



DECISION DIAGNOSTICS CORP.

ANNUAL REPORT FOR OTC PINK
MANAGEMENT'S DISCUSSION & ANALYSIS
Report for the Year Ended
December 31, 2019

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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 GenUltimate! Precis test strips, products for off-shore sales. The company has begun Definitive Agreement writing with a large Eastern European distributor for their distribution in the Russian Federation and aligned countries. Both of these products will primarily be sold as an international private label market entry. Export Certificates for GenUltimate! Sure and GenUltimate! Precis have been allowed, and manufacturing and sales were scheduled to begin in February 2020, until the advent of the Coronavirus shut down of our Korean contract manufacturer. There is no domestic or North American markets for these products.

In addition, the company's GenChoice! glucose test strip has completed its clinical trials and filed a 510K application with the U.S. FDA for its clearance. The company has had eleven formal communications with the FDA, inclusive of a face-to-face meeting with FDA management and the review staff. We expect clearance of this product, although we have moved the completion and shipment of our Covid-19 products, due to emergency, ahead of our GenChoice. The explanation below is a done in a manner that all readers will understand.

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. Subsequently we learned for the first time the use of words "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. It was explained 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.

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 develop a coronavirus test.

We had decided that if such a test methodology were possible it was worthwhile from a humanitarian standpoint to use our limited resources at least to try to develop such a test. A few days later we received three cites from The Bio regarding technical papers written in the last five years where the researchers and scientists discussed in those white papers the ability to use a method called impedance to identify and classify certain (now familiar) classes of virus. All three papers described their methodologies in detail and included sample data sets.

In all three cases the 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 impedance (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 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.

As quickly as it could the company engaged Matthew Musho, PhD (holder or collaborator in 32 patents published in parallel fields) and his wife Leslie to assist in the design of a testing method and device for the measurement of Covid-19.

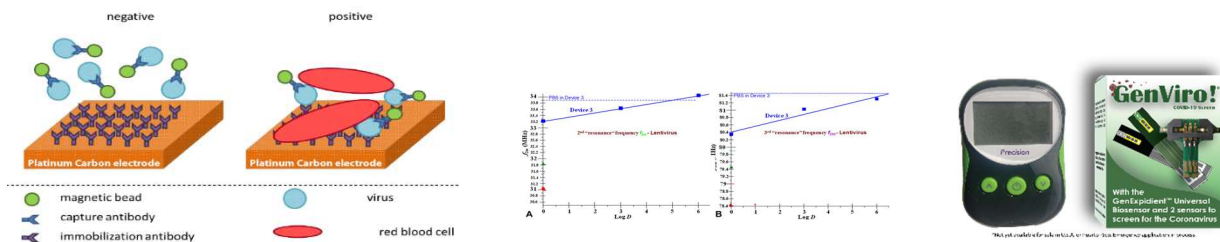
<https://patents.justia.com/inventor/matthew-k-musho>

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 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.

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 the company's existing Precise or Avantage glucometers, because they were completed products, having been tested to great length, and now to be adapted for detection of Covid-19 instead of whole blood glucose. In addition, the resulting chemistry would necessarily run using a patient's (small sample of) whole blood taken from a finger prick, and later defined as 1-2 microliters (a small drop on a finger tip), and perform the test and provide a result in one minute or less (later redefined as 15 seconds or less), with at least a 95% accuracy. Mr. Berman believed this device was capable of 97-98% accuracy. Three alternative designs were provided and given to the company on March 2. Two of the designs were diagrammed by Mathew Musho, PhD, the third design by a chemist and engineer from The Bio in Korea. The chosen of the three alternative product designs would bear 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 sample, 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 entire process took 13 days. The last of these days used to determine which of the two Musho specifications was to be chosen. The design provided by The Bio was discarded because it could not be read on the existing company meter technology, and therefore would require additional development. At the end of this process, the company chose to produce the product shown in the illustrations, the second of the two Musho alternative versions, but shortly thereafter to begin work on the other Musho specification, to be used as a confirmation tool.

