U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(MARK ONE)
[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended February 28, 2017

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from _____ to _____

Commission file number: 000-52735

METASTAT, INC.
(Exact name of Registrant as Specified in Its Charter)

NEVADA	**20-8753132**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
27 Drydock Ave., 2nd Floor **Boston, Massachusetts**	**02210**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 531-6500**

SECURITIES REGISTERED PURSUANT TO SECTION 12 (B) OF THE ACT: **NONE**
SECURITIES REGISTERED PURSUANT TO SECTION 12 (G) OF THE ACT:
COMMON STOCK, PAR VALUE $0.0001 PER SHARE

Name of each exchange on which registered: **The OTCQB marketplace**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Non-accelerated filer	☐
Accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

(Do not check if a smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the shares of common stock, par value $0.0001 per share, of the registrant held by non-affiliates on August 31, 2016 was approximately $2.6 million, which was computed upon the basis of the closing price on that date.

There were 4,807,942 shares of common stock of the registrant outstanding as of May 26, 2017.

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INTRODUCTORY NOTE

Except as otherwise indicated by the context, references in this Annual Report on Form 10-K (this "Form 10-K") to the "Company," "MetaStat," "we," "us" or "our" are references to the combined business of MetaStat, Inc., a Nevada corporation, and its consolidated subsidiary.

Special Note Regarding Forward-Looking Statements

The statements contained in this Form 10-K, including under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other sections of this Form 10-K, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

PART I

Item 1. BUSINESS

Overview

MetaStat is a biotechnology company focused on discovering and developing personalized therapeutic (Rx) and diagnostic (Dx) treatment solutions for cancer patients. Our Mena protein isoform "driver-based" diagnostic biomarkers also serve as novel therapeutic targets for anti-metastatic drugs. Unlike surrogate cancer markers, which are indirect measures of cancer and its progression, our driver-based biomarkers are the critical components of intracellular cancer pathways responsible for driving the aggressive activity of cancer cells. Our core expertise includes a deep understanding of the mechanisms and pathways that drive tumor cell invasion and metastasis, as well as drug resistance to certain targeted therapies and cytotoxic chemotherapies. We are developing therapeutic product candidates and paired companion diagnostics based on a novel approach that makes the Mena isoform protein a drugable target.

Our integrated Rx/Dx strategy for treating cancer patients has three key product development programs:

1) **Therapeutic (Rx) candidates**: Our drug discovery program is focused on the development of novel therapeutic product candidates that target the Mena protein isoform. We are investigating therapeutic candidates for the potential to prevent or delay aggressive cancer from spreading and becoming resistant to other commonly used targeted and cytotoxic therapies. In targeting the movement of tumor cells from the primary site to distant sites, we are directly addressing the major contributor to the deaths of cancer patients. Elevated expression of Mena^{INV}, a Mena protein isoform also drives resistance to certain Receptor Tyrosine Kinase (RTK) inhibitors that target EGFR, HGFR, IGF-R1 and other key receptors, as well as cytotoxic chemotherapeutics, including anti-microtubule agents, such as docetaxel, paclitaxel and albumin-bound paclitaxel. We believe co-administration of an effective anti-Mena therapeutic agent provides an opportunity to expand the utility of these therapies and addresses a significant challenge to the clinical management of advanced cancers. RTK and anti-microtubule drugs are widely used to treat a number of types of cancer, including ovarian, breast, lung cancer, squamous cell carcinoma of the lung, colorectal cancer, Kaposi's sarcoma, cervical cancer and pancreatic cancer. We are using multiple targeted approaches including proprietary small molecules, therapeutic peptides, camelid nanobodies, monoclonal antibodies and RNA-based technologies to test therapeutic candidates in our *in vitro* and *in vivo* metastatic models for efficacy in reversing Mena-dependent phenotypes of drug resistance, tumor cell invasion, dissemination, and metastasis. Our objective is to select suitable drug candidates to advance into human clinical studies. We plan to use the Mena^{INV} companion diagnostic assay to identify and select appropriate patient populations most likely to benefit from targeted Mena isoform therapy. Our therapeutic program will be implemented using internal resources and in partnership with therapeutic biopharmaceutical companies.

