



**DECISION DIAGNOSTICS CORP.**

**QUARTERLY REPORT FOR OTC PINK  
MANAGEMENT'S DISCUSSION & ANALYSIS  
Report for the Quarter Ended  
March 31, 2019**

**Trading Symbol: DECN  
CUSIP Number: 243443 108**

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

### Overview

Decision Diagnostics Corp. is a 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, and 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 GenSure! glucose test strip, a product for off-shore sales which is complete and available for sales, but will primarily be sold as an international private label market entry. GenSure! and the legacy glucometers that accept this test strip no longer meet most International (ISO) standards.

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 already had four formal correspondences with the FDA and has been notified that its 510K application has progressed passed into the advanced review phase. Regarding additional product development, the company has completed advanced development work and third party testing of its GenUltimate! TBG test strip and Precise meter and are ready to begin patient testing (first level clinical trials) in the next 75 days. In association with the company's advanced development engineers, company CEO Keith Berman asked the engineers to change the chemistry foundation of the GenUltimate! TBG system to work in an identical manner with the company's GenUltimate test strip, thereby allowing the company to offer three products, each serving its own somewhat unique purposes, all running on the same test strip foundation, an FDA cleared device.

As an off-shore product GenSure! a test strip that runs on two existing legacy meters, and if sold, will only be sold in select international markets where the product will not encounter certain performance criteria issues created by the legacy metering platform that the GenSure! test strip runs on. The GenSure! product, although sharing many similarities with the company's GenUltimate! product, does not have the capability of chemistry or feature upgrade and as a result is viewed in the market and by DECN as a small niche product. Further, there is not nor ever has there been a market in the U.S. for GenSure! and the legacy manufacturer is pulling the legacy predicate product out of the EU and those countries that follow the guidance of ISO 15197:2013 and ISO 15197:2015. We have identified international distributors for this product but the international markets for GenSure! has recently become limited. Nonetheless having a finished product is better than having no product at all, so the company will continue to perform compatibility testing with the family of legacy meters on which GenSure! will run.

Resources permitting, as 2019 progresses, 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 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 expert organization that is writing 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.

The U.S. FDA, in a manner similar to prescription drugs, regulates diagnostic test kits and at-home patient testing products in a similar but somewhat streamlined process, to the regulation of prescription medicine. The regulatory standard used for the Genstrip 50 was the 510k pre-market and post-market processes. The same process was used for the GenChoice! product and will be used for GenUltimate! TBG products beginning with the 510k clearance with the FDA during the summer of 2019. Both the GenChoice! and GenUltimate! TBG products will be sold internationally while the U.S. FDA 510k applications are pending. This is a process that several American manufacturers are following to get market penetration in advance of the slower moving FDA 510K clearance process.

Previous to the company becoming a research, development and manufacturing company, we did play a small part in the distribution of legacy diabetic test strips and meters. From 2005 and until 2013, the company contracted with independent pharmacies for use of their prescription drug distribution licenses. At that time the company made market and sold brand name over the counter pharmaceutical items with a concentration in legacy diabetic test strips. The brand name products we distributed, for the most part, did not require a doctor's prescription for anything other

than insurance benefit compliance. Our previous business model worked well in the previous regulated environment, although the financial benefits were stressed by major changes made to the Federal Medicare plan that have led to substantially lower rates of reimbursement and ultimately an unprofitable business model. The company's current business model is to provide its own technologies, competing against legacy manufacturers on the basis of lower price and elevated product performance.

#### 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  $\pm$  8% system. Current ISO (2015) and FDA (2014) guidelines call for glucose monitoring systems to meet a  $\pm$  15% standard, whereby the meter and strip must be within  $\pm$  15% of a reference method in repeated testings 95% of the time. GenUltimate! and GenChoice! are  $\pm$  15% test strips, 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  $\pm$  8%, 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. 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! TBG system is not yet available for sale or distribution in the U.S. or Puerto Rico.