Product Design 1 (chosen)

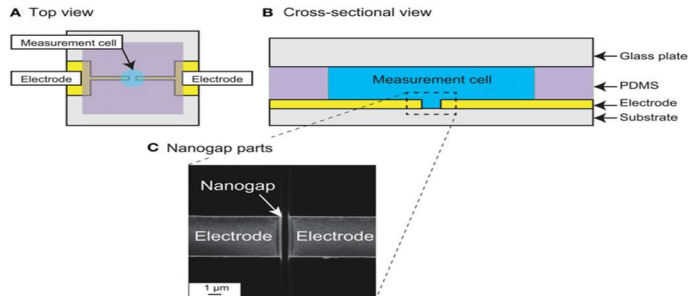


The design above is in many regards similar to the direct antibody antigen approaches favored by some of the competitive companies in the Covid-19 testing field. But the major difference (magic) is that the approach used by the company in its GenViro! product allows for swift (15 seconds or less) results using a minimum of blood from a finger prick. As of this writing, work has commenced on the product specification above 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. The company is operating on an 8-week development schedule and is some 10 days into this schedule. The current development cycle is considered advanced development. For FDA EUA filing and the granting of a Pre-EUA by the FDA, the company is preparing its final working concept filing, to be completed within days of this writing.

On April 1, 2020 the company plans to begin development work on its second product design, a confirmation test for Covid-19. This test, a hybrid but direct antibody/antigen (IGG) method, again making use of the company's

expertise in biosensors, will be designed to be used on those the tested Positive Covid-19, and those that tested Negative but are suspected to be false Negatives. This product design is not yet in the advanced development cycle.

Product Design 2 (confirmation)



As stated, the company anticipates filing its latest and complete EUA documents with the FDA during the week beginning March 30, 2020, for the registration of its Covid-19 test for Point of Care and At-Home usage. The company is unsure if the At-Home use application can be cleared for Pre-UEA at this point, owing to the historical use of EUA being limited to Point of Care uses. However, the company is in the process of completing packaging and package inserts for three versions of its GenViro! Product, GenViro! Point of Care, GenViro! At-Home use, and GenViro! International in English, Spanish, French, German and Russian languages. The most immediate request made to the FDA will be for Pre-UEA, the new accepted standard for emergency diagnostic products.

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 and are ready to begin patient testing (clinical trials) in Korea. A clinical site at a prestigious Korean research hospital has been identified and appropriate documentation filed with the Korean FDA. This application was delayed for 30 days beginning in August 2019 when DECN CEO Berman requested the development engineers for the TGB product to change the active enzyme in the chemistry to a variant of Glucose Dehydrogenase (GDH), which provided the TGB product an added precision in use. Earlier 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, same chemistry, same family of meters, thereby allowing the company to offer three essentially identical products, each serving its own somewhat unique purposes, all running on the same test strip foundation, an FDA cleared device. 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 recovers from the Korean experience with the Covid-19 virus that began in Korea in late January 2020 and reached critical proportions in February 2020. The main needs now to begin manufacturing of this new version (Version 3) test strip is certain tooling needed to be added at the company's manufacturing facility. Gen 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.

GenUltimate!®
& **GenUltimate!®**
TBG

GenUltimate!® TBG is Designed to be the Most Accurate Home Monitoring System on the Market Today

GenUltimate!® with many of the wonderful TBG performance characteristics, has a brand new look! The quality you know and love wrapped up in a new package!

For Use With: GenUltimate!® TBG Test Strips

For Use With: OneTouch® Ultra®, Ultra2® & UltraMini® Meters

For Use With: OneTouch® Ultra®, Ultra2® & UltraMini® Meters

50 Test Strips

100 Test Strips

High Precision Glucose Monitoring System

Not yet for Sale in the USA or Puerto Rico

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. 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, as 2019 transitions into 2020, 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.

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 will endeavor to expand the credit line for the management of our GenChoice! and GenUltimate! TBG products in 2019. 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. Current ISO (2015) and FDA (2014) 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. PetSure! was the first marketable product to make use of the GenChoice! technology foundation, and is currently selling 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. .



As of this writing, GenUltimate! Precis and GenChoice! products are not yet 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 in our 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).

