Credit Resources, replacing our pervious line. This credit line was for $12.5 million, but with the velocity of our product sales, could yield over $250 million in annually available credit. We never did draw down any credit financing from ACR, although we many times tried. On December 14, 2015 this credit line expired. Subsequently we learned that ACR and its parent, Platinum Credit became the subject of several Federal criminal investigations and trials. In September 2016, the major funds controlled by Platinum filed for liquidation. The company immediately froze all of its securities held by Platinum, securities paid from 2007 through 2014, but none subsequently. Platinum had not been granted any requests for any conversion or sale transactions since December 2014. As a part of this liquidation the company is now seeking return of most of the securities granted to the Platinum funds from 2007 through 2014.

We will from time to time continue to seek a combination of equity and long-term debt financing as well as other traditional cash flow and asset backed financing to meet our financing needs and to reduce our overall cost of capital. Additionally, in order to accelerate our growth rate and to finance general corporate activities, we may supplement our existing sources of funds with financing arrangements at the operating system level or through additional short-term borrowings. As a further capital resource, we may sell or lease certain rights or assets from our portfolio as appropriate opportunities become available. However, there can be no assurance that we will be able to obtain any additional financing, on acceptable terms or at all.

Results of Operations for the three months ended September 30, 2020 and 2019, compared.

The following tables summarize selected items from the statement of operations for the three months ended September 30, 2020 compared to 2019.

REVENUE, COST OF SALES, AND GROSS PROFIT:

	Three Months Ended September 30,			
	2020	2019	3 Months	%Δ
Revenue	$ 520,698	528,458	(7,760)	-1.47%
Cost of sales	424,721	404,024	20,697	5.12%
Gross profit	95,977	124,434	(28,457)	-22.87%
	18.4%	23.5%		

Revenue and Cost of Sales remained relatively level for the three months ended September 30, 2020 compared to 2019.

OPERATING EXPENSES:

	Three Months Ended September 30,			
	2020	2019	3 Months	%Δ
Expenses:				
General & administrative expenses	116,391	154,497	(38,106)	-24.66%
Consulting	145,225	40,612	104,613	257.59%
Compensation expense	73,239	111,991	(38,752)	-34.60%
Professional fees	107,943	103,257	4,686	4.54%
Total expenses	442,798	410,357	32,441	7.91%

Three months ended September 30, 2020 and 2019, compared:

General and administration expenses include bad debt, office expenses (including rent, cleaning and maintenance, utilities, and telephone), insurance, and bank charges. During the quarter ended September 30, 2020, general and administrative expenses decreased by $38,106 to $116,391 (2019 - $154,497) due primarily to the COVID-19 pandemic mandatory shutdown.

Consulting expenses for the quarter ended September 30, 2020, increased $104,613 to $145,225 (2019 - $40,612). The increase is due primarily to adding additional consultants to assist with the company's new GenViro! Swift Covid-19 testing product.

Compensation expense for the quarter ended September 30, 2020 decreased $38,752 to $73,239 (2019 - $111,991). The decrease is due primarily to the COVID-19 pandemic mandatory shutdown, which resulted in our laying off internal staff during this time of business shutdown.

Professional fees include accounting services, legal fees and regulatory reporting compliance. The fees remained relatively constant for the quarter ended September 30, 2020 as compared to 2019. We anticipate our legal fees to continue in 2020.

OTHER INCOME (EXPENSE):

	Three Months Ended September 30,			
	2020	2019	3 Months	%Δ
Other income (expense):				
Financing costs	(4,325,383)	-	(4,325,383)	100.00%
Interest expense, net	(127,546)	(29,869)	(97,677)	-327.02%
Gain on inventory liabilities	65,372	-	65,372	100.00%
Total other income (expense)	(4,387,557)	(29,869)	(4,357,688)	-127.02%
Taxes:				
State	(841)	-	(841)	100.00%
Net income/loss	$ (4,735,220)	(315,793)	(4,419,427)	1399.47%

Quarter Ended September 30, 2020 and 2019, compared:

Our other income and expense increased an overall $4,357,688 from $29,869 for quarter ended September 30, 2019, to $4,387,557 for the quarter ended September 30, 2020. Other expense includes costs related to our financing activities associated with our debt and equity offerings of $4,325,383 (2019 - $0) and interest expense of $127,546 (2019 - $29,869). We also incurred a gain on inventory liabilities of $65,372 (2019 - $0) due to a reconciliation of balances due with our primary supplier.