From time to time, when economic conditions warrant and given market conditions, we distribute other brand name prescription and non-prescription diagnostics products, as well as several lines of ostomy, wound care and post-surgery medical products, although these healthcare channels have also undergone two major market changes and disruptions since July 2013. Until these markets “settle down,” if they ever do, we have determined that we will maintain our contacts but currently refrain from competing.

Our main product was the Genstrip 50 and its successor brand the GenUltimate!, both of improved performance and design improvements and a rebranding and development (from scratch) of the original Shasta Technologies Genstrip. Both of these glucose test strips are of our manufacture. We have maintained FDA registered contract manufacturers in Pennsylvania and South Korea. We ended our association with the contract manufacturer in Pennsylvania as of March 31, 2017. The original GenStrip was cleared for market by the FDA on November 30, 2012. By virtue of our written agreements with Shasta in 2011, we were granted an irrevocable license to prosecute their 510k application with the U.S. FDA, and we succeeded. This was no small feat. We introduced the original Genstrip in March 2013. We then acquired Genstrip from Shasta Technologies LLC on March 20, 2014 and in late June 2014 we made the first branding changes owing to Shasta's poisoned relationship with the FDA. We began work on the GenUltimate! product in July 2015 and introduced this test strip (vs. our GenStrip) in April 2016. The original Shasta Genstrip and our Genstrip 50 have been discontinued. All GenUltimate! product is manufactured to our specifications and under our oversight in Korea.

#### 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. While this litigation continues, both our PharmaTech subsidiary and the FDA lawyer have 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, the state where both Shasta and our PharmaTech subsidiary are primarily located (our nexis). We intend to finally value our acquisition of GenStrip/GenUltimate in 2Q 2019.

The worldwide market for at-home blood glucose testing is an estimated \$17.2 billion as of 2017, 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 Johnson & Johnson Lifescan Inc. Ultra legacy product. J&J, which had owned Lifescan for more than 25 years, recently 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 J&J 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, J&J 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).

Throughout 2012 in anticipation of the introduction of Genstrip, we evaluated our brand-name distribution model, a model that provided streams of revenue but extremely low profit margins, and over the course of the last 36 months we phased out sales of those brand name products that had been a backbone of our distribution business. In addition the brand name products distribution business created a situation where we had been distributing legacy products that competed directly with our GenUltimate! Phasing out these brand name products lowered our order (revenues) intake but allowed us to become a manufacturer, at a higher level in the greater market channel. The company will continue to direct its marketing efforts to ambulatory and semi-ambulatory older Americans afflicted with diabetes and complications caused by diabetes and old age.

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.

We also intend to acquire additional private companies, or partner with small engineering companies that have developed technology requiring either regulatory approval, distribution expertise or both. The market for diabetes testing products is already in the tens of billions of dollars continues to grow rapidly. We have earmarked additional capital investment in 2019 for our Korean contract manufacturer and advanced development partner, who recently opened a second manufacturing line, primarily for the manufacture of GenUltimate! and its offspring, the GenUltimate! 4Pets and the GenUltimate TBG.

The company's current proprietary product offering, cleared by the FDA for commercial distribution on November 30, 2012, and now in its later branded version, the GenUltimate! blood glucose diagnostic test strip for at-home testing. Genstrip, the original product, is a product originally conceived by Shasta Technologies LLC, who proved incapable of attaining the necessary regulatory approvals after two attempts, 2009 and 2010/2011. In addition the original Shasta concept could not clear the FDA 510K process on the basis of performance, and had to undergo major design changes and a new 510K application that was eventually sponsored by us. 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 a much smoother review and 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). Since the company plans additional similar products in the future for other diagnostic platforms, in fact a product announced still in the current reporting year, the Genstrip/GenUltimate! experience, however slow and unresponsive it was, has provided lessons and experience which is already being put to use. 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 not yet seen this 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. Nonetheless, we are confident that our new products will enjoy a speedier FDA review process. As a result of previous delays and failures by Shasta Technologies in completing its FDA 510k approval application, and then problems Shasta encountered in prosecuting its two original applications with FDA staff, the company changed its contractual responsibilities and obligations in June 2011 to include program management, regulatory process management, management of the manufacturing forecasting and distribution processes, and new products planning and development. Further (eventually fatal) on-going problems encountered by Shasta, which on their face proved irresolvable, presented the company with an opportunity that we seized. On March 20, 2014 our Pharma Tech Solutions, Inc. subsidiary acquired the intellectual property, the marks, and the GenStrip cleared 510(k). Subsequently we accomplished a rebranding of the original Genstrip product (as GenUltimate!), built manufacturing protocols, implemented a robust Quality System throughout 2014 and 2015, and then developed the