2) **Companion Diagnostics (CDx):** Our companion diagnostic program is focused on developing companion tests to be used in combination with cancer drugs, that provide essential information for the safe and effective use of a corresponding drug or biological product to improve patient outcomes. We are developing quantitative immunofluorescent, or QIF companion diagnostic assays using our proprietary monoclonal antibodies, or Mabs, that predict how well a cancer patient is likely to respond to treatment with RTK inhibitors and anti-microtubule drugs. Not everyone responds in the same way to these treatments. Patients with tumors expressing high levels of Mena have been shown to develop resistance to treatment with RTK inhibitors (EGFR, HGFR and IGF-R1inhibitors) and anti-microtubule drugs (docetaxel, paclitaxel and albumin-bound paclitaxel). Our companion diagnostics aim to help oncologists refine diagnosis and tailor treatment strategies, saving patients precious time and expense by predicting response to these therapies prior to administration. We are exploring business development opportunities with pharmaceutical and biotechnology companies developing next generation RTK inhibitors and anti-microtubule drugs who see the value of companion diagnostics that identify patients most likely to benefit from these treatments. We believe using our proprietary companion diagnostics to target appropriate patient populations creates selective therapeutic opportunities to repurpose shelved drug candidates that have previously failed clinical testing or enhance the probability of success of drugs currently under development.

3) **Prognostic Diagnostics (PDx):** Our prognostic diagnostic program is focused on developing diagnostic tests that predict the risk of future metastasis in cancer patients following initial treatment of their primary tumor. Our first prognostic diagnostic product candidates, the MetaSite *Breast*™ and MenaCalc™ tests, aim to provide actionable information to early stage breast cancer or ESBC patients and their physicians regarding the risk of distant metastasis and if the use of adjuvant chemotherapy is warranted. We are seeking to monetize or commercialize our CLIA-validated prognostic diagnostic tests for breast cancer through strategic partnerships. Our MetaSite *Breast*™ test has been shown to be complementary to the Oncotype DX test, the most widely used breast cancer gene panel assay. These published results were presented at the San Antonio Breast Cancer Symposium in December 2016. We plan to develop additional prognostic diagnostic tests based on the Mena^{INV} biomarker for additional indications including lung, prostate and colorectal cancers.

Business Strategy

Our vision is to become a leading healthcare company focused on advancing the field of personalized medicine. Since discovering a methodology to make Mena protein isoform targets drugable, our business strategy evolved from a pure play prognostic diagnostic company to a value-added integrated Rx/Dx company focused on therapeutics and companion diagnostics. We have leveraged our technology and core expertise to broaden our intellectual property position through a deep understanding of the functionality of Mena protein isoforms and their roles in shaping the tumor microenvironment and driving the spread of aggressive cancers. To this end, we are currently testing several therapeutic product candidates in our research and development laboratories and have filed provisional methods, use and composition of matter patents.

Key elements of our integrated Rx/Dx strategy are to:

- Continue advancing our pre-clinical therapeutic discovery and development programs focused on the Mena protein isoform drug targets using different approaches developed (i) internally or through in-licensing, and (ii) in collaboration with strategic partners. These therapeutic approaches include small molecule inhibitors, therapeutic peptides, camelid nanobodies, monoclonal antibodies, and RNA-based technologies;

- Expand access to the Mena^{INV} companion diagnostic test to ensure broad adoption through development of alternative test methods and kits that can be run on a wide variety of different instrument platforms and seeking marketing authorization approvals from applicable regulatory agencies including the FDA and EMA;

- Use our driver-based biomarkers to identify shelved drug candidates that have previously failed clinical testing or drug candidates currently under development that represent suitable candidates for co-development with our companion diagnostics;

- Innovate and advance our patent and intellectual property portfolio supporting our licensed platform technologies. We plan to augment our internal capabilities through product in-licensing, selective acquisitions, R&D collaborations and strategic partnerships to facilitate broadening of our product pipeline and extension of our novel proprietary technologies;

- Commercialize our diagnostic assays through our state-of-the-art CLIA-certified and state-licensed laboratory. We plan to maintain our commercial CLIA-certified laboratory and in parallel pursue non-exclusive strategic partnerships with organizations that have established high complexity, IHC, QIF compatible digital CLIA-certified labs; and

- Pursue a de-risked commercialization strategy of our diagnostic tests based on non-exclusive agreements with strategic partners and/or Contract Sales Organizations (CSO) in the U.S. and distributors in Europe and throughout the rest-of-world. We seek commercialization partners that have existing commercialization infrastructure, established distribution channels, and strong relationships with our target audience in the medical community. Our goal is to avoid the cost and risk associated with building a new sales and marketing infrastructure. Initially, we plan to build the necessary commercial infrastructure only when needed to supplement existing partnerships and not economically available through third party vendors. As profitability and market penetration grow, we may supplement our strategic partnership/CSO strategy with a phased-in internal sales and marketing effort.

