



**Decision Diagnostics Corp.**

**QUARTERLY REPORTING FOR OTC PINK  
Management's Discussion & Analysis**

**Quarterly Report for the Period Ended**

**March 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 nationwide prescription and non-prescription diagnostics and home testing products distributor and the manufacturer of the Genstrip 50 and GenUltimate! glucose test strips, class II medical devices for at-home use for the measurement of glucose. The U.S. FDA, in a manner similar to prescription drugs, regulates diagnostic test kits and at-home patient testing products similarly to the regulation of prescription medicine. The regulatory standard used for the Genstrip 50 and the later GenUltimate! was the 510k process. Both products make use of the same FDA 510k clearance (GenUltimate! is a trade name and registered Trademark of Pharma Tech Solutions, Inc.). The company has, since 2005 and until 2013, contracted with independent pharmacies for use of their prescription drug distribution licenses. However, the products we currently distribute, for the most part, do not require a doctor's prescription for anything other than insurance benefit compliance. Our business model works well in this regulated environment, although the financial benefits are now limited by major changes made to the Medicare plan that have lead to substantially lower rates of reimbursement.

Our subsidiaries, Pharma Tech Solutions, Inc. and PDA Services, Inc. operate in several healthcare products distribution channels. In addition our subsidiary Decision IT Corp. engages in the acquisition and holding of Intellectual Property including Patents and Trademarks. Our new subsidiary PharmaTech Sensor Development Corp. was incorporated to work with our Korean partner and manage an inventory credit line. From time to time, when economic conditions warrant and given market conditions, we distribute 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 market changes since July 2013 and we have determined that we will maintain our contacts and agreements but will refrain from competing. Our main product is the Genstrip 50 (and GenUltimate!), a slight rebranding of the original Shasta Technologies Genstrip, cleared for market on November 30, 2012. By virtue of our our written agreements with Shasta, we were granted an irrevocable license to prosecute their 510k application with the U.S. FDA, and succeeded. We introduced Genstrip in March 2013. We acquired Genstrip from Shasta Technologies LLC on March 20, 2014 and in late June 2014 we began the minor branding changes. Shasta Technologies had a long-standing difficult relationship with the U.S. FDA and was the subject of a worldwide Safety Notice on April 29, 2014, effectively ending Shasta's ability to be a player, due to irreparable regulatory deficiency in the highly regulated medical device industry. The company's acquisition of Genstrip (now Genstrip 50 and /gen/ultimate!) was fortuitous given the finality and outcome of Shasta Technologies' troubles with the FDA.

The U.S. FDA cleared the Shasta Genstrip product for sale in the U.S. on November 30, 2012. The worldwide market for at-home blood glucose testing is an estimated \$22.5 billion. Genstrip50 (and GenUltimate!) compete directly with one of the largest worldwide platform manufacturer for at-home blood glucose testing, a product currently used daily by over 3 million diabetes afflicted Americans. In addition, since the medical device employed by this legacy platform manufacturers, Genstrip50 (and GenUltimate!) also compete in the overall at-home testing market by offering an economical solution to former users of the legacy platform providers product. In that regard, Genstrip50 (and GenUltimate!) are unique as our major business focus is directed toward diabetics who have attempted a change of glucose monitoring platforms (systems) or those currently using the legacy products but are dealing with escalating prices and lower insurance reimbursements.

Throughout 2012 in anticipation of the introduction of Genstrip and finally Genstrip50 (and GenUltimate!), 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 own Genstrip 50. Phasing out these brand name products lowered our order intake by approximately \$4,850,000 in the first two quarters of 2016 but allowed us to become a manufacturer and product specifications design agent, at a much higher level in the large 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 business through subsequent acquisitions of private businesses and strategic partnerships with larger private pharmacies and finally to manufacturing our own Class II medical device products.

On November 1, 2011 we completed the acquisition of Diagnostic Newco LLC from its owner Kimberly Binder. Diagnostic Newco LLC is a design company that specializes 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 Genstrip 50 and GenUltimate!, making subtle changes to packaging design among other responsibilities. She will also be responsible for the package design for new diagnostic products the company is currently working on. Ms. Binder is also owner of GenstripDirect, LLC and Full Circle Diabetes LLC, her own distribution companies, separate from her company related responsibilities. Ms. Binder is also the Company's designated agent for FDA matters.