improved GenUltimate! product. 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.

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 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. Discussions with this retailer and other similarly situated retailers had been on a litigation induced hiatus since our litigation with Lifescan, Inc. began in earnest in March 2013. Lifescan Inc., until October 2018, 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. The company believes there will be additional limitations as long as Johnson & Johnson and/or their successors spend large sums to discredit the company and its products. 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.

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 3<sup>rd</sup> 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 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 in Washington, DC (the patent court). That appeal is nearing the point where a court ordered mediation and oral arguments are to be scheduled. Oral arguments to the patent court judge panel are expected in June 2019.

#### The Current Business

Currently the diabetes testing market is 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 very 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 huge 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.

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 are scheduled in the month of May 2019 at both Walmart and CVS pharmacies, primarily for our GenUltimate TBG products.

The company in the past has also offered information technology solutions in several medical care market channels by providing physicians with information at the point of care. Our products, unlike those from many other medical information companies, make use of smart cell phones such as the Apple iPhone, the Motorola and Samsung Droids and a wide selection of Microsoft Windows based smart phones and operate in either in a wireless or "wired" mode, which allow physicians to carry, access and update their patients' histories, also known as electronic medical records or EMR, medication data, and best care guidelines - *all at the point of care*, or from any other location the physician may be located. In addition, the company's products employ proprietary mathematical game theory features adapted by the company for medical use that allow acceptance of diagnoses and treatment protocols where the medical information may have originated from one or several locations and one time or several times. Since the advent of "Obamacare," promising products like our own struggled to gain market acceptance in a reimbursement challenged market. The company cannot yet venture opinions or forecasts for its IT products now that the Trump administration is trying to redevelop healthcare. While we have kept up with the evolving regulatory changes, we do not foresee implementation of our products and networks in the near future. We do not assign any value on our balance sheet to our IT products.

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. 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. Thus, 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!. Initial accounts that we have 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 in a manner similar to our earlier situation with Retail Monster. The company has promised PARAGON that we will take legal action against these people should this activity continue.



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 we completed additional financing transactions with both Alpha, 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. The company in early March 2019 again turned to Alpha, most recently borrowing \$250,000 as we finance the completion of our GenUltimate! TBG product, pay for the prosecution of our GenChoice 510K application, and pay for the additional manufacturing facility in Korea.

The company entered into three international agreements throughout 2017 and 2018. The first agreement, executed through the company’s exclusive Korean agent, allows for delivery of the GenUltimate!, GenChoice! and GenSure! (and certainly the GenUltimate! TBG product when available) in quantity for sale in the Korean, Taiwan, Hong Kong, Vietnam and Thailand markets market. As of this writing, the Korean partners have ordered and paid for over 324,000 pieces (units/boxes) of GenUltimate! In addition the company, through its Korean master distributor has begun sales in Vietnam. The company’s second international agreement was through a South American financier who has businesses in Bolivia and Spain. This group initially placed a single two-year (term) order for approximately \$17 million in GenUltimate! test strips, GenUltimate! meters and the company’s new (2017) Firefly! Lancets. The South American financier also notified the company that he and those closely associated with him wished to subscribe to a \$3.25 million to \$5.0 million capital investment in the company. The group then signed and executed a Subscription Agreement for the company’s Preferred D shares in April 2017.