We began our transition into these medical products channels on November 1, 2011 when we completed the acquisition of Diagnostic Newco LLC from its owner Kimberly Binder. Diagnostic Newco LLC was a design company that specialized in product packaging design, medical products advertising design and graphic art. Ms. Binder subsequently joined the staff of the company's Pharma Tech Solutions, Inc. subsidiary specifically for these purposes, and has worked closely with the contract manufacturers for GenUltimate!, making subtle changes to packaging design and more recently integrating the new FDA UDI product identification data system, among other responsibilities. She is also responsible for the package design for new diagnostic products the company is currently working on, including the GenSure! and the upcoming GenChoice! and GenUltimate! TBG products. Ms. Binder is

also owner of Genstrip Direct LLC and Full Circle Diabetes LLC, her own distribution companies, which she operates separately from her (Decision Diagnostics Corp. and Pharma Tech Solutions, Inc.) company related responsibilities.

The original Shasta product was acquired by our Pharma Tech subsidiary on March 20, 2014, and fits into a diagnostic product niche, fitting nicely into the world-wide self-test (home test) market that has been growing at a 15% annual rate. Since GenUltimate! is a rather unique product offering, employing a brand name razor blade only model (diagnostic test strip) into a razor (diagnostic meter) -- razor blade (diagnostic test strip) market, the Genstrip 510(k) application made for unusual challenges for the FDA and an educational challenge and opportunity for the company. In fact, the company only concluded its dealings with the FDA in March 2016, but has had subsequent issues pre and post market review staff, an on-going process that was begun on a very sour note by Shasta in October 2009 and ended even more sourly in early 2014. The company believes that upcoming product offerings such as the GenChoice! and GenUltimate! TBG products, which will also be regulated by the FDA but we hope will go through the rigorous comment process, particularly since receipt of a directed landmark ruling by the U.S. FDA, covering our third party developed diagnostics (developed, in development and to be developed). The FDA, however, is accountable to no third party and while we did win major victories and we did deal with certain biases and retaliation during the GenStrip 510K prosecution, we have seen this same type of treatment for our GenChoice! product. However, we remain ever vigilant and continue to retain litigation counsel.

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.

On the business side, in June 2010 the company was approached by the largest retailer in the world for the distribution and sale of the Genstrip product, then about to enter the 510k regulatory review process, at over 5,000 retail stores worldwide. A contract with this retailer was negotiated in September 2010 and subsequently renegotiated and renewed in April 2011 and then for a third time Beginning in November 2016, and as soon as the retail contract was agreed to and as a means to conduct market research, the company began seeking pre-conditioned letters of intent (pre-orders) for Genstrip, while continuing the prosecution of the 510(k) application on behalf of Shasta Technologies before the FDA.

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.

“The doctrine of equivalents is a legal rule in many (but not all) of the world's patent systems that allows a court to hold a party liable for patent infringement even though the infringing device or process does not fall within the literal scope of a patent claim, but nevertheless is equivalent to the claimed invention(s).”

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 appeal, thus ending this litigation.

The Current Business

In the next 120 days the company expects to enter the Covid-19 test kit market with unique, cost effective, accurate and wholly proprietary products. 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.

The current foundation business is focused on the diabetes testing market, a market 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 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. 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. Although this has been part of the company's plans in the recent past, the difficult litigation with Johnson & Johnson as well as the advent of the July 2013 and July 2016 changes to Medicare reimbursement (and followed by private insurers) and the October 2016 reimbursement engineering, pharmacy business models are now blurred. Thus the company successfully added on-line sales to its business model.

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, Jet.com 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.

In June 2017 we were notified by Amazon.com, the largest retail portal for our products where we now currently sell approximately 35,000 boxes of GenUltimate per month, that the listings for our products had been “hacked” by ghost sellers -- individuals and people who listed our products, accepted orders and cash money from diabetics, but were unknown to the company. Oftentimes product was never delivered to the diabetic even after receipt of payment. This practice called freeloading (by Amazon) is not rare, but once started it is difficult to eradicate. The company had to replace almost 6,500 units of GenUltimate as a result of the freeloading. In March 2018 another 3,000 boxes were replaced, leading to lower sales margins in the periods where the replacements took place. The company is in on-going friendly negotiations with its distributors to provide compensation for the effect of the freeloaders. While freeloaders had a cost basis of zero, legitimate sellers and distributors were forced to compete with

these zero cost sellers. Prices for GenUltimate plummeted and by October 2017 the product in its largest portal showed a price decline on average of 35%.