We recorded a net loss for the quarter ended September 30, 2020, of $4,735,220 compared to a net loss in 2019 of $315,793. The change is due primarily to the financing costs associated with our previous debt and equity offerings where the holder elected to partially convert the debt into equity.

Results of Operations for the nine months ended September 30, 2020 and 2019, compared.

The following tables summarize selected items from the statement of operations for the nine months ended September 30, 2020 compared to 2019.

REVENUE, COST OF SALES, AND GROSS PROFIT:

	Nine Months Ended September 30,			
	2020	2019	9 Months	%Δ
Revenue	$ 1,457,354	$ 1,646,369	(189,015)	-11.48%
Cost of sales	1,063,058	1,224,058	(161,000)	-13.15%
Gross profit	394,296	422,311	(28,015)	-6.63%
	27.1%	25.7%		

Revenue and Cost of Sales decreased for the nine months ended September 30, 2020 compared to 2019. The decrease is due primarily to the global effects of the COVID-19 pandemic and related mandatory business shutdown.

OPERATING EXPENSES:

	Nine Months Ended September 30,			
	2020	2019	9 Months	%Δ
Expenses:				
General & administrative expenses	905,665	768,995	136,670	17.77%
Consulting	179,274	160,959	18,315	11.38%
Compensation expense	239,270	338,947	(99,677)	-29.41%
Professional fees	431,085	505,629	(74,544)	-14.74%
Total expenses	1,755,294	1,774,530	(19,236)	-1.08%
Net operating (loss)	(1,360,998)	(1,352,220)	(8,778)	0.65%

Nine months ended September 30, 2020 and 2019, compared:

General and administration expenses include bad debt, office expenses (including rent, cleaning and maintenance, utilities, and telephone), insurance, and bank charges. During the nine months ended September 30, 2020, general and administrative expenses increased by $136,670 to $905,665 (2019 - $768,995) due primarily to a blend of recognizing $450,000 in bad debt reserves due to the COVID-19 pandemic and mandatory business shutdown in quarter ended March 31, 2020, and the resulting reduction of operational overhead also associated with COVID-19.

Consulting expenses for the nine months ended September 30, 2020, increased $18,315 to $179,274 (2019 - $160,959). The increase is due primarily to the addition of consultants related to our completion activities associated with our GenViro! Swift Covid-19 testing product.

Compensation expense for the nine months ended September 30, 2020 decreased $99,677 to $239,270 (2019 - $338,947). The decrease is due primarily to the COVID-19 pandemic mandatory shutdown, which resulted in our laying off internal staff during this time of business shutdown.

Professional fees include accounting services, legal fees and regulatory reporting compliance. The decrease in professional fees of $74,544 to $431,085 (2019 - $505,629) is due primarily due to a lull in the need for these professional services during 2Q and early 3Q 2020. We do anticipate our legal fees to continue in 2020.

OTHER INCOME (EXPENSE):

	Nine Months Ended September 30,			
	2020	2019	9 Months	%Δ
Other income (expense):				
Financing costs	(20,759,448)	(313,254)	(20,446,194)	6527.03%
Interest expense, net	(467,435)	(506,051)	38,616	7.63%
Loss on write-down of obsolete inventory	(304,276)	(162,359)	141,917	87.41%
Other income - PPP grant	10,000	-	10,000	100.00%
Gain on intellectual property settlement	-	1,340,000	(1,340,000)	-100.00%
Gain on inventory liabilities	165,372	-	165,372	100.00%
Total other income (expense)	(21,355,787)	358,335	(21,430,290)	6722.07%
Taxes:				
State	(1,927)	-	(1,927)	100.00%
Net income/loss	$ (22,718,712)	$ (993,884)	(21,440,995)	2157.29%

Nine months ended September 30, 2020 and 2019, compared:

Our other income and expense increased an overall $21,430,290 from $358,335 for nine months ended September 30, 2019, to $(21,355,787) for the nine months ended September 30, 2020. Other expense includes costs related to our financing activities associated with our debt and equity offerings of $20,759,448 (2019 - $313,254l) and interest expense of $467,435 (2019 - $506,051). We also incurred a loss on write-down of obsolete inventory of $304,276 (2019 - $162,359) and a gain on intellectual property settlement in the quarter ended September 30, 2019 of $1,340,000 (2020 - $0) and a gain on inventory liabilities of $165,372 (2019 - $0) due to a reconciliation of balances due with our primary supplier.