After delivery of approximately 11,000 pieces (units) of GenUltimate!, 3,000 GenUltimate! meters and cases of lancets delivered to Bolivia, the company was contacted by authorities in the U.S. and then again several months later by regulators in Spain concerning the partners and silent partners involved with this international agreement. As a result of these contacts, the company, on March 20, 2017, terminated the Preferred D Subscription Agreement and terminated the International Distribution Agreement.

In June 2018 the company came to terms with a third international distributor who will sell the company’s products in Mexico, Puerto Rico and in select South American countries. Initially the sales by the distributor will be our GenUltimate! test strips and meters, and our GenSure! test strips and meters. Governmental approval is needed for these products. This distributor has gotten off to a slow start.

We have received multiple inquiries from companies interested in perhaps collaborating with the company for the implementation of its cell phone centric technologies MD@Hand and MD@Work. However, the market available for products similar to MD@Hand and MD@Work has changed since its introduction in 2009. The legal challenges to the new health care law and the federal government’s inability to enact regulations have altered the landscape, again. We remain in discussions with multiple concerns for the marketing of our MD@ products, and any agreement we may enter will require us to provide contract software programming, providing a new source of revenue for the company. In addition to any proposed partnerships, we continue to discuss alternative propositions with other interested companies ranging from clinical laboratories, service organizations owned or aligned with medical health insurers, a medical content provider and legacy healthcare systems companies. There remains sustained interest in our MD@ technology. We may or may not entertain additional proposed partnerships for our implementation of the cell phone centric technologies, which has been hindered, as has the overall market, by the slow implementation of regulations, protocols and data formats by the Federal government, as well as a change in previously announced Federal government monetary incentives.

#### 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. And finally, Shasta confessed to patent infringement of J&J’s three patents.

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.

In August 2016 the company settled an insurance matter with Gotham Insurance, an IP Defense insurer, and Shasta covering legal fees associated with the 2011 and 2012 lawsuits brought by Lifescan, Inc. This settlement included a stipulation by Shasta to cease contacting and sharing confidential documents with persons who identified themselves as DECN shareholders. Several of these persons who contacted Shasta also contacted the aforementioned Retail Monster management. Shasta immediately breached this agreement, as they have breached every agreement we have executed with them. This legal settlement with the insurer does not preclude the company from pursuing Shasta, its principals and these “shareholders” in its omnibus lawsuit brought against Shasta et al. in 2014. Nor did this settlement preclude the company from pursuing Shasta for attempting to execute an illegal embargo, along with a former contract manufacturer against the company. 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 are pursuing collection of this judgment in Minnesota, California and Oregon. 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 that includes our FDA lawyer).

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 [www.pharmatechsolutionsinc.com](http://www.pharmatechsolutionsinc.com) and [www.genultimate.com](http://www.genultimate.com). and [www.decisiondiagnostics.com](http://www.decisiondiagnostics.com). Additional web sites will be added for our GenChoice! product (site now in FDA 510K prosecution) and our GenUltimate! TBG product.

As a part of the company’s strategic plans, we have applied (to register) for twelve Trademarks with the USPTO. The company’s Genstrip product is a registered Trademark of Shasta Technologies LLC. Our applications were filed with the USPTO in 1Q and 2Q 2015 and throughout 2016, 2017 and 2018. 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 31, 2019, 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.

Beginning in the 4<sup>th</sup> Quarter 2015 and through 2nd Quarter 2016 the company suffered severe inventory shortage of the Genstrip 50 product at various times, owing to the timing of the various settlements with Johnson & Johnson by Shasta and a contract manufacturer, Conductive Technologies, Inc. For some period of time Conductive refused, due to their settlement with Johnson & Johnson, to ship to the company certain quantities of the Genstrip 50 product, but did ship product for their own account using regulatory license and trade names owned by the company. These actions by Conductive Technologies, Inc. and Shasta amounted to an illegal embargo of the company’s products since neither Shasta, nor CTI retained the right to manufacturer or sell the products in the United States without the company’s exclusive approval. In November 2018 the company brought suit against CTI and Shasta in Pennsylvania to bring about compensation for this illegal embargo. The case against Shasta resulted in a \$3.6 million judgment.