With the assistance of Amazon, who themselves became a distributor of GenUltimate!, the company was able to overcome some of these issues. With the assistance of Amazon we reordered our selling practice, implementing base (floor) pricing and implementing real-time policing of listings. As a result, we were able to overcome this freeloading practice. Prices have recovered about one half of the Fall 2017 decline. We are currently in the process of raising prices again. Also, as a result of the “Amazon debacle,” the company also eliminated many small distributors of GenUltimate! from the Amazon portal. In 1Q 2019 we further eliminated a group of our wholesalers who may still sell our products, but not on Amazon. While these actions had the effect of lowering sales throughout 2018 and into 2019, our margins and our sales levels are recovering, as our sales increase. The effect of barring wholesalers from selling on Amazon cost the company \$90,000 to \$120,000 in sales for 1Q 2019, mostly through lower inventory levels by our wholesalers. Subsequently, the advent of Covid-19 closed down our Korean contract manufacturer from mid-February through March 27. Our Korean contract manufacturer was the only finished goods producer of our GenUltimate! and PetSure! products. This bottleneck was alleviated as of March 27, but sales were greatly impaired during 1Q 2020.

In March 2017 the company was contacted by the retail giant Walmart, who along with their acquired on-line retailer Jet.com, are attempting to duplicate and surpass the Amazon portal. Our GenUltimate! products have been sold on Walmart’s (and Jet.com’s) portals since November 2016. In the 2018 discussions Walmart offered us preferential listings on portals and Walmart Depot stocking at their regional transit facilities. We also began discussions, now in process, for the manufacturer of a Walmart house brand version of our GenUltimate! As a result of our agreements with Walmart, GenUltimate! is now sold and fulfilled directly by Walmart. In addition, Walmart has implemented a large on-line store pickup, allowing GenUltimate! users to pick their GenUltimate! product up at Walmart stores. We accepted Walmart’s offer (who wouldn’t) and changed our distribution agreement with Walmart (and Jet) so that Walmart would sell and fulfill our products directly. We accomplished this while still selling our products directly through Walmart. This business model is called cannibalization with the goal of overall sales maximization. Walmart customers who previously received standing orders for their legacy J&J Lifescan test strips are a part of this new program. The company believes this to be a market enhancing deal since Walmart will become both a “push” and a “pull” retailer. No special pricing of our GenUltimate! products was required to implement this plan, owing, no doubt, to the footprint we have established on the other large on-line portals. Walmart purchase orders for Walmart sales of our products have increased dramatically. We continue to evaluate our prospects with Walmart and we believe we will move toward a global agreement with Walmart for our GenUltimate!, PetSure! and GenChoice! (when cleared) and GenUltimate! TBG products. Meetings were scheduled in the month of May 2019 at both Walmart and CVS pharmacies, primarily for our GenUltimate TBG products. Subsequently we are gearing up our Covid-19 kit business quickly, albeit because of the times, using remote capabilities to reach out to Walmart, CVS, many, many others in the USA, Canada, and internationally.

In March 2016 we also retained a product source company called Retail Monster, to represent our products to large drug chains (“big box pharmacy”), large retailers, chain grocers and the like. Unfortunately the arrangement with Retail Monster did not succeed, primarily because a group of company shareholders and persons claiming to be shareholders poisoned our relationship with Retail Monster early in our contract term, by advocating during repeated calls, a “palace coup.” After these incursions by shareholders and persons claiming to be shareholders, our relationship with Retail Monster remained cordial but was, unfortunately, destined to fail. The two companies decided to end the engagement on December 31, 2016.

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. These Marketplaces are fast growing sister organizations to these retailers, and typically not a part of legacy manufacturers 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. In mid-March 2016 the largest US retailer agreed to raise the company’s standing to the highest retail “rung” by offering a new supplier contract and in mid-March 2018 this retailer and its recently acquired wholesale products partner contacted the company and implemented a direct relationship. This decision led to inquiries by other big box sellers.

In March 2019 we entered into a long term relationship with PARAGON Sales and Marketing Inc. to support the national growth of both our branded and private label retail products sold under our "Gen" brand, and our private label brands of Alltara!, ConsumerValue!, Infatig!, and Medicius!. We have expanded this relationship to include our Covid-19 sales and distribution efforts.