We recorded a net loss for the nine months ended September 30, 2020 of $22,719,712 compared to a net loss in 2019 of $993,884. The change is due primarily to the financing costs associated with our previous debt and equity offerings, some dating back to 2015.

Liquidity and Capital Resources

A critical component of our operating plan impacting our continued existence is the ability to obtain additional capital through additional equity and/or debt financing. We do not anticipate generating sufficient positive internal operating cash flow until later in 2020, as a result of several factors, including the change in our status from exclusive distributor of our GenStrip 50 (now GenUltimate!) our pet testing products and new products coming on-line, to the manufacturer of this product (now in process), complete additional financial service company acquisitions and generate substantial revenues, which may take the next few years to fully realize. We anticipate that in the next 12 months that we will be starved for cash from time to time as the need for cash to finance our FDA 510K prosecutions and product developments will outstrip our abilities to raise cash from traditional sources. The company's Board has established and reaffirmed that the company will **not** allow our need for cash to be exploited by toxic funding entities. We will, from time to time seek to raise capital from small funds. Our current cash position is critical.

As our GenUltimate! product grows along its product life cycle, and as we launch new products such as our GenChoice! and GenUltimate TBG products, we may not obtain the necessary capital to pursue our strategic plan. As of this writing we are in a short term "cash crunch." If this crunch continues it could materially impact our operations. However, the company is securing a revolving debt credit line and expects handsome settlement cash from two lawsuits.

As of September 30, 2020, we had cash and cash equivalents of $615,500, inventory of $188,506, and accounts receivable of $1,193,697. Net cash used by operating activities for the nine months ended September 30,

2020 was $1,417,495. Current liabilities of $5,543,413 consisted of: $1,649,900 of accounts payable and accrued liabilities, contingent legal fees of $240,000, short-term inventory financing of $229,490, and notes payable and OID of $3,367,356. As of September 30, 2020, we have a negative working capital of $3,545,710.

The accompanying financial statements have been prepared contemplating a continuation of the Company as a going concern. The Company has reported an accumulated deficit of $72,448,636 and a net loss of $22,718,712 for the nine months ended September 30, 2020. Additional investments are being sought, but we cannot guarantee that we will be able to obtain such investments. Financing transactions may include the issuance of equity or debt securities, obtaining credit facilities, or other financing mechanisms. However, the trading price of our common stock and conditions in the U.S. stock and debt markets could make it more difficult to obtain financing through the issuance of equity or debt securities. Even if we are able to raise the funds required, it is possible that we could incur unexpected costs and expenses, fail to collect significant amounts owed to us, or experience unexpected cash requirements that would force us to seek alternative financing. In the summer of 2019, we withdrew our registration statement filed under Reg. A with the U.S. Securities and Exchange Commission. We did so because we had been informed that a single entity, or related entities, was preparing to buy all of the underlying securities registered in the Reg. A, and thereby take control of the company. Withdrawal of this registration created a "cash crunch" down line. Our current cash position is critical. Thus, if we issue additional equity or debt securities, stockholders may experience additional dilution or the new equity securities may have rights, preferences or privileges senior to those of existing holders of our common stock. If additional financing is not available or is not available on acceptable terms, we may have to curtail our operations.

Cash to Operating Activities

During the nine month ended September 30, 2020, operating activities used cash of $1,417,495 compared to using cash of $1,027,906 in 2019. Our net operating loss for the nine months ended September 30, 2020 was $22,718,712 and included shares issued for financing fees of $20,759,448 (2019 - $313,254), shares and options issued for services of $nil (2019 - $25,000), bad debt write-off of $450,000 (2019 – $175,000), gain on inventory liabilities of $165,372 (2019 - $nil), loss on write-down of obsolete inventory of $304,276 (2019 – $162,362), and gain on intellectual property of $nil (2019 - $1,340,000). Our change in accounts receivables increased $447,575 to a use of $598,530 (2019 – $150,955 use). Our change in inventory increased $231,426 to a use of $326,147 (2019 - $94,721 use). Accounts payable and accrued liabilities increased $295,259 from a source of $561,380 (2019 - $266,121). Accrued interest decreased by $192,138 to $313,913 source (2019- $506,051 source) due primarily to Original Issue Discounts totaling $376,089 recorded in the quarter ended March 31, 2019 (2020 - $nil) that were mutually identified by us and our noteholders during the course of a normal review of our debt with them. Our contingent liabilities remained constant in 2020 as compared to 2019 due to the recognition of liability due to our involvement in legal matters.