We also intend to acquire additional private companies, focusing on small engineering companies that have developed technology requiring either regulatory approval, distribution 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.

The company's current proprietary product offering, cleared by the FDA for commercial distribution on November 30, 2012, is the Genstrip50 (and GenUltimate!) blood glucose diagnostic test strip for at-home testing. Genstrip is a product originally conceived by Shasta Technologies LLC, and acquired by our Pharma Tech subsidiary on March 20, 2014, fits into a diagnostic product niche and will sell into the world-wide self-test (home test) market that is expected to grow to \$32 billion worldwide by 2017. Since Genstrip 50 is a rather unique 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 presented some unusual challenges for the FDA and an educational challenge and opportunity for the company. Since the company plans additional similar products in the future for other diagnostic platforms, and in fact has contracted with our Korean partner to develop two such parallel products, the "Genstrip" experience, however slow and unresponsive it was, has provided lessons and experience.

Two years (and growing) is a standard development to market timeline for in-vitro diagnostic products similar to Genstrip50 (and GenUltimate!). As a result of previous delays by Shasta Technologies in completing its FDA approval application [510(k)] and then problems Shasta encountered in prosecuting its original application 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 on-going problems encountered by Shasta, which on their face appeared 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).

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 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 have been on a litigation induced hiatus since our litigation with Lifescan, Inc. began in earnest in late March 2013. Lifescan Inc. is a division of Johnson & Johnson. This litigation was finally brought to a merciful end on April 28, 2016. There are no victors in complex litigation although in the three cases we settled with Johnson & Johnson, we were paid a healthy sum to drop our counter-claims against Johnson & Johnson.

Currently that market is dominated by four large pharmaceutical manufacturers who provide very similar and equally focused products, selling at essentially equal prices. Genstrip50 (and GenUltimate!) introduction, even

with the fits and starts, will not only allow the company to achieve market share but because of the business model to be employed by Genstrip50 (and GenUltimate!) is different than those models employed by the major market players, the company may be able to change the market, lowering average price 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. In the recent past our model might have been called a private label model or a value added model, but with the advent of the July 2013 changes to Medicare (and followed by private insurers), pharmacy business models are now blurred.

We also offer 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.

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. In April 2016 we signed a wide reaching agreement with Bentonville, AR based Retail Monster LLC. "Monster" is going to represent the Company in 17 "A" list retailers in the U.S. and Canada.

In March 2016 we accepted assignment/transfer of special intellectual property which shall serve our business interests now and into the future. We finalized an arrangement with Alpha Capital Anstalt ("Alpha") on during 1<sup>st</sup> quarter March 31, 2016 whereby Alpha purchased an 18-month 15% OID derivative instrument in the amount of \$275,000 from the company to facilitate the acquisition of this intellectual property. Terms of this agreement with Alpha call for a 15% OID with both redemption and conversion features and 50% Warrant coverage (for follow-on investment). The conversion feature set the conversion price as the closing price of the company's common stock on March 27, 2015 less \$.02 per share. We completed another transaction with Alpha in June 2015 under similar terms to the March 2015 transaction. On the most recent transaction Alpha financed our acquisition of specialty manufacturing equipment to facilitate our contract manufacturer in Korea. In addition we accepted a derivative subscription from Alpha in December 2015 and a credit line derivative subscription in April 2016. These latest subscriptions total \$1.15 million.

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. In January 2015 the Company suspended working on this product until the Cloudia product was made easier to use by a diabetic. We eagerly await this generation 2 Cloudia. The company has also adapted its smart cell-phone medical software, an outgrowth of the company's MD@Hand development, so that users can monitor and track their diabetes treatment and monitoring on their smart cell phones. This software will also be adapted for future users of its internally developed Discretion product.

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. All of our discussions are with companies are much larger than Decision

Diagnostics. 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 \$20 billion at home testing market. Shasta was in default of this 2010 Agreement, and owed the company in excess of \$2 million in “delay” penalties, which they were unable to pay, so 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. On March 20, 2014 we acquired the GenStrip intellectual property, its marks and the cleared 510(k). On April 30, 2014 we first implemented our FDA mandated Quality Plan and are now operating as the manufacturer (operator) of the GenStrip 50.