Scientific Background and Technology

Our proprietary and patented platform technologies are derived from novel ways of observing cancer cell behavior in living functioning tumors in live animals and are based on the discovery of a common pathway for the development of aggressive or metastatic cancer in solid epithelial-based tumors. These technologies are the result of nearly 20 years of study and collaboration among four scientific/academic institutions, including Massachusetts Institute of Technology ("MIT"), Albert Einstein College of Medicine ("AECOM"), Cornell University ("Cornell"), and the IFO-Regina Elena Cancer Institute in Rome, Italy ("IFO-Regina" and, collectively with MIT, AECOM, and Cornell, the "Licensors"). This collaboration has enabled us to understand the underlying biology, including the direct mechanisms of action and specific microenvironmental factors that drive systemic metastasis and drug resistance to certain cancer treatments.

As described in *Nature Reviews Cancer* (Condeelis and Segall, 2003), multiphoton-based intravital imaging was used to capture real-time high-resolution, three-dimensional images of cancer cell behavior in live breast cancer tumors. This led to new insights about the mechanisms or drivers of cell migration during invasion and intravasation, and information about the microenvironment that is required for driving these key steps in metastasis.

The Licensors were the first to discover the mechanism by which metastatic breast cancer cells polarize, move toward and invade blood vessels and intravasate into circulating blood in search of a new host or metastatic site. As described in *Cancer Research* (Wyckoff et al., 2004) and further detailed in *Cell* (Condeelis and Pollard, 2006), breast cancer migration, invasion and metastasis is driven by a self-propagating paracrine loop between perivascular macrophages that secrete epidermal growth factor (EGF) and tumor cells, which secrete colony-stimulating factor (CSF)-1. EGF elicits several responses including chemotaxis (chemical-induced movement) that recruits cancer cells along the extra-cellular matrix towards and into blood vessels. An artificial blood vessel was developed using a microneedle that mimics this chemotactic signaling to attract, capture, and isolate a discrete population of metastatic cancer cells, which was first described in *Cancer Research* (Wyckoff et al., 2000). As first published in *Cancer Research* (Wang et al ., 2004), gene expression analysis of these invasive cancer cells was performed and compared against a general population of cancer cells that resulted in the identification of a specific gene expression profile or "invasion signature" of highly metastatic breast cancer cells that exhibit a rapid amoeboid migratory phenotype. Analysis of the invasion signature showed that number of genes were identified that must be coordinately up or downregulated in the invasive tumor cells in order for their invasion to lead to cancer metastasis. One of the key upregulated genes in invasive tumor cells encodes Mena, an actin regulatory protein, which is central in the regulation of the pathways encoded by the invasion signature.

Further intravital imaging led to the discovery of the micro-anatomical site in the tumor microenvironment, or "portal" in the blood vessels that metastatic cells squeeze through to enter the blood stream. This portal was originally named the "Tumor Microenvironment of Metastasis (TMEM)", however we have re-named this site of metastasis in breast cancer the "MetaSite™". The MetaSite™ is consists of three cells in direct apposition: an endothelial cell (a type of cell that lines the blood vessels), a peri-vascular macrophage (a type of immune cell found near blood vessels), and a tumor cell that expresses the Mena protein. Clinical data initially presented in *Clinical Cancer Research* (Robinson *et al.*, 2009) showed the density of these "portals" or MetaSites™ present in a tumor tissue sample correlated to the probability of distant cancer metastasis. This is the basis of our prognostic diagnostic test for breast cancer, the MetaSite *Breast*™ test, which is more fully described herein.