Cash from Investing Activities

During the nine months ended September 30, 2020, investing activities used $75,565 in cash (2019 - $100,875 use) related wholly to our intellectual property.

Cash from Financing Activities

During the nine months ended September 30, 2020, financing activities produced net cash of $1,994,226 (2019 – $820,015). This change is primarily a result of successful debt offerings in 2020.

Internal and External Sources of Liquidity

Alpha Credit Resources LLC (formerly Centurion Credit)

On November 17, 2007, we entered into an agreement with Alpha Credit Resources LLC to secure a $1,000,000 revolving credit facility that is geared specifically to our business. As of October 2008, the company renewed its agreement with Alpha Credit Resources LLC until November 17, 2009 and as an inducement to renew the credit line was increased to $2,000,000, with additional seasonal increases to $2,500,000. In September 2010 we began discussions with Alpha Credit for an additional $6.0 million credit facility to provide available credit to finance

sales of our new at-home testing diagnostic product. The company last borrowed funds using the credit line in the Year ended December 31, 2011. The agreement matured on December 31, 2011 without renewal. In December 2013 we again renewed our credit line with Alpha Credit, expanding our credit line to $12.5 million (Fourth Omnibus Renewal). As a part of the most recent renewal agreement all previous accrued debt and interest owed Alpha Credit was reduced to $0.00. Alpha Credit Resources breached this renewal agreement. The agreement was allowed to come to term. In April 2016 the company brought its disputes with Alpha Credit to the attention of new management and while working on a resolution, the parent of Alpha Credit and its sister operations became embroiled in two Federal investigations. Subsequently the funds that capitalized Alpha went into liquidation. The company was standing still until these investigations are brought to a conclusion, but in 1Q 2018 we decided to cancel 1,000 Class B Preferred shares that Alpha did not earn, and over 300,000 shares of Preferred E stock that was not earned, and may have been a part of a scheme to defraud the company as principals of Alpha's parent are now on trial, in sentencing proceedings, or both.

Cash Flow.

Since inception, we have primarily financed our cash flow requirements through the issuance of common stock, the issuance of notes and sales generated income. With anticipated growth in 2020 we may, during our normal course of business, experience net negative cash flows from operations, pending receipt of revenue, which often are delayed because of the nature of the healthcare industry. Further, we may be required to obtain financing to fund operations through additional common stock offerings and bank or other debt borrowings, to the extent available, or to obtain additional financing to the extent necessary to augment our available working capital.

Satisfaction of our cash obligations for the next 12 months.

As of September 30, 2020, our cash balance was $615,500. Our plan for satisfying our cash requirements for the next twelve months is through additional equity, third party financing, and/or debt financing. We anticipate sales-generated income during that same year of time, but do not anticipate generating sufficient amounts of positive cash flow to meet our working capital requirements. Consequently, we intend to make appropriate plans to insure sources of additional capital in the future to fund growth and expansion through additional equity or debt financing or credit facilities. We are currently experiencing a substantial "cash crunch." We are in the middle of three new product launches, two 510K applications (one in process and one almost complete) and their prosecution, an expansion to our manufacturing facilities, growth in a segment of overseas business, the funding of the commercialization of two products and the antecedent activities, and the prosecution and/or settlement of three legal actions. The company is in need of additional capital, estimated to be approximately $1 million, to bridge to upcoming capital events, a settlement of a lawsuit with Johnson and Johnson, and the beginning of the partnership agreement discussed below.

As we expanded operational activities, we may continue, from time to time, to experience net negative cash flows from operations, pending receipt of sales or development fees, and will be required to obtain additional financing to fund operations through common stock offerings and debt borrowings to the extent necessary to provide working capital. It was not until the company entered into the agreement with Alpha Credit Resources, LLC that the company could fill orders for patients and customers on a continuous basis. Until the Alpha Credit line was put in place, we managed to keep a small portion of our distribution activities going when our limited resources allowed us which remains true as of this filing.