During the 4<sup>th</sup> Quarter 2015 and first 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. For some period of time the company’s contract manufacturer was unable, due to their settlement with Johnson & Johnson, to ship to the company certain quantities of the Genstrip product. This problem began to clear up in late March 2016, and with the advent of adding the GenUltimate! product from Korea, shortages have been alleviated. The company’s capacity for Genstrip 50 and GenUltimate! production is now 500,000 packages per month (50 strips per package).

We currently employ five professionals at 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 as a means to fulfill our quality commitment to the FDA. This office is staffed by our Principal Executive who commutes several times monthly (especially during manufacturing runs) from California. We also maintain a new Quality Assurance office at our California facility to fulfill our FDA commitment for Korean manufactured products. 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).

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. The company’s application is currently being supplemented to meet several recent SEC penny stock rules, and the company has received a proposed solution for the penny stock rules issue from OTCMarkets, but more importantly the company’s sponsoring brokerage unexpectedly and without notice voluntarily shut down as of May 31, 2015. Thus, we are seeking a new sponsoring relationship. Prior to the shutdown of this brokerage, the company did secure the approval of its Designated Advisor for Disclosure (DAD), a mandated part of the process.

#### **Business activities throughout the next three months:**

The company’s business on a day-to-day basis includes the distribution of our GenStrip 50, and the distribution of prescription and non-prescription diagnostics, at-home testing, post-surgical products.

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.

Our business objectives include:

1. The practice of specializing in the distribution of Genstrip50 (and GenUltimate!) and several brand-name medical diagnostic and medical disposable products associated with the on-going care of diabetes-inflicted patients, and the world-wide distribution of our new proprietary diagnostic product Genstrip50 (and GenUltimate!).
2. Combining our wholesale and retail drug distribution with our cell phone centric technologies, creating wholesale and retail ePharmacies similar in function to existing Internet pharmacies but directed to serving the large base of underinsured and uninsured Americans; and
3. Providing medical communication and EMR medical history and storage devices based on networks of smart cell phones. These products are believed to provide benefits of on demand medical information to private practice physicians, licensed medical service providers such as diagnostic testing laboratories, and medical insurers. We have created cell phone-centric products and a suite of Internet enhanced software applications that include those features that specifically respond to the requirements of the practicing physician and the regulations currently being promulgated by the Federal government.

We also have adapted our medical communications and EMR technologies to service the real estate management and hotel/motel/convenience industries in their own commercial settings. In March 2010, our Board approved the sale of the company's hotel/motel technologies and business base so we can focus on our core medical IT and medical distribution businesses. In past years when we had market focus on the hotel/motel industry, our real estate and hotel/motel objectives include building electronic commerce networks based on personal digital assistants (PDA) and pad based computers to the hotels, motels and single building, multi-unit apartment buildings with a desire to offer local advertising and electronic services to their tenants/guests.

### Financing Requirements

At March 31, 2016, we had cash of \$1,411,576 and negative working capital of \$636,594. We anticipate that we will require \$56 million in trade debt financing to finance our expected sales of Genstrip50 (and GenUltimate!), 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. This credit line terminated without the Company drawing down any funds. We will from time to time continue to seek a combination of equity and long-term debt financing as well as other traditional cash flow and asset backed financing to meet our financing needs and to reduce our overall cost of capital. Additionally, in order to accelerate our growth rate and to finance general corporate activities, we may supplement our existing sources of funds with financing arrangements at the operating system level or through additional short-term borrowings. As a further capital resource, we may sell or lease certain rights or assets from our portfolio as appropriate opportunities become available. However, there can be no assurance that we will be able to obtain any additional financing, on acceptable terms or at all.

### Results of Operations for the three months ended March 31, 2016 and 2015 compared.

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

	Three Months Ended			
	March 31,			
	2016		2015	
Revenue	\$ 163,849	\$ 89,104	74,745	83.88%
Cost of sales	111,860	63,158	48,702	77.11%
Gross profit	51,989	25,946	26,043	100.38%
	31.73%	29.12%		

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 2016, but will enhance sales of our Genstrip50 (and GenUltimate!) as we continue to develop our marketing and distribution channels.