The Mena protein isoforms and our driver-based biomarkers

Mena, a member of the Ena/VASP family of proteins, regulates cytoskeletal dynamics, membrane protrusion, and cell movement, adhesion and shape change in a variety of cell types and contexts by influencing the geometry and assembly of actin filament networks. The growth and elongation of actin fibers, part of the cell's cytoskeleton, are controlled by a process that caps their ends. Mena interferes with the actin capping allowing the actin fibers to lengthen by continuously polymerizing, thus pushing forward the leading edge of the cell. A detailed summary of the Mena protein was published in *Trends in Cell Biology* (Gertler and Condeelis, 2011).

The Mena gene can be alternatively spliced to produce multiple isoforms of which the Mena11a and MenaINV isoforms dominate. Alternative splicing is the process by which exons within a pre-mRNA transcript of a gene are differentially spliced, resulting in multiple protein isoforms being encoded by a single gene. Post-transcriptional processing of the Mena gene provides anopportunity for gene regulation and increases the functional informational capacity of the gene. These small differences in Mena structure produce large differences in Mena protein function. The Mena gene corresponds to a 570-amino acid protein with the MenaINV isoform containing a supplementary exon corresponding to a 19-amino acid addition to the EVH1 domain of the protein. Mena11a contains a supplementary exon corresponding to a 21-amino acid addition to the EVH2 domain of the protein. The invasive Mena isoform, MenaINV, and the less dangerous Mena isoform, Mena11a , play distinct roles in cancer morphology. In research published in *Development Cell* (Philippar *et al*., 2008), MenaINV was shown to promote invasion and metastasis by helping cancer cells subvert normal regulatory networks regulating cell motility and increasing sensitivity to the chemo-attractant EGF by up to forty (40x) times. MenaINV allows cancer cells to respond to lower EGF concentrations.

Results published in *Clinical Experimental Metastasis* (Roussos *et al.*, 2011) showed that MenaINV expressing tumor cells are significantly less cohesive and have discontinuous cell-cell contacts compared to Mena11a expressing tumor cells. Metastatic breast cancer cells expressed 7.5-fold more MenaINV than non-metastatic cells. Furthermore, MenaINV expression correlated with MetaSite™ score, while Mena11a did not. These results suggest that MenaINV, but not Mena11a, is associated with intravasation and metastasis. Our MenaCalc™ test, is based on determining the relative levels of the Mena protein isoforms, which is more fully described herein.

Further, in a nonclinical proof-of-concept study published in *Breast Cancer Research* (Roussos *et al.*, 2010), the role of Mena in tumor progression and metastasis was investigated. A “Mena null” mouse, a mouse unable to produce the Mena protein or its isoforms was developed. These Mena null mice were crossbred with polyoma middle T oncoprotein or “PyMT” mice (mice genetically predisposed to spontaneously develop highly metastatic breast cancer tumors). The resulting Mena null PyMT mice were compared to control PyMT mice. Both groups of mice developed breast cancer tumors, however, the Mena null mice’s tumors stayed localized while the control mice developed systemic metastasis. More importantly, all the control mice succumbed to metastatic disease while the Mena null mice showed significant survival advantage with most dying of old age.

As described in *Nature Reviews Cancer* (Kavallaris, 2010), microtubules are critical cytoskeletal structures that mediate cell division. The primary building block of microtubules is tubulin and Tubulin Binding Agents (TBAs), such as taxanes, which are potent anti-mitotic agents that inhibit cellular growth, drug binding, and/or cell signaling. TBAs, in part, act to stabilize microtubules thus preventing dynamic microtubule polymerization and activity. Although TBAs are a widely used chemotherapeutic regimen, predicting patients who are resistant and/or who will become resistant is problematic and largely unresolved. Although there are several possible mechanisms of resistance, one possible mechanism is augmenting the actin cytoskeleton as these two independent cytoskeletal systems have been shown to interact and influence one another as detailed in *Nature Cell Biology* (Rodriguez *et al*., 2003) and *Cancer Metastasis Review* (Hall *et al.*, 2009). Specifically, agents that inhibit actin de-polymerization as shown in *Cancer Research* (Dan *et al.*, 2002) and/or promote actin polymerization, like Mena^{INV}, may confer and therefore be used to predict resistance to TBAs or taxane-based drugs.