Predictions of future operating results are difficult to ascertain due to our historic operating activities. The recent addition of a credit line has helped but we have found it increasingly difficult to transact commerce in the very cash intensive prescription drug industry. Thus, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of commercial viability, particularly companies in new and rapidly evolving technology markets. Such risks include, but are not limited to, an evolving and unpredictable business model and the management of growth. To address these risks we must, among other things, implement and successfully execute our business and marketing strategy, continue to develop and upgrade technology and products, respond to competitive developments, and continue to attract, retain and motivate qualified personnel. There can be no assurance that we will be successful in addressing such risks, and the failure to do so can have a material adverse effect on our business prospects, financial condition and results of operations.

In March 2019 the company received its first communication from a 3rd party company about its new GenUltimate! TBG product and technology. Subsequently the company received additional communiques. Propositions covered much of what could be expected in a complicated M&A transaction.

The company's Board entered a process of interview and elimination. This process concluded on June 30, 2019. The company asked this entity to clarify the earn-out.

Expected purchase or sale of plant and significant equipment.

We anticipate the purchase of significant equipment for our Covid-19 products to be placed and used by our Korean contract manufacturer. The cost of this equipment is anticipated to be $1 million. We have previously disclosed other of these investments in previous reports.

Going Concern

The financial statements included in this report have been prepared in conformity with generally accepted accounting principles that contemplate the continuance of the Company as a going concern. The Company's cash position is currently inadequate to pay all of the costs associated with testing, production and marketing of products. Management intends to use borrowings and security sales to mitigate the effects of its cash position, however no assurance can be given that debt or equity financing, if and when required will be available. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and classification of liabilities that might be necessary should the Company be unable to continue existence.

Contingencies and Litigation

We transact commerce in several medical products market channels. We also transact commerce by licensing our proprietary medical software that functions by moving confidential medical data through our proprietary medical information technology devices and networks. Our original Genstrip product required initial regulatory approval by the USFDA as well as on-going USFDA approvals during the product life cycle. Further, Genstrip required medical patient trials and competes directly with a major platform manufacturer. We insure against any claims made against the company for our Genstrip product.

Our GenSure product is sold only in international markets. We are protected against claims of patent and/or trademark infringement by virtue of our 2016 settlement agreement with Johnson & Johnson and two J&J divisions.

Our GenChoice! and GenUltimate! TBG products will be sold worldwide. The company will have to protect against claims of infringement for both of these products. Patent and trademark infringement suits are often filed for strategic business reasons, having only a passing relationship to the patents or trademarks claimed to be at issue.

Healthcare, especially those segments where the company competes, is also very litigious. Competing companies often use litigation as a marketing tool, bringing litigation as a means to protect market share and limit market exposure. The medical industry is also intertwined. From time to time, we may become involved in claims and litigation that arise out of the normal course of business, such as litigation that emerges from disputes over damaged, missing or contaminated product, litigation that arises over payment disputes or claims of fair value. We may also become involved in disputes that arise over the business or business practices of our suppliers, payers and customers. It is not uncommon in our industry to find that a litigant has filed claims in multiple jurisdictions involving the same transaction or a single transaction. The company maintains substantial insurance coverage against suits that may arise over issues of damaged, recalled or counterfeit product and other product liability issues. The company has also been a victim of the unapproved acts of prior management. These acts have resulted in claims from individuals and entities since the Board relieved former management of duty in 2006. Nonetheless, these claims have resulted in the use of management time and company resources to investigate, litigate, or settle. In addition, the company accrues contingent legal fees and product liability fees. As of September 30, 2020, our accrual was $485,069.

From time to time, the company may also be subject to demands from individuals or entities. These demands and disputes may consume management time and company resources. Other than as noted below, if there is such a

disclosure, there are no pending matters at the current time that in management's judgment may be considered potentially material to us.

In December 2018 the company and Mr. Berman were sued by a former employee who made employment practices claims. This employee had been terminated some 16 months earlier, for insubordination. The company filed a counter-suit against the former employee for misappropriating and hiding company property, secrets, and for violating HIPAA statutes as a result of these actions. The company and Mr. Berman are both insured against these types of lawsuits. In 1Q 2020, with the assistance and resources of its insurer, this lawsuit was settled.