The inventory problem began to clear up in late May 2016, and with the advent of adding the GenUltimate! product from Korea, shortages have been 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). Recently, 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!

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. On May 12, 2015 the company made an application for a tier change to the OTCQX (common) tier. When the company’s common stock fell in price beneath the \$.10 threshold, and when our sponsoring broker shuttered his operation, our application went into hiatus. Subsequently, the company received direct communication from OTCMarkets concerning a new uplist program offered, beginning May 18, 2017, whereby the company might uplist within the OTCMarkets tiers as a Current Alternative reporting company and filer.

Instead of this uplisting, 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 company’s Board of Directors expected, and much less 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), distribution of our GenSure! product (25 count and 50 count versions), and our PetSure! products (30 count and 60 count versions), and in 2019 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), sometime later in 2019. Our GenSure! will be sold only in certain international markets. The company is currently prosecuting its application for 510K clearance of its GenChoice! product (25 count, 50 count and 100 count versions). The GenChoice! product will be sold worldwide. Within 180 days of this writing the company will have concluded the clinical analyses and filed for 510K clearance for its GenUltimate! TBG product (25 count, 50 count and 100 count versions and a meter designed with young diabetics in mind). The GenUltimate! TBG product will be sold worldwide and will, most likely, require a strategic partner. Two prospective partners have contacted the company, one making a preliminary offer of a complex M&A transaction, the other offering cash, and a wanting a license to the GenUltimate! TBG product. We are currently in on-going negotiations with the 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 (seen above), building a technology foundation around its GenUltimate! technology.

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.

In mid-2017 the company embarked on an ambitious plan to re-brand all of its products, existing and upcoming, to sell into what is more commonly known as the private label marketplace, or the co-brand markets. These markets overlap to a high degree with what is also historically known as the "big-box" market. The rebranding contingency eventually grew to change the entire scope of our products developed for private label sales. In traditional diabetic supplies markets the packages had to include claims made in the original 510K application, plus new international symbiology and UDI identification. Packaging of the products was typically designed to accommodate the capacities of the automation that packaged the products themselves. There was no magic involved with packaging. The 25, 50 and 100 count packages sold by the entire industry grew out of the capabilities of the automated packaging machines and equipment, not some grand plan. The entire industry became "me-too." The insurance reimbursement models associated with these 25, 50 and 100 count packages (overwhelmingly 50 count boxes) arose for the same reasons.

Companies in the manufacturing and marketing channels in the industry all employ these 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!.

Beginning in November 2009, we introduced our cell-phone centric medical IT products that offer solutions in medical care and management by providing physicians with information at the point of care. We eagerly await the new version of some sort of national health plan, which might finally create markets for our products.

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 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 4Q 2018 and 1Q 2019 the company has accomplished the following milestones.

1. 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.
2. We began FDA 510K prosecution, patient clinical, 3<sup>rd</sup> 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.
3. We are pressing our suit against Johnson & Johnson and several divisions for manufacturing products that infringe on our patents. We won a major early battle in this suit where the trial judge granted us the opportunity to argue the Doctrine of Equivalents, an important concession in this case given J&J's penchant for the twisting of words and drawing lines through random dots. We lost a mid-stream battle and are now appealing to a court where we have had major rulings, of the same type (twisting of facts by J&J) in our favor in the past. This suit began its prosecution phase on March 15, 2017 with the trial judge's early

ruling. We filed our appeal in the United States Federal Circuit Court of Appeals (the patent court) and expect oral arguments to commence and a mediation in June 2019.

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 two patents (in 3Q 2019) for our GenUltimate! TBG and GenPrecis meters and test strips, and for our newest adaptation of our GenChoice! TBG meter and test strips.

On April 23, 2019 the company received its fourth communique from the U.S. FDA, related to its 510K prosecution and request for clearance related to our GenChoice! product. While all written communications with the FDA are considered formal, and the company had received three previous communiques, the April 23 letter marked the first request for additional information after a total review of our 510K application and request for clearance. The company plans its formal written response no later than May 21.