Initial accounts were assigned to PARAGON for big box and private brand big box agreements include Walmart, CVS, Walgreens, Costco, Kroger and Cardinal Health. PARAGON will also work closely with us in evaluating other potential new retail product categories and products that we may launch in both branded and private label offerings in the future. Sadly, shareholders and non-shareholders have already attempted to contact PARAGON, one such incursion occurring during the writing of our 3Q 2019 Quarterly Report. The company has promised PARAGON that we will take legal action against these people should this activity continue. Instead we were notified that PARAGON contacted their own commerce lawyer and in addition verified the person (name, address, etc.) behind the incursion.



Alltara choice, and GenUltimate TBG is 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 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 we completed additional financing transactions with both Alpha and/or, Sovereign, and Licgo. Our most recent transactions with Alpha also financed an inventory credit line for the company so that we can meet many of the requirements of the largest retailers and maintain at least \$300,000 in stock on hand at any time. 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 June 2018 the company came to terms with an international distributor who would sell the company's products in Mexico, Puerto Rico and in select South American countries. Initially the sales by the distributor would have been our GenUltimate! test strips and meters, and our GenUltimate! Sure test strips and meters. Governmental approval was needed for these products. This distributor did not distinguish themselves and the association was ended.

However, 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 must complete an "accuracy" test for the GenPrecis! product, complete the packaging in several Eastern European languages, and then schedule a manufacturing line.

Additional Background and Foundation

In May 2010, we entered into agreement with Shasta Technologies, Inc. and Broadtree, Inc. This agreement granted our Pharma Tech Solutions, Inc. subsidiary the exclusive marketing rights to a new diagnostic product not yet on the market named Shasta Genstrip (“Genstrip”). The Genstrip product was developed to compete against the market leader in the then \$6.5 billion at home testing market. Shasta was in default of this 2010 Agreement within 90 days of its initiation. Penalties under that agreement and monies owed totaled in excess of \$2 million in “delay” penalties, which they were unable to pay. In April 2011, the company renegotiated its agreement changing its many roles and adding responsibility for regulatory approval, manufacturing and forecasting, international sales and additional sales markets in the U.S. Shasta defaulted under this agreement as well. On March 20, 2014 we acquired the GenStrip intellectual property, its marks and the cleared 510(k). Shasta defaulted on this agreement as well. In addition Shasta breached or defaulted on two insurance settlement agreements, owing to the aforementioned J&J litigation. Shasta also confessed to patent infringement of J&J’s three patents and for one reason or another thought it was in their best interest to sue their previous FDA lawyer, who supposedly did not stop Shasta from commercially damaging themselves.

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 nine 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 (site now in FDA 510K prosecution), 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 and 2019. 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 March 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 and Genviro!.

As a result of a product embargo by Shasta and Conductive Technologies, Inc. the company ran into an inventory shortage, and in fact ran out of product on several occasions. However, the inventory problem began to clear up in late May 2016, and with the advent of adding the GenUltimate! product from Korea, shortages were alleviated. The company’s capacity for GenUltimate! production is now 750,000 packages per month (50 count and 100 count packages), for the new GenSure! product 100,000 packages per month (25 count and 50 count packages) and the new GenChoice! product (initial) 150,000 packages per month (50 count and 100 count packages). A mega-retailer has requested minimum inventories of finished product of 150,000 units/boxes. We expect other retailers to make similar requests. The manufacture of GenUltimate! and GenSure! are very similar and this capacity can be viewed as interchangeable. Similarly the manufacture of GenChoice! and GenUltimate! TBG will be similar to the manufacture of GenAccord! and GenCambre! Manufacture of GenPrecis will require additional investment in plant and machinery. The company is also in discussions with Korean contract manufacturers to augment our GenViro! Products, a product line we expect to require capacity to manufacture millions of these kits.

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 our GenViro! product has been unprecedented, at least for us, both from large USA based manufacturers and distributors, as well as those overseas. We have thus far decided to take on our Russian Federation partner to distribute our GenViro! test kits in the Russian Federation and elsewhere in Eastern Europe.

The company’s stock currently trades on the OTCMarkets OTC Pink Current tier of the market. The company’s shares are DTC and DWAC eligible.

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! Precise 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!.