We were in litigation with Lifescan Inc. a subsidiary of Johnson & Johnson beginning in September 2011. Lifescan had maintained throughout that our Genstrip (now known as GenUltimate!) product infringed on three of their patents. One of these patents became the subject of peripheral litigation activities, and two Appeals (one for each side) to the U.S. Appeals Court for the Federal Circuit (the patents appeals court). In January 2016 the Court of Appeals for the Federal Circuit ruled in its Mandate that this one foundational patent and the claims made by the assignee Lifescan, Inc. was struck (killed) due to obviousness (a clever wording meant to obscure a connection between the Lifescan, Inc. invention and earlier generation technologies dating back to the late 1970s). Throughout this Appeal process, and a litigation process waged through the USPTO, the company prevailed. In addition, as a result of certain claims and allegations made by Lifescan after the close of the USPTO final determination (in favor of the company), the office of the Solicitor General intervened against Lifescan Inc. in the Federal Circuit court and was of great assistance in getting the Lifescan, Inc. patent revoked. Nonetheless the seeming baseless allegations and claims made by Lifescan against the company have taken their toll, limited our ability to sell our GenStrip (now known as GenUltimate) to large entities ("big box stores") and greatly extended the court processes.

In May 2016 the company became aware of a clause Lifescan had inserted in its Franchise agreements. This clause set a penalty structure whereby should any Franchisee who also bought non-Lifescan products (but more clearly our GenUltimate) they would lose their access to product rebates, and in certain instances their Franchise. Once aware of these illegal tie-ins the company complained to the Federal government, and in January 2017, for the first time since the onset of litigation with J&J, the tie-in clause was globally lifted by J&J. During the pendency of the 2011 and 2012 lawsuits, Lifescan was guilty of a number of unethical practices.

In March 2016 the company filed suit against Johnson & Johnson and two Lifescan divisions through our two IP subsidiaries. DECN filed the lawsuit in the United States District Court, District of Nevada, in Las Vegas, NV, Case 2:16-cv-00564, titled Pharma Tech Solutions, Inc. et al v. Lifescan, Inc. et al naming Johnson & Johnson and its divisions Lifescan, Inc. and Lifescan Scotland Ltd. for alleged infringement in relation to U.S. Patent numbers 6,153,069, an apparatus patent, and 6,413,411, a method patent. The suit sought at least $400 million in provable damages. The company lost this lawsuit on a contested technicality, and also lost its appeal.

In November 2018 the company filed a lawsuit in Pennsylvania court against Conductive Technologies, Inc. (CTI) and Shasta Technologies LLC, alleging, among other things, that these two former partners colluded along with Lifescan, Inc. to illegally embargo the company's GenUltimate! product and technology, and to attempt to seize this product and associated Intellectual Property. The suit emerged as a result of a settlement the former partners entered into with Lifescan, Inc. and Johnson & Johnson to settle their issues (at our expense) in the above discussed patent infringement lawsuits of 2011 and 2012. On December 31, 2018 the Pennsylvania court granted the company a judgment in the amount of $3,600,000 against Shasta Technologies LLC. The company had been in the process of enforcing the judgment in the states of Minnesota, Oregon (Shasta's domicile), and California. In late April 2019 the company filed and received a Writ of Attachment from the State of California Superior Court and proceeded to execute on this Writ.

Activities to enforce the judgment against Shasta in Minnesota and California ended the litigation and collection activities against Shasta as of the period ended June 30, 2019. The company, upon conclusion of the litigation then valued its acquisition of technology and Marks in the financials for the period ended June 30, 2019. The company shows a one-time gain in the 2Q 2019 period. Litigation against CTI continues. Recently the company was made aware of a conflict that involved a sister company of CTI, whereby this sister company had extensive undisclosed contract dealings with J&J. At the time of the Settlement by Shasta and CTI with J&J, CTI had recently appointed a new Chairman, the then CEO of the sister corporation. The company believes that this new Chairman, in an effort to

preserve another agreement with J&J immediately ordered settlement with J&J and as a result of this settlement with J&J became the architect of the embargo against the company and its products, forcing the company to redevelop GenUltimate in Korea, at a cost of $660,000. CTI also used the company's client list obtained as a part of the J&J litigation and hired a company distributor to distribute the company's products to other of the company's distributors. The company is seeking settlement with CTI but will be forced going forward to expand its suit against CTI to add the sister corporation and its Chairman to the expanded lawsuit.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results or operations, liquidity, capital expenditures or capital resources that is material to investors.

Error Repair

The company will endeavor to repair any and all errors that new sets of eyes find in this document after posting, whether these errors are in spelling, grammatical, punctuation related or numeric. We are not perfect and we remind others that the people who point our errors out to us, along with their public comments, are not perfect either.