#### OPERATING EXPENSES:

	Three Months Ended		3 months	% change
	March 31,			
	2016	2015		
<b>Expenses:</b>				
General & administrative expenses	120,167	79,299	40,868	51.54%
Consulting	22,382	17,798	4,584	25.76%
Payroll expense	6,600	15,116	(8,516)	-56.34%
Professional fees	1,259,155	1,308,891	(49,736)	-3.80%
Total expenses	1,408,304	1,421,104	(12,800)	-0.90%

**General and administration** expenses include office expenses (including bad debt, rent, cleaning and maintenance, utilities, and telephone), insurance, and bank charges. During the three months ended March 31, 2016, general and administration expenses decreased by \$12,800 to \$1,408,304 (2015 - \$1,421,104). The decrease was due primarily to a \$50,000 reduction in professional fees to \$1,259,155 (2015 - \$1,308,891). General and administration expenses historically account for approximately 2% of our total revenue. During the current year the amount we have spent on our general and administrative costs has increased, however due to our decline in revenue the expense as a percentage of revenue has increased to 860%. As we experience growth in revenues, general and administration expenses are expected to decrease on a percentage of revenue basis.

**Consulting expenses** for the three months ended March 31, 2016 remained relatively unchanged as compared to 2015. 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 2016 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 totaling \$1,259,155 remained relatively unchanged compared to 2015 (\$1,308,891). The costs are primarily from 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. Through March 31, 2016 we anticipated our legal fees to continue until all ongoing litigation issues with the division of Johnson & Johnson (J&J) are resolved. All of the J&J initiated litigation was settled in the Company's favor in April 2016.

#### OTHER INCOME (EXPENSE):

	Three Months Ended		3 months	% change
	March 31,			
	2016	2015		
<b>Other income (expense):</b>				
Financing costs	(102,657)	(16,965)	(85,692)	100.00%
Interest expense, net	-	(71,816)	71,816	-100.00%
Settlement expense	-	(204,000)	204,000	100.00%
Total other income (expense)	(102,657)	(292,781)	190,124	-64.94%

Our other income and expense decreased an overall \$190,124 from \$292,781 in 2015 to \$102,657 in 2016. Other income and expense includes costs related to our financing activities associated with our debt and equity offerings of \$102,657 (2015 - \$16,965) and settlement expense of \$0 (2015 - \$292,781).

We recorded a net loss for the three months ended March 31, 2016 of \$1,461,372 compared to a net loss in 2015 of \$1,689,151. Our total operating and non-operating expenses in 2016 totaled \$1,510,961 compared to \$1,713,885 in 2015, representing an overall decrease in total expenses of \$202,924. This change was primarily the result of litigation defense costs.

### **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 2016, 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 March 31, 2016, we had cash and cash equivalents of \$1,411,576, inventory of \$110,446, prepaid expenses of \$1,609,362, and accounts receivable of \$100,761. Net cash used by operating activities for the three months ended March 31, 2016 was approximately \$722,553. Current liabilities of \$3,868,739 consisted of: \$731,064 of accounts payable and accrued liabilities, contingent legal fees of \$240,000, subscriptions payable of \$1,562,500, and notes payable of \$1,335,175. As of March 31, 2016, we have a negative working capital of \$636,594.

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 \$39,525,696 and a net loss of \$1,461,372 for the three months ended March 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 three months ended March 31, 2016, operating activities used cash of \$722,553 compared to using cash of \$608,027 in 2015. Our operating loss for 2016 was \$1,461,372 and included shares issued for financing fees of \$102,657 (2015 - \$16,965), and shares issued for consulting and compensation expenses of \$490,000 (2015 - \$527,500). Our change in accounts receivables increased \$56,236 to \$24,525 (2015 - \$31,711 decrease). Our change in prepaid expenses decreased by \$9,813 to \$187 (2015 - \$10,000). Our change in inventory increased \$162,890 to \$105,996 (2015 - \$56,894 increase). Our change in accounts payable and accrued liabilities decreased by \$257,840 to \$12,180 (2015 - \$245,660 increase). Contingent legal fees increased \$240,000 (2015 - \$0) based on our expected current unbilled legal fee expenses. Accrued interest decreased by \$71,816 to \$0 (2015 - \$81,816) related to conversion of debt and interest to shares of \$0.001 par value common stock. Our contingent liabilities remained constant in 2016 as compared to 2015 due to the recognition of liability due to our involvement in legal matters. Our year to year change in Cash to Operating Activities was the direct result of three factors: (a) the changes to Medicare reimbursement taking effect on July 1, 2013, (b) the on-going litigation with the division of

Johnson & Johnson, and (c) the inability of the previous Genstrip50 (and GenUltimate!) manufacturer Shasta Technologies to implement an acceptable quality plan with the USFDA, and in general manage the manufacturing of a regulated healthcare device.