In March 2019 the company announced the hiring of PARAGON Marketing and Sales, Inc., a nationwide retail accounts sales and management firm. The company has assigned several high worth "big box" retail accounts to PARAGON, including Walmart Stores, CVS Pharmacies, Walgreens Pharmacies, Cardinal Health (Wholesale), McKesson (private label brands), Kroger and others.

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!.

Our 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!, GenChoice!, and GenUltimate! TBG products. We also intend to add several brand-name medical diagnostic

and medical disposable products, lancets through our Firefly! product, as well as several lines of insulin syringes and pen needles, all associated with the on-going care of diabetes-inflicted patients, and the world-wide distribution of our proprietary diagnostic 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 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 on September 3, 2019. First deliveries for this test strip designed and provided for the benefit of big box stores will be in the 3rd week in September.
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. We began FDA 510K prosecution, patient clinical, 3rd Party testing and/or clinical trials of two new test strip products, our GenChoice! and GenUltimate! TBG test strips and the GenUltimate! TBG Precise meter. Neither the PetSure! nor GenUltimate! 4Pets products required live patient (pet) clinical testing. We most recently added GenChoice! TBG to our Advanced Development schedule.
5. 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.
6. The company has retained patent counsel to file three patents (in 3Q 2019) for our GenUltimate! TBG and GenPrecis meters and test strips, and for our newest adaptation, our two GenViro! Covid-19 test kits.

Financing Requirements

At December 31, 2019, we had cash of \$114,334 and negative working capital of \$3,644,036. We anticipate that we will require up to \$250 million in [trade debt financing](#) to finance our expected sales of our GenViro!, 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. 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. Fancy derivative and/or toxic equity financing will not 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 July 2019 CEO Keith Berman approached the company Board of Directors with a plan and offer to, from time to time, lend the company up to \$450,000 through a combination of sources available to him. The Board accepted this offer, which came without pre-condition. Mr. Berman made it clear that he would rather lend the company money himself or through close friends and family, than instead to sell low priced equity to small institutions. Through this writing, the entirety of this \$450,000 has been rendered.

In March 2020 the company entered into four Notes (loans) with its main investor, Alpha Capital Anstalt for a total of \$1 million. As of this writing, Alpha has rendered \$700,000 in loans, based on Alpha's funding and fulfillment of three of these Notes. The remainder of the \$1 million in loans from Alpha is anticipated during the week beginning March 30, 2020.

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 previous 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 years ended December 31, 2019 and 2018, compared.

The following tables summarize selected items from the statement of operations for the years ended December 31, 2019 compared to 2018.

	Year Ended			
	December 31,			
	2019	2018	12 Months	%Δ
Revenue	\$ 2,379,234	\$ 2,235,989	143,245	6.41%
Cost of sales	1,528,882	1,454,819	74,063	5.09%
Gross profit	850,352	781,169	69,183	8.86%

Revenue and Cost of Sales remained relatively static for the year ended December 31, 2019 as compared to 2018.

OPERATING EXPENSES:

	Year Ended			
	December 31,			
	2019	2018	12 Months	%Δ
Expenses:				
General & administrative expenses	952,123	541,950	410,173	75.68%
Consulting	200,269	130,658	69,611	53.28%
Compensation expense	416,527	473,973	(57,446)	-12.12%
Professional fees	575,815	1,487,750	(911,935)	-61.30%
Total expenses	2,144,735	2,634,331	(489,596)	-18.59%

Year Ended December 31, 2019:

General and administration expenses include bad debt, office expenses (including rent, cleaning and maintenance, utilities, and telephone), insurance, and bank charges. During the year ended December 31, 2019, general and administrative expenses increased by \$410,173 to \$952,123 (2018 - \$541,950) due primarily to a standard increase general overhead and payroll related items, and a one-time bad debt write-off of \$175,000, which amounted to the remainder of the product sold prior to our settlement with Lifescan/J&J and increased marketing efforts in 2019 as compared to 2018.

Consulting expenses for the year ended December 31, 2019, increased \$69,611 to \$200,269 (2018 - \$130,658). The increase is due primarily to our “normalization” of outside marketing consultants as we continue to increase the visibility of our product lines.

Compensation expense for the year ended December 31, 2019 remained relatively static as compared to 2018.