As described above, Mena promotes cancer cell invasion and migration toward blood vessels by potentiating EGF signaling. Data published in November 2015 in *Molecular Biology of the Cell* (Hughes *et al.*, 2015) describes how Mena associates constitutively with the tyrosine phosphatase PTP1B to mediate a novel negative feedback mechanism that attenuates RTK signaling. On EGF stimulation, complexes containing Mena and PTP1B are recruited to the EGF receptor, or EGFR, causing receptor dephosphorylation (the removal of phosphate groups that can prevent ligation) and leading to decreased motility responses. When MenaINV is expressed, PTP1B recruitment to the EGFR is impaired, providing a mechanism for growth factor sensitization to EGF, as well as HGF and IGF, and increased resistance to EGFR and Met inhibitors. Notably, MenaINV disrupts this negative feedback mechanism to drive sensitivity to EGF, HGF, and IGF growth factors and resistance to RTKs that target EGFR, HGFR (c-Met), and IGF-R1. Disruption of this attenuation by MenaINV sensitizes tumor cells to low growth factor concentrations, thereby increasing the migration and invasion responses that contribute to metastasis.

Genetic, epigenetic, and gene expression alterations often fail to explain adaptive drug resistance in cancer. Kinase inhibitor resistance often involves upregulation of poorly understood "bypass" signaling pathways. Results published in April 2016 in *Cancer Discovery* (Miller et al., 2016) show that extracellular proteomic adaptation is one path to bypass signaling and drug resistance. Kinase inhibitors, particularly targeting MAPK signaling, increase tumor cell surface receptor levels due to widely reduced proteolysis, allowing tumor signaling to circumvent intended drug action.

Results published in *Clinical Experimental Metastasis* in March 2016 (Oudin et al., 2016) demonstrated the specificity and utility of a Mena^{INV} isoform-specific monoclonal antibody in *in vitro* models.

As described in a study published in *Molecular Biology of the Cell* in October 2016, (Oudin et al., 2016) Mena^{INV} was associated with metastasis by driving chemotaxis via dysregulation of phosphatase PTP1B and more recently in haptotaxis via interaction with integrin a5b1. The results demonstrate that Mena^{INV}-driven haptotaxis on fibronectin gradients requires intact signaling between a5b1 integrin and EGFR, which is influenced by PTP1B. Furthermore, Mena^{INV}-driven haptotaxis and extracellular matrix reorganization both require the Rab-coupling protein RCP, which mediates a5b1 and EGFR recycling. Finally, Mena ^{INV} promotes synergistic migratory response to combined EGF and fibronectin *in vitro* and *in vivo*, leading to hyperinvasive phenotypes. This demonstrates that Mena^{INV} is a shared component of multiple prometastatic pathways that amplifies their combined effects, promoting synergistic cross-talk between RTKs and integrins.

Data published in January 2017 in *Molecular Cancer Therapeutic*s (Oudin et al., 2017) show Mena/Mena^{INV} confer resistance to the taxane paclitaxel, but not to the widely-used DNA-damaging agents doxorubicin or cisplatin. Furthermore, paclitaxel treatment does not attenuate growth of Mena^{INV}-driven metastatic lesions. Mechanistically, Mena isoform expression alters the ratio of dynamic and stable microtubule populations in paclitaxel-treated cells. Mena expression also increases MAPK signaling in response to paclitaxel treatment. Decreasing ERK phosphorylation by co-treatment with a MEK inhibitor restored paclitaxel sensitivity by driving microtubule stabilization in Mena isoform-expressing cells. These results reveal a novel mechanism of taxane resistance in highly metastatic breast cancer cells and identify a potential combination therapy to overcome such resistance.

As a result of the above, we believe there is a scientific rationale and biological basis to develop and explore anti-metastatic drugs that target the Mena protein isoforms, and the utility of Mena^{INV} tests to predict patient response to select RTKs and taxane-based chemotherapies in the treatment of breast cancer, colorectal, non-small cell lung cancer or NSCLC, pancreatic and other cancers.

Cancer Background

Cancer is a complex disease characterized most simply by uncontrolled growth and spread of abnormal cells. Cancer remains one of the world's most serious health problems and is the second most common cause of death in the United States after heart disease. The American Cancer Society, or ACS estimates in 2017, there will be nearly 1.7 million new cases of cancer and approximately 600,000 deaths from cancer in the United States alone.

When dealing with cancer, patients and physicians need to develop strategies for local, regional, and distant control of the disease. Ultimately, however, aggressive cancer that spreads or “metastasizes" to other parts of the body is responsible for more than 90% of all cancer related deaths in patients with such common types of solid tumors as breast, lung, prostate and colon. The most common methods of treating cancer are surgery, radiation and drug therapy, or a combination of these methods, with varying degrees of benefit and side effects that may not always justify the expense and burden of the therapy.

MetaStat’s therapeutic drug targets and driver-based cancer biomarkers are common to a type of cancer called carcinoma which are malignancies of epithelial tissue and represent approximately 80-90% of all cancer cases. Our product candidates have the potential to have broad pan-cancer applicability to redefine diagnosis and tailor treatment.

Prior to the advent of personalized medicine, most cancer patients with a specific type and stage of cancer received the same treatment, which historically consisted of cytotoxic chemotherapies, including taxanes, such as paclitaxel and docetaxel. These chemotherapies kill rapidly proliferating cancer cells through non-specific mechanisms, such as deterring cell metabolism or causing damage to cellular components required for survival and rapid growth. While these drugs have been effective in the treatment of some cancers, many unmet medical needs remain. This approach is not optimal as some treatments worked well for some patients but not for others.

Differences in the genome and how these genes are expressed, called the expressome, explain many of these differences in response to treatment. The convergence between understanding the expressome and our ability to identify and develop biomarkers for certain disease is accelerating growth and interest in personalized medicine and the attractiveness of our intergraded Rx/Dx strategy.

Advances in personalized medicine and cancer treatment are progressing rapidly and are enabling a shift in clinical treatment from a one-size-fits-all approach to one that is highly individualized. Recently, more targeted therapies and immunotherapies have represented some of the most promising agents in development for the treatment of cancer. Targeted therapies are drugs that block the growth and spread of cancer by interfering with specific molecules that are involved in the growth, progression and spread of cancer. Targeted therapies, such as RTK inhibitors that selectively target kinase signaling pathways, are designed to preferentially kill cancer cells and spare normal cells, improve efficacy and minimize side effects. RTK inhibitors typically have less severe side effects than cytotoxic chemotherapies, however, a main limitation is that a significant number of patients do not respond to treatment, and the emergence of secondary drug resistance for those patients that do show an initial benefit. The use of predictive biomarkers allows oncologists to better understand and overcome drug resistance through the clinical assessment of rational therapeutic drug combinations. The ability to treat the patient relying on validated data will improve patient outcomes and eliminate excessive cost in the health care system.

Research and development of targeted therapies and immunotherapies is rapidly accelerating. Between the 2005 and 2013, there were approximately 680 clinical trials in the United States investigating personalized medicine in oncology. In 2016, we believe this number exceeded 3,000 clinical trials. To keep pace with this shift to personalized medicine, there is an increasing focus on the use of companion diagnostics to guide physicians in selecting the most appropriate therapy for each patient.

We believe as the number of available targeted therapies expands and as physicians gain further experience using molecular biomarkers in their routine treatment decisions, the market potential of our anti-metastatic drugs and companion diagnostics will grow.

Product Pipeline

Based on our integrated Rx/Dx strategy, we are developing anti-metastatic therapeutics, companion diagnostics to predict drug response and define patient populations, and prognostic diagnostics for risk of cancer metastasis.

Therapeutics (Rx)

During 2016, we developed a methodology that makes the Mena protein isoform a drugable target. We are testing preclinical therapeutic candidates in our research and development laboratory using our *in vitro* and*in vivo* metastatic models for efficacy in reversing Mena-dependent phenotypes of drug resistance, tumor cell invasion, dissemination, and metastasis. Our objective is to select suitable drug candidates to advance into human clinical studies either alone or in combination with strategic clinical development partners.

Rationale for targeting Mena protein isoforms

The goal of treatment with anti-Mena therapeutics is to reduce the activity or expression of the Mena protein and thereby reverse the Mena-dependent cancer phenotypes of drug resistance, tumor cell invasion, dissemination, and metastasis. In targeting the movement of tumor cells from the primary site to distant sites, we are directly addressing the major contributor to the deaths of cancer patients. Since elevated expression of Mena protein isoforms also drives resistance to certain RTK inhibitors and cytotoxic chemotherapeutics, co-administration of an effective anti-Mena therapeutic provides an opportunity to expand the utility and effectiveness of these drugs by addressing a significant challenge to the clinical management of advanced cancers. These drugs are widely used to treat a number of types of cancer including ovarian, breast, lung cancer, squamous cell carcinoma of the lung, colorectal cancer, Kaposi's sarcoma, cervical cancer and pancreatic cancer.

Diagnostics (Dx)

Mena^{INV} Assay

We are currently developing a MenaINV assay for use as both a companion diagnostic and prognostic diagnostic. The MenaINV assay is currently undergoing analytical validation. The MenaINV assay is a tissue-based QIF assay that measures expression levels of the MenaINV protein isoform and is broadly applicable to many epithelial-based solid tumors, including breast, lung, colorectal and prostate cancers, among others. The MenaINV protein isoform is key potentiator and modulator of cellular phenotype and behavior, including increasing cell chemotaxis, motility, migration and invasiveness and are central to the metastatic cascade. Overexpression of MenaINV and down regulation of Mena11a in tumor cells correlate with increased metastatic potential and decreased overall survival.

Mechanism-of-action for use as a companion diagnostic to predict RTK inhibitor drug response

Mena participates in a mechanism that attenuates RTK signaling by interacting with the tyrosine phosphatase PTP1B and the 5‟ inositol phosphatase SHIP2. Elevated expression of Mena^{INV} disrupts this regulation, and results in a pro-metastatic phenotype characterized by increased RTK activation signaling from low ligand stimulation and resistance to targeted RTK inhibitors.

A main limitation of therapies that selectively target kinase signaling pathways is a significant number of patients do not respond and for those patients that do respond the emergence of secondary drug resistance after an initial benefit. We believe the Mena^{INV} assay has the potential to be used as a highly actionable clinical biomarker and/or companion diagnostic to predict response to targeted RTK inhibitors.

Mechanism-of-action for use as a companion diagnostic to predict anti-microtubule drug response

Taxane-based drugs, including paclitaxel and docetaxel are widely used and highly efficacious as single chemotherapy agents or in combination with other chemotherapeutic drugs to treat breast, lung, ovarian, pancreatic and other cancers. Side effects associated with taxane-based treatment include bone marrow suppression, nausea, vomiting, hair loss and peripheral neuropathy. Taxanes interfere with the normal breakdown of microtubules which are critical cytoskeletal structures that mediate cell division. The primary building block of microtubules is tubulin and TBAs such as taxanes, which are potent anti-mitotic agents that inhibit cellular growth, drug binding, and/or cell signaling. The Mena protein participates in a mechanism of dynamic cytoskeletal changes through actin polymerization allowing for active cell motility and thus invasion. Taxane-based chemotherapeutic treatments act to stabilize cytoskeletal elements thus preventing active mitosis (cell division) and/or motility (cell movement). *In vitro* and *in vivo* studies have demonstrated increased expression of the Mena protein isoforms desensitize cells to taxane-based treatments.

There is a significant clinical need to develop biomarkers that predict response to initial treatment or the development of secondary resistance to taxane-based chemotherapy, while minimizing the risk of unnecessary side effects. We believe the Mena^{INV} assay has the potential to be used as a highly actionable clinical biomarker and/or companion diagnostic to predict response to taxane-based drugs.

Liquid blood-based biopsy

There is excitement within the oncology community about the promise of liquid biopsy assays for their potential to improve cancer diagnosis and optimize patient care. Should the prognostic and predictive role of MenaINV be clinically validated using FFPE tissue for patients treated with RTKs and taxane-based chemotherapies, we believe there will be a compelling need for the development of a blood-based version of the MenaINV assay. In addition to allowing for repeat non-invasive testing, a blood-based MenaINV test would be especially useful for patients with advanced cancer undergoing multiple cycles of treatment to predict initial drug response or the development of secondary resistance. We intend to evaluate the potential for developing the blood-based version of the MenaINV assay through collaborative research and development partnerships with companies developing compatible exosome and/or circulating tumor cell (CTC) technology platforms.

MenaCalc™ Assay

The MenaCalc™ test has been analytically validated under CLIA, tested in 3 clinical studies in over 1,400 patients, and is available for clinical use in most states. The MenaCalc™ assay is being developed as a prognostic diagnostic and intended for all patients with early stage invasive breