



**Decision Diagnostics Corp.**

**ANNUAL REPORT FOR OTC PINK  
Management's Discussion & Analysis  
Annual Report for Year Ended  
December 31, 2016**

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 the Genstrip 50 and GenUltimate! glucose test strips, both Class II medical devices for at-home use for the measurement of glucose. The company also has its GenSure! glucose test strip, a product for off-shore sales, and GenChoice! glucose test strip, both alternative test strips now in advanced development. The GenSure! product has completed its clinical trials, and is currently in registration and is seeking a CE mark in the EU, and will be launched in late May 2015. The GenChoice! product will enter clinical trials in mid-April 2017. At the conclusion of the clinical trials, the GenChoice! product will be registered in the EU and an application for 510K pre-market will be filed with the FDA.

The U.S. FDA, in a manner similar to prescription drugs, regulates diagnostic test kits and at-home patient testing products 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 will be used for the GenChoice! test strip beginning in late May 2017. Previous to this change in business model, 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 lead to substantially lower rates of reimbursement and ultimately an unprofitable business model.

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! and our in development GenSure! and GenChoice! products. Our newest subsidiary Pharmatech Sensor Development Corp. manages an inventory credit line to finance inventory purchases of our Genstrip 50 and GenUltimate! products. The company has discontinued its GenStrip 50 product and ended the selling of the last of the inventory in November 2016.

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 and we have determined that we will maintain our contacts but will refrain from competing. Our main product was the Genstrip 50 and currently the GenUltimate! both of improved performance and a rebranding and redevelopment of the original Shasta Technologies Genstrip. Both of these glucose test strips are of our manufacture. We maintain FDA registered contract manufacturers in Pennsylvania and Korea. 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. 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. We began work on the GenUltimate! product in July 2015 and introduced this improved test strip (vs. our GenStrip) in April 2016. The original Shasta Genstrip and our Genstrip 50 have been discontinued.

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 Warning Letter on April 8, 2014, and when they refused to respond to this Warning Letter, the FDA then broadcast a worldwide Safety Notice on April 29, 2014, effectively ending 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 possibly been thinking. The company's acquisition of Genstrip (now GenUltimate!) was fortuitous in its timing given the finality and outcome of Shasta Technologies' troubles with the FDA.

The worldwide market for at-home blood glucose testing is an estimated \$12.5 billion. GenUltimate! competes directly with one of the largest worldwide platform manufacturers the venerable Johnson & Johnson (Lifescan Inc.). GenUltimate! were developed for use on their OneTouch Ultra legacy system for at-home blood glucose testing, a system currently used daily by over 3 million diabetes afflicted Americans. 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, designed to meet new European Union standards 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 insurance reimbursements. At the time of the introduction of GenStrip in March 2013, J&J controlled just under 30% of this market and 100% of its own Lifescan, Inc. OneTouch Ultra market.

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 30 months we have 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 were selling products that competed directly with our GenUltimate!. Phasing out these brand name products lowered our order 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. The company, originally a medical IT company with proprietary IT product lines, acquired its medical products distribution business in late 2004 through a merger with Phoenix, Arizona based CareGeneration, Inc. We have grown the original CareGeneration concept through subsequent acquisitions of private businesses and strategic partnerships with larger private pharmacies.

On November 1, 2011 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 has 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 upcoming GenSure! and GenChoice! products. Ms. Binder is also owner of GenstripDirect 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. In December 2011 we made another small acquisition, to acquire the services of Mr. Patrick DeParini. We are moving quickly to achieve our goal of becoming a vertically integrated, full service value added provider of products and services to an ever-growing market. The at-home diabetes testing market continues to grow as diabetics continue to be diagnosed and treated. The market for diabetes testing products is expected to grow from a current \$22.5+ billion worldwide base in 2016 to over \$25 billion in 2018. We also intend to make a capital investment later in 2017 in our Korean contract manufacturer and advanced development partner.

The company's current proprietary product offering, cleared by the FDA for commercial distribution on November 30, 2012, is its newer version 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 and had to undergo major design changes and a new 510K application that was eventually sponsored by this company. 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 recently (March 15, 2016)

concluded its dealings with the FDA pre and post market review staff, an on-going process that was begun on a sour note by Shasta in October 2009. The company believes that future product offerings that will be regulated by the FDA will be a much smoother process, particularly since receipt of this landmark March 15 ruling by the U.S. FDA, covering our third party developed diagnostics. 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.

Until our receipt of the landmark 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! We are confident that new products will enjoy a much speedier FDA review process. As a result of previous delays and failures by Shasta Technologies in completing its FDA approval application [510(k)] 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. 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 (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 product 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 will continue under the GenUltimate! brand, and will include 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 late March 2013. Lifescan Inc., 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. The settlements provided a hard-fought victory for the company. During the remainder of 2016, we settled these lawsuits in a novel manner, where Johnson & Johnson paid the company a settlement amount, rare in matters where the payor initiated the strike suit in the first place. J&J, as a part of the settlement, also granted the company licenses to three of J&J patents (one subsequently lost 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 January 2016 the US Supreme court ruled that the Doctrine of Laches, a defense used by many Defendants in patent infringement suits could not be used. This ruling further deprived J&J of defenses against the company's patent infringement claims.

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. 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 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. Although this has

been part of the company's plans in the recent past, the difficult litigation as well as the advent of the July 2013 and July 2016 changes to Medicare (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, Jet.com and approximately 500 other on-line cooperatives. The company considers this rapid adoption to be a huge success gained in a very short period of time.

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 Palm Pre, the Google Droid 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 new administration While we have kept up with the evolving regulatory changes, we do not foresee implementation of our products and networks in the near future.

In October 2014 we adopted a value added/private label business model to address the issues brought to our market by the radical reimbursement changes by the federal Medicare program. We also hired a market executive with over 40 years of experience to implement our new strategy. We have doubled down on this strategy and now employ not only the services of the aforementioned expert, but also additional partners and colleagues of his including the professional who put together the "big box" pharmacy private label plan for diabetic test strips. In March 2016 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 Retail Monster. After these incursions by shareholders and persons claiming to be shareholders and although the relationship with Retail Monster remained cordial, the two companies decided to end the engagement on December 31, 2016. Nonetheless, 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. 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.

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") and Licgo Partners and their sister fund Navesink Device Initiatives, 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 we completed additional financing transactions with both Alpha and Licgo. Our most recent transactions with Alpha also financed an inventory credit line for the company so that we can meet the requirements of the largest retailers and maintain at least \$400,000 in stock on hand at any time. Alpha also financed our acquisition of new specialty manufacturing equipment to facilitate our contract manufacturer in Korea as they develop our new GenChoice! product.

In the Fall of 2014 the company announced its Discretion cloud wireless glucose monitoring product concepts, which will be manufactured for the company according to spec by its Korean contract manufacturer. In April 2015 the company entered into discussions with [HMD Biomedical, Inc.](#) in Taiwan for the importing of HMD's FDA cleared "Cloudia," product as a placeholder until the company's Discretion Messenger product for children will

be ready. We ended our discussions with HMD Biomedical in October 2016, after determining that the “Cloudia” product was not robustly developed enough for North American markets and to further develop this product would require another 510(k) approval from the U.S. FDA. The company was concerned that a revised “Cloudia” might not be able to meet the more stringent ISO 15197:2013 and FDA Guidance 2014 requirements. To that end, the company’s exclusive agent in Korea was contacted by the Korean government, who apparently are willing to finance the Discretion Messenger initiative through its advanced development, clinical trials and FDA prosecution. Different than, for example, an NIH grant, this grant from the Korean government, if accepted by the company, would include investment in the company’s contract manufacturer as well. The company has recently completed a further development of its MD@Hand product, allowing diabetic users of the company’s Discretion products to monitor and track their diabetes treatment and testing on their smart cell phones. The company plans to spin-off its other MD@Hand and Residenceware technologies in a larger M&A transaction now in process.

The company entered into two international agreements in the latter part of 2016. The first agreement, executed through the company’s exclusive Korean agent, allows for delivery of the GenUltimate! product in quantity to the Korean market. As of this writing, the Korean partners have ordered and paid for over 40,000 pieces (units) of GenUltimate! Another almost 20,000 pieces (units) are on order for April 2017. The company’s second international agreement is through a South American financier who has businesses in Bolivia and Spain. This group has placed orders for approximately \$17 million in GenUltimate! product, GenUltimate! meters and the company’s new (2017) Firefly! Lancets. Almost 11,000 pieces (units) of GenUltimate!, 3,000 GenUltimate! meters and cases of lancets have been delivered to Bolivia. In addition, the South America financier has funded the company’s regulatory applications (through a Spanish pharmaceutical company) with the EU, to gain “CE” marking for its GenUltimate! and GenSure! products in return for the Spanish distribution rights to these two products. And lastly, the South American financier has 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. As of this writing the company has not concluded this capital investment but intends to speak to this issue in the upcoming 1Q 2017 Quarterly Report..

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.

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. 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. 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.

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. The stipulation gained in insurance settlement with Shasta does not preclude the company from pursuing Shasta, its principals and these “shareholders” in its omnibus lawsuit brought against Shasta et al. in 2014. The company plans to amend its 2014 complaint to name additional Defendants including those persons who owned stock in the company who may have traded stock in the market based on information and documents provided by Shasta.

We currently employ seven 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 in York, PA and our exclusive agent in Seoul, Korea maintains another office as a means to fulfill our quality commitments to the FDA. Our telephone number is (805) 446-1973 and our website addresses are [www.decisiondiagnostics.com](http://www.decisiondiagnostics.com) and [www.pharmatechdirect.com](http://www.pharmatechdirect.com) and [www.genultimate.com](http://www.genultimate.com).

As a part of the company’s strategic plans, we have applied (to register) for seven 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 3Q 2016. 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 December 31, 2016 the company has received registration confirmation from the USPTO for the following Marks:

“Alltara!”  
“GenUltimate!”  
“GenSure!”  
“GenChoice!”  
“GenAccord!”  
“GenCambre!”  
“Firefly!”

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 was unable, due to their settlement with Johnson & Johnson, to ship to the company certain quantities of the Genstrip 50 product. This 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 625,000 packages per month (50 count and 100 count packages), for the new GenSure! product 250,000 packages per month (25 count and 50 count packages) and the new GenChoice! product 400,000 packages per month (50 count and 100 count packages). Recently, a mega- retailer has requested minimum inventories of finished product of 350,000. We expect other retailers to make similar requests.

The company’s stock currently trades on the OTCMarkets OTC Pink Current tier of the market. The company’s shares are DTC 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, we have been in contact with OTCMarkets and we plan to revive our application after we complete an M&A transaction. To that end we have agreed to work with an M&A partner, a current SEC filer with a large shareholder base. We have executed a Preliminary Agreement and are in the final stages of completing a Definitive Agreement. We anticipate closing this transaction during second quarter 2017.

**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). Also within 90 days of this writing, the company will introduce its GenSure! product which has recently concluded its clinical analyses. GenSure will be sold in certain International markets. In the next

120 days the company will have concluded the clinical analyses and filed for 510K clearance for its GenChoice! product (50 count and 100 count versions). The GenChoice! product will be sold worldwide.

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. Unlike other medical information systems using standard computer terminals or even palm-sized computers (PDA's), our software applications operate on a series of late generation smart e-cell phones including the Apple iPhone, the Palm Pre, the Google Droid, several makes of RIM's Blackberry and many versions of the Microsoft Windows smart phones. Our products allow physicians to access and update their patients' histories, medication data, and best care guidelines - *all at the point of care*. The company's Electronic Medical Records software is believed to be the first EMR application running on any palm sized mobile device. Recently we ported our software to run on a series of pad computers such as Apple iPad and the 'Droid powered pads. We eagerly await the new version of the 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 GenSure! products, and then completion of the GenChoice! product. 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 product GenUltimate! product.
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).
3. Continue to implement the plans provided by our agent MWK LLC, and secure big-box pharmacy chains, chain grocers and nationwide retailers.

### **Recent Business Milestones**

In 2016 the company has accomplished the following milestones.

1. We completed the design and manufacture of GenUltimate! glucose test strips for the U.S. and international markets.
2. We began advanced development of two new test strip products, our GenSure! and GenChoice! test strips. GenSure! is slated for a May 2017 product launch, GenChoice!, which requires FDA clearance, is slated to be ready for market in late 2017.
3. We settled our lawsuit with the divisions of Johnson & Johnson. Although settlements of litigation typically have no winners, in this case the company benefitted through the receipt of a cash settlement payment as well as licenses to pursue Johnson & Johnson's test strip patents.
4. We brought suit against Johnson & Johnson and several divisions for manufacturing products that infringe on our patents. Recently 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. This suit began its prosecution phase on March 15, 2017 with the trial judge's early ruling.
5. Our Discretion Messenger wireless glucose monitoring device and test strips has received an offer of a grant from the Korean government for its advanced development, clinical trials and FDA prosecution. Discretion Messenger is a product designed for diabetic children and their parents and caregivers. The company's grant was delayed by political issues that arose with the South Korean government.
6. 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 been the most successful endeavor since our inception.



## Financing Requirements

At December 31, 2016, we had cash of \$1,351,860 and working capital of \$288,562. We anticipate that we will require \$56 million in trade debt financing to finance our expected sales of Genstrip 50, as the current litigation ends in the company's favor. In March 2012 we renewed our agreement with Alpha Credit Resources ("ACR") to obtain this debt financing. In November 2013 we executed a new line of credit with Alpha Credit Resources, replacing our previous line. The new credit line is for \$12.5 million, but with the velocity of our product sales, could yield over \$250 million in annually available credit. We have not yet drawn down any credit financing from ACR. 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 twelve months ended December 31, 2016 and 2015 compared.

The following tables summarize selected items from the statement of operations for the twelve months ended December 31, 2016 compared to 2015.

	Year Ended			
	December 31,			
	2016	2015	12 Months	% Δ
Revenue	\$ 1,092,842	\$ 514,994	577,848	112.20%
Cost of sales	603,064	220,957	382,107	172.93%
Gross profit	489,778	294,037	195,741	66.57%
Gross profit margin %	44.82%	57.10%	33.87%	

During fiscal 2013, we determined to discontinue our wholesale distribution business. The decline in revenue was anticipated and the direct result of our phasing out of sales of brand name diagnostic products as a result of the Medicare Competitive Bidding that went into effect January 1, 2013 and locked into place in all 50 states as of July 1, 2013. The net effect of these Medicare changes lowered reimbursement rates for all of the company's existing product lines by 68%. In addition, the overall at home testing market was already being hindered by the general poor economic conditions, longer payment cycles from insurers, additionally, our business model did not include the sale of retail brand-name products. These conditions may continue throughout 2017, but will enhance sales of our GenStrip 50 as we continue to develop our marketing and distribution channels.

## OPERATING EXPENSES:

	Year Ended			
	December 31,			
	2016	2015	12 Months	% Δ
<b>Expenses:</b>				
General & administrative expenses	571,407	810,026	(238,619)	-29.46%
Consulting	524,659	146,015	378,644	259.32%
Compensation expense	36,920	33,804	3,116	9.22%
Professional fees	2,122,445	1,774,441	348,004	19.61%
Total expenses	3,255,431	2,764,286	491,145	17.77%

**General and administration** expenses include office expenses (including bad debt, rent, cleaning and maintenance, utilities, and telephone), insurance, and bank charges. During the twelve months ended December 31, 2016, advertising increased by \$27,500 to \$27,500, (2015 - \$0) due to the direct result of launching our online sales

program, general and administration expenses decreased by \$238,619 to \$571,407 (2015 - \$810,026). The decrease was due primarily to a general decrease in overhead expenses. As we experience growth in revenues, general and administration expenses are expected to decrease on a percentage of revenue basis.

**Consulting expenses** for the twelve months ended December 31, 2016 increased \$378,644 to \$524,659 (2015 - \$146,015). Historically, management shifts its labor requirements between, outside consultants, casual labor and in-house management dependent upon availability and cost effectiveness of resources. During 2016 and 2015, the majority of our labor was derived from the use of outside consultants. Our compensation structure is comprised of both cash and equity of the Company. We intend to continue to compensate our consultants with equity of the Company into 2017 until such time our revenues provide sufficient cash flows to cover these expenses. The launch of our Genstrip 50 product in March 2013 required substantial adding of resources. The company decided to add temporary consulting talent rather than hiring and educating its own talent. We have more recently begun replacing our consultants with alliances with industry independent contractors.

**Professional fees** include accounting services, legal fees and regulatory reporting compliance. The significant increase in professional fees of \$348,004 to \$2,122,445 (2015 - \$1,774,441) is due primarily to an increase in professional advisement and legal fees incurred in connection with our current litigation wherein we engaged additional legal counsel to assist in the review of potential new sales/distributing agreements as well as to review general corporate matters. We anticipate our legal fees to continue into 2017.

#### **OTHER INCOME (EXPENSE):**

<b>Other income (expense):</b>					
Financing costs		(1,020,817)		(16,965)	(1,003,852) 100.00%
Interest expense, net		(294,261)		(281,319)	(12,942) 4.60%
Loss on write-down of obsolete inventory		(242,736)		-	(242,736) 100.00%
Gain on lawsuit settlement		146,863		-	146,863 100.00%
Gain on patent licenses		1,000,000		-	1,000,000 100%
Total other income (expense)		(410,951)		(298,284)	(112,667) 37.77%

Our other income and expense increased an overall \$112,667 from \$298,284 in 2015 to \$410,951 in 2016. Other income includes gain on lawsuit settlement of \$146,863 and a gain on patent licenses of \$1,000,000. Other expense includes costs related to our financing activities associated with our debt and equity offerings of \$1,020,817 (2015 - \$16,965) and loss on write-down of obsolete inventory of \$242,736 (2015 - \$0).

We recorded a net loss for the twelve months ended December 31, 2016 of \$3,180,068 compared to a net loss in 2015 of \$2,771,345. Our total operating and non-operating expenses in 2016 totaled \$3,176,604 compared to \$2,768,533 in 2015, representing an overall increase in total expenses of \$408,071. This change was primarily the result of professional fees.

#### **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 2017, as a result of several factors, including our on-going litigation with a division of Johnson & Johnson, and the change in our status from exclusive distributor of our GenStrip 50, 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 believe we are adequately capitalized in the near term, but as our Genstrip 50 product grows along its product life cycle, we may not obtain the necessary capital to pursue our strategic plan, and in the ultimate negative situation, we may have to cease or significantly curtail our operations. This would materially impact our ability to continue operations.

As of December 31, 2016, we had cash and cash equivalents of \$1,351,860, inventory of \$407,463, prepaid expenses of \$1,611,995, and accounts receivable of \$537,131. Net cash used by operating activities for the twelve

months ended December 31, 2016 was approximately \$2,880,639. Current liabilities of \$3,619,888 consisted of: \$723,171 of accounts payable and accrued liabilities, accrued interest of \$355,055, and notes payable of \$2,301,661. As of December 31, 2016, we have a positive working capital of \$288,562.

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 \$41,366,005 and a net loss of \$3,180,068 for the twelve months ended December 31, 2016. 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. Further, 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 will have to curtail our operations

### **Cash to Operating Activities**

During the twelve months ended December 31, 2016, operating activities used cash of \$2,881,338 compared to using cash of \$1,223,878 in 2015. Our operating loss for 2016 was \$3,180,068 and included shares issued for financing fees of \$1,020,817 (2015 - \$16,965), shares issued for services of \$582,100 (2015 - \$622,750), a gain on patent license of \$1,000,000 (2015 - \$0), and a loss on writedown of obsolete inventory of \$242,736 (2015 - \$0). Our change in accounts receivables increased \$554,048 to a use of \$411,844 (2015 – \$142,204 increase). Our change in prepaid expenses decreased by \$24,855 to \$2,820 (2015 – \$27,675). Our change in inventory increased \$733,186 to a use of \$645,749 (2015 - \$87,437 increase). Our change in accounts payable and accrued liabilities increased by \$473,999 to a use of \$20,073 (2015 –\$453,926 increase) due primarily to the amount payable for two acquired patents at June 30, 2015. Accrued interest increased by \$179,310 to \$415,175 (2015- \$235,865) related to our convertible debt offering. Contingent legal fees increased by \$240,000 to \$240,000 (2015 - \$0) related to our legal defense matters. Our contingent liabilities remained constant in 2016 as compared to 2015 due to the recognition of liability due to our involvement in legal matters.

### **Cash from Investing Activities**

During the twelve months ended December 31, 2016, investing activities used cash of \$321,680 (2015 - \$556,662) due primarily to the acquisition of additional specialty manufacturing equipment in 2016 compared to specialty manufacturing equipment and two patents in 2015.

### **Cash from Financing Activities**

During the twelve months ended December 31, 2016, financing activities produced net cash of \$3,927,750 (2015 – \$657,666). This change is primarily a result of debt and equity offerings in 2016.

### *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. The company is standing still until these investigations are brought to a conclusion.

### ***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 2017 we may, during our normal course of business, experience net negative cash flows from operations, pending receipt of revenue, which often are delayed because of the nature of the healthcare industry. Further, we may be required to obtain financing to fund operations through additional common stock offerings and bank or other debt borrowings, to the extent available, or to obtain additional financing to the extent necessary to augment our available working capital.

### ***Satisfaction of our cash obligations for the next 12 months.***

As of December 31, 2016, our cash balance was \$1,351,860. 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.

Healthcare, especially those segments where the company competes, is a very litigious. Competing companies often use litigation as a marketing tool, bringing litigation as a means to protect market share and limit market exposure. The medical industry is also intertwined. From time to time, we may become involved in claims and litigation that arise out of the normal course of business, such as litigation that emerges from disputes over damaged, missing or contaminated product, litigation that arises over payment disputes or claims of fair value. We may also become involved in disputes that arise over the business or business practices of our suppliers, payers and customers. It is not uncommon in our industry to find that a litigant has filed claims in multiple jurisdictions involving the same transaction or a single transaction. The company maintains substantial insurance coverage against suits that may arise over issues of damaged, recalled or counterfeit product and other product liability issues. The company has also been a victim of the unapproved acts of prior management. These acts have resulted in claims from individuals and entities since the Board relieved former management of duty in 2006. Nonetheless, these claims have resulted in the use of management time and company resources to investigate, litigate, or settle. In addition, the company accrues contingent legal fees and product liability fees. As of December 31, 2016, our accrual was \$240,000 and \$245,069.

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.

We were in litigation with Lifescan Inc. a subsidiary of Johnson & Johnson beginning in September 2011. Lifescan had maintained throughout that our Genstrip product infringed on three of their patents. One of these patents has become 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. Recently, 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 has 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 Genstrip 50 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 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 a 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 December 2014 counsel for Lifescan wrote a letter to the trial judge who is hearing all three 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 in the Federal District Court of Nevada against Lifescan, Inc., Lifescan Scotland, Ltd. and Johnson & Johnson, citing infringement of two patents owned by the company. After an exchange of demand letters and posturing by the Defendants, including Defendant's Motion to Dismiss, the company prevailed in an important early determination by the trial judge. At a hearing in March 2017 the Federal judge denied Lifescan's Motion to Dismiss, granted the company's request to allege the Doctrine of Equivalents and set dates beginning in early April 2017 and ending in early November 2017 that could set the stage for a ruling. Sometime in June 2017 the company expects to amend its suit a second time and name other "infringers" as well as adding additional counts to the suit. Federal rules for patent infringement suits have changed, and these suits are now adjudicated over an 18-24 month period. The trial judge's ruling in mid-March seems to foot with this schedule. In addition, if the schedule set by the judge does not end the litigation, there are five scheduled Mediations in front of a Federal Judge Magistrate pushing the process along.

On May 20, 2016 the company settled all of Lifescan's patent infringement claims as well as the company's Anti-trust and false advertising counter-claims against Lifescan, Inc. and Johnson & Johnson. Neither side in these litigations was a clear winner. The company's products were artificially denied a market for almost 3 years, but on the other hand, the company did receive rare settlement monies and other compensation from Lifescan in a suit where Lifescan was the Plaintiff. The amount of the settlement monies received by the company was confidential, as is often the case when Plaintiffs dismiss or lose a complex case, but confidentiality aside, the entire settlement was structured as a license agreement whereby Lifescan, Inc. granted licenses to the company for its test strip patents in return for accommodations regarding the anti-trust and false advertising claims made by the company. The licenses to the Lifescan Inc. patents were of great value to the company in the overall settlement, as will be seen later in 2017.

### **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.