#### **Business Model Evolution**

The company has proven feasibility of its “TBG” technology for its GenUltimate! TBG product (now ready for clinical trial), its GenChoice! TBG product, now moving into advanced development, and its upcoming GenAccord! TBG product, for another legacy system. In the case of the GenAccord! TBG, there will not be an alternative test strip developed and marketed in advance of the “TBG” version. In this case we will only market the “TBG” version where the one version will work with the legacy meters, as well as our own meter. This marks a change in our business model where previously we attempted to bring to market an alternative version of a legacy test strip, achieve FDA clearance, and then some time later bring the “TBG” features and improvements on-line. With the advent of “TBG,” the company is transitioning to be a legacy system developer and manufacturer, while still maintaining compatibility with the older legacy meters and test strips.

There will be two universal statements that can be made about the “TBG” products:

1. TBG products will have precision and accuracy that sets new industry standards, performing with almost perfect linearity, and at +/- 7.5% 97-98% of the time.
2. TBG products will in a sense replace their legacy counterparts, making each new “TBG” product available to the legacy manufacturer on a license with royalty basis, with a cash payment transfer for exclusivity.

The company has also retained counsel, who represents the company in other matters, to file patents with the USPTO for the protection of our “TBG” technologies. The company envisions four patents in all, two in 3Q 2019 for the protection of our GenUltimate! TBG and GenPrecis! meters and test strips, and two in 4Q 2019 for our (newest) GenChoice! TBG product. Patents provide substantial added value to a company’s technologies. Monies gained in any settlement with the Johnson & Johnson litigation will be first applied to the cost of development of the company’s three “TBG” products, then to the three expected FDA 510K prosecutions, and finally to the patents prosecutions.

## Financing Requirements

Commented [K1]:

At March 31, 2019, we had cash of \$294,113 and negative working capital of \$1,935,993. We anticipate that we will require \$64 million in **trade debt financing** to finance our expected sales of GenUltimate!, GenUltimate! TBG, and GenChoice!, as the current litigation ends in the company's favor. Trade debt financing is traditional debt where the borrower borrows cash 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. The lender may be a bank, finance company or insurance company. Fancy derivative and/or toxic equity financing will not be used. We will operate our operations like a business. This 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 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, and 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. In September 2016, the major funds controlled by Platinum filed for liquidation. The company immediately froze all of its securities held by Platinum, and notified the funds liquidator that we had been working with the former management of Platinum to effect return of a sizable majority of the securities held by Platinum. 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 quarters ended March 31, 2019 and 2018, compared.

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

	Three Months Ended			
	March 31,			
	2019	2018	3 Months	%Δ
Revenue	\$ 561,393	\$ 559,004	2,389	0.43%
Cost of sales	373,556	346,174	27,382	7.91%
<b>Gross profit</b>	187,837	212,830	(24,993)	-11.74%
	33.46%	38.07%		

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

**OPERATING EXPENSES:**

	Three Months Ended			
	March 31,			
	2019	2018	3 Months	%Δ
<b>Expenses:</b>				
General & administrative expenses	408,329	146,618	261,711	178.50%
Consulting	49,413	31,685	17,728	55.95%
Compensation expense	124,463	108,122	16,341	15.11%
Professional fees	294,920	446,151	(151,231)	-33.90%
Total expenses	877,125	732,576	144,549	19.73%

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 March 31, 2019, general and administration expenses increased by \$261,711 to \$408,329 (2018 - \$146,618) due primarily to 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. We continue to be more efficient with our general and administrative overhead resulting in overall lower costs.

Consulting expenses for the quarter ended March 31, 2019, increased \$17,728 to \$49,413 (2018 - \$31,685). 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 quarter ended March 31, 2019 increased \$16,341 to \$124,463 (2018 - \$108,122) due primarily to a general increase in converting from contract consultants to full time employees performing daily operating services.

Professional fees include accounting services, legal fees and regulatory reporting compliance. The decrease in professional fees of \$151,231 to \$294,920 (2018 - \$446,151) 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 2019.

**OTHER INCOME (EXPENSE):**

	Three Months Ended			
	March 31,			
	2019	2018	3 Months	%Δ
<b>Other income (expense):</b>				
Financing costs	-	(6,000)	6,000	100.00%
Interest expense, net	(406,732)	(47,409)	(359,323)	-757.92%
Loss on write-down of obsolete inventory	(162,359)	-	(162,359)	100.00%
Total other income (expense)	(569,091)	(53,409)	(515,682)	-557.92%

Our other income and expense increased an overall \$515,682 from \$53,409 for the quarter ended March 31, 2017, to \$569,091 for the quarter ended March 31, 2018. Other expense includes costs related to our financing activities associated with our debt and equity offerings of \$0 (2018 - \$6,000) and interest expense of \$406,732, which includes Original Issue Discounts of \$376,089 (2018 - \$47,409). We also incurred a loss on write-down of obsolete inventory in the quarter ended March 31, 2019 of \$162,359 (2018 - \$0).



We recorded a net loss for the quarter ended March 31, 2019 of \$1,258,379 compared to a net loss in 2018 of \$573,155. Our total operating and non-operating expenses for quarter ended March 31, 2019 totaled \$1,446,216 compared to \$785,985 in 2018, representing an overall increase in total expenses of \$660,231. This change was primarily the result of a combination of the one-time write-off of bad debt, our agreement with Alpha Capital for the (non cash) recording of OID, and losses on obsolete inventory due to the end of our litigation with Shasta that resulted in a write-down of 60,000 pieces of GenStrip previously tied up in three litigations.

### **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 March 31, 2019, we had cash and cash equivalents of \$294,113, inventory of \$159,534, and accounts receivable of \$907,680. Net cash used by operating activities for the quarter ended March 31, 2019 was approximately \$597,725. Current liabilities of \$3,302,195 consisted of: \$1,036,780 of accounts payable and accrued liabilities, accrued interest of \$26,048, contingent legal fees of \$240,000, and notes payable of \$1,699,367. As of March 31, 2019, we have a negative working capital of \$1,935,993.

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 \$47,856,007 and a net loss of \$1,258,379 for the quarter ended March 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 will create 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 March 31, 2019, operating activities used cash of \$597,725 compared to using cash of \$272,697 in 2018. Our operating loss for 2019 was \$1,258,379 and included amortization of prepaid legal fees of \$101,239 (2018 - \$250,000), shares issued for financing fees of \$0 (2018 - \$6,000), shares and options issued for services of \$12,000 (2018 - \$0), bad debt write-off of \$175,000 (2018 - \$0), and loss on write-down of obsolete inventory of \$162,359 (2018 - \$0). Our change in accounts receivables increased \$22,692 to a use of \$132,883 (2018

– \$110,191). Our change in inventory increased \$171,232 to a use of \$71,178 (2018 - \$100,054 source). Our change in accounts payable and accrued liabilities remained unchanged at \$6,511 from March 31, 2019 to 2018, comparatively. Accrued interest increased by \$359,323 to \$406,732 source (2018- \$47,409 source) due primarily to Original Issue Discounts totaling \$376,089 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 quarter ended March 31, 2019, investing activities used \$16,925 in cash (2018 - \$0). The increase is due primarily to the acquisition of additional legal work on our intellectual property (patents) in 2019.

#### **Cash from Financing Activities**

During the quarter ended March 31, 2019, financing activities produced net cash of \$550,005 (2018 – \$120). 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 2019 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 March 31, 2019, our cash balance was \$294,113. 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.

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.

#### *Expected purchase or sale of plant and significant equipment.*

We do not anticipate the purchase or sale of any plant or significant equipment in the United States or Canada; as such, items are not required by us at this time. We have, however and from time to time, purchased specialty equipment for our Korean initiative. We have disclosed these investments previously in this document.

#### *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 March 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. Both the company and Mr. Berman intend to defend and prosecute vigorously.

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 the Spring of 2013, fearing the impact of the GenStrip product in an open market, Lifescan took it upon themselves to violate a court protective order and prepared and sent out thirty page certified (veiled threat) letters to customers of the company and the customers of the company's customers, making it clear to these entities that should they do business with the company, or buy GenStrip (now GenUltimate) product from others doing business with the company, they could or would be added as defendants to the patent infringement suit. Most independent pharmacies in the U.S. sell less than a case (24 boxes) of any single brand of glucose test strips monthly. It is easy to ascertain that an independent pharmacy would choose not to "poke the bear" and risk a several hundred thousand dollar defense, rather than halting sales of GenStrip. Some large retailers were visited or called by Lifescan management and provided with face to face veiled threats. Lifescan even calculated that by breaching the protective order, the sanctions they would be assessed would amount to far less than the business loss they would otherwise suffer. Slowly however, the litigation environment enjoyed by Lifescan changed.

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. For example, in December 2014 counsel for Lifescan wrote a letter to the trial judge who was hearing all three of the original patent matters. This letter outlined a series of issues involving Lifescan's lead damages "expert" during litigation proceedings. Lifescan's expert claimed educational and qualification credentials that were not true at the time of the "expert" testimony, and are not true even today. This expert also assisted Lifescan's counsel in at least one other case, and other companies' counsels in unrelated cases. Testimony from this expert, in each instance, allowed the Plaintiffs in these cases to secure court rulings to the detriment of the Defendants. In the company's case this expert was used twice and assisted Lifescan to receive preferential treatment from the court for setting of a litigation bond to cover potential damages, wherein the "expert" through testimony limited the scope and calculation of damages in the setting of the damages protection afforded by the litigation bond and the damages resulting from Lifescan's violation of the court protective order. Lifescan's letter admonition came over a year after their successful use of this "expert."

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 seeks at least \$400 million in provable damages.

Fearful that the allegations in the suit were spot on, Lifescan filed a Motion to Dismiss which was denied. J&J, consistent with their historic tactical pattern of litigation delay, then filed a Motion for Summary Judgment. Despite a low probability of success, and the absence of legal appeal option for these Motions, J&J has through its filing successfully delayed the legal process for thirteen months to date. The trial judge has also ruled that PharmaTech would be permitted to file an amended complaint which could include further detail concerning patent infringement under the Doctrine of Equivalents; a significant advantage which minimizes the companies' burden in infringement cases. Once this Motion activity is concluded the company believes that the legal pendulum once again reverts in the direction of our potent legal position, where it should remain for the remainder of the litigation. In October 2018 the trial judge granted J&J/Lifescan's Motion for Summary Judgment. The company immediately appealed. The case is now at the U.S. Court of Appeals for the Federal Circuit in Washington, DC and is tracking toward oral arguments and a mediation in June 2019. The company is optimistic that we will prevail in the patent court and either can resolve the dispute in mediation, or can resolve the dispute after the patent court rules, or if a contemplated business arrangement comes to fruition. However, we are a growing business and the burden placed on the company through litigation with a Fortune 20 company is expensive and impeding. Thus, we plan to bring up creative methods to settle the current suit against J&J in mediation prior to the oral arguments, which will be heard the next day. We are optimistic that the new owner of Lifescan, who is still infringing our patents, will seek the same path to settlement. However, this in no way means that we are giving up on the litigation. Over the past 7 years Lifescan/J&J has been a bad actor throughout, but our current scenario could prove to be a win-win.

In November 2018 the company filed a lawsuit in Pennsylvania court against Conductive Technologies, Inc. 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 is now 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. Activities to enforce the judgment against Shasta in Minnesota and California, if successful, will end other litigation involving the company and its FDA lawyer against Shasta, and allow the company a benchmark to finally value its 2014 acquisition of the GenStrip product, the 510K transferred to us by Shasta in 2014, and associated Marks.

**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.