### **Cash from Investing Activities**

During the three months ended March 31, 2016, investing activities used cash of \$283,000 (2015 - \$260,742) due primarily to the acquisition of one patent in 2016 compared to specialty manufacturing equipment and two patents in 2015.

### **Cash from Financing Activities**

During the three months ended March 31, 2016, financing activities produced net cash of \$1,790,001 (2015 - \$277,852). This change is primarily a result of the sale of equity 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 June 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. 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. This agreement came to term on December 13, 2015 without any borrowings having occurred.

### ***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 2016 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, 2016, our cash balance was \$1,411,576. 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; as such, items are not required by us at this time.

#### ***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 GenStrip 50 and GenUltimate! products required initial regulatory approval by the USFDA as well as on-going USFDA approvals during the product life cycle. Further, these products required medical patient trials and competes directly with a major platform manufacturer.

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. We have in the past (and currently) defended cases brought by Plaintiffs asserting these types of claims.

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 have defended cases of this nature. Often these cases spin out of control. For instance we have been sued in several jurisdictions that involved the same or a single business transaction. Often these cases involve substantial over-prosecution where the company and its directors have been held accountable by Plaintiffs for things said or written in public by anonymous persons.

We may also become involved in disputes that arise over the business or business practices of our suppliers, payers and customers, people or entities that we not be familiar with. 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, 2015, our accrual was \$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 material or potentially material to us.

Johnson & Johnson, Lifescan, Inc. and Lifescan Scotland Ltd.

We have been in litigation with Lifescan Inc. a subsidiary of Johnson & Johnson since September 2011. Lifescan has maintained throughout that our Genstrip product infringes on three of their patents. One of these patents has become the subject of peripheral litigation activities, and three Appeals to the U.S. Appeals Court for the Federal Circuit (the patents appeals court). Throughout this Appeal process, and a litigation process waged through the USPTO, the company has 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. In January 2016 the Federal Circuit court ruled against Lifescan/J&J by issuing a Rule 36 pronouncement, a ruling without written analysis, a tool typically used when the court finds that the appellant's argument is without merit. Lifescan/J&J has indicated that they intend to file for a rehearing no later than April 6.

The seeming baseless allegations and claims made by Lifescan against the company have taken their toll, limited our ability to sell Genstrip 50 (and GenUltimate!) to large entities ("big box stores") and greatly extended the court processes. In fact the office of the solicitor, in written pleadings, accused Lifescan/J&J of "sandbagging."

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 the same 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 has changed.

In the spring of 2015, Lifescan, perhaps realizing litigation reality, dismissed all of their claims involving one patent, with prejudice, and dropped (with prejudice) all damage claims on a second of their three patents. Two of Lifescan/J&J's patents have now expired and the litigation surrounding them has moved into a dueling court Motion exercise. The third Lifescan patent, the foundation patent for their OneTouch Ultra product, is clinging to life in an appeals court, with the office of the Solicitor General intervention, that patent was terminated in USPTO court hearings and appeals, because this patent contained unpatentable technology and patent claims.

More recently, during the writing of this document, the company has requested again, all documents related to communication with these besieged customers of the company, and the customers of the company's customers. Certified mail leaves an audit trail, and soon through the court discovery process for a \$12.7 million court bond surety, the company will be able to get to the bottom of this illegal behavior. Proving this behavior would help the prospects of Genstrip 50 and GenUltimate! dramatically.

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 late March 2016 the Company filed a patent infringement suit in the District Court of Nevada against Johnson + Johnson and several divisions. This suit is separate from the collection of suits that were heard in San Francisco, CA.

On May 9, 2016 the U.S. Court of Appeals for the Federal Circuit ruled against Lifescan’s appeal for a re-hearing and an en banc hearing. A Mandate from the court will issue on May 17, 2016. Lifescan’s ‘105 patent, the foundation for so much of this litigation was revoked.

Certain of the three cases in front of the trial judge in the Federal District court, have most recently been ordered to mediation for the third time, as the disposition of these cases nears conclusion. On April 28, 2016 the mediation took place and was successful. The trial judge filed an “end of cases” ruling on April 29, 2016.

### **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.