Professional fees include accounting services, legal fees and regulatory reporting compliance. The decrease in professional fees of \$911,935 to \$575,815 (2018 - \$1,487,750) is due primarily to a decrease in legal fees incurred in connection with our product development costs wherein we engaged additional legal counsel in 2018 to assist in the review of potential new sales/distributing agreements and review general corporate matters. We anticipate our legal fees to continue into 2020.

OTHER INCOME (EXPENSE):

	Year Ended			
	December 31,			
	2019	2018	12 Months	%Δ
Other income (expense):				
Financing costs	(348,655)	(195,877)	(152,778)	100.00%
Interest expense, net	(2,666,898)	(190,210)	(2,476,688)	-1302.08%
Loss on write-down of obsolete inventory	(162,359)	(902)	(161,457)	100.00%
Gain on intellectual property	1,340,000	-	1,340,000	100.00%
Total other income (expense)	(1,837,913)	(386,989)	(1,450,924)	-1002.08%

Year Ended December 31, 2019:

Our other income and expense increased an overall \$1,450,924 from \$(386,989) for year ended December 31, 2018, to \$1,837,913 for the year ended December 31, 2019. Other expense includes costs related to our financing activities associated with our debt and equity offerings of \$348,655 (2018 - \$195,877) and interest expense of \$2,666,898 (2018 - \$190,210). Included in the 2019 interest expense is Original Issue Discounts of \$2,240,858 (2018 - \$0). We also incurred a gain on intellectual property in the year ended December 31, 2019 of \$1,340,000 (2018 - \$0) due to the out of court settlement with Shasta Technologies, LLC, whereby we were granted unobstructed rights to their patents.

We recorded a net loss for the year ended December 31, 2019 of \$3,132,295 compared to a net loss in 2018 of \$2,240,220. This change was due primarily to the recording of OID at year end totaling \$2,240,858 the recognition of a gain on intellectual property due to the out of court settlement with Shasta Technologies, LLC, whereby we were granted unobstructed rights to their patents in 2019 as compared to 2018.

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 2019, 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 December 31, 2019, we had cash and cash equivalents of \$114,334, inventory of \$166,635, and accounts receivable of \$1,045,166. Net cash used by operating activities for the year ended December 31, 2019 was approximately \$1,114,671. Current liabilities of \$4,972,419 consisted of: \$1,253,892 of accounts payable and accrued liabilities, accrued interest of \$348,549, contingent legal fees of \$240,000, and notes payable and OID of \$2,794,673. As of December 31, 2019, we have a negative working capital of \$3,644,036.

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 \$49,729,923 and a net loss of \$3,132,295 for the year ended December 31, 2019. 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. Recently, 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 year ended December 31, 2019, operating activities used cash of \$1,114,671 compared to using cash of \$1,322,946 in 2018. Our net operating loss for 2019 was \$3,132,295 and included amortization of prepaid legal fees of \$101,239 (2018 - \$750,000), shares issued for financing fees of \$348,654 (2018 - \$195,876), shares and options issued for services of \$25,000 (2018 - \$0), bad debt write-off of \$175,000 (2018 - \$0), loss on write-down of obsolete inventory of \$162,359 (2018 - \$0), and gain on intellectual property of \$1,340,000 (2018 - \$0). Our change in accounts receivables increased \$241,523 to a use of \$270,370 (2018 - \$511,893 use). Our change in inventory increased \$144,225 to a use of \$78,282 (2018 - \$65,943 source). Accrued interest increased by \$2,476,688 to \$2,666,898 source (2018- \$190,210 source) due primarily to Original Issue Discounts totaling \$2,240,858 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 2019 as compared to 2018 due to the recognition of liability due to our involvement in legal matters.

Cash from Investing Activities

During the year ended December 31, 2019, investing activities used \$116,375 in cash (2018 - \$90,300 use) related wholly to our intellectual property.

Cash from Financing Activities

During the year ended December 31, 2019, financing activities produced net cash of \$986,622 (2018 - \$683,242). This change is primarily a result of successful debt and equity offerings in 2019.

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 March of 2012, we executed a renewal agreement with Alpha Credit. The renewal Year matured on December 31, 2012. We borrowed no money under this 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 December 31, 2019, our cash balance was \$114,334. 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 December 31, 2019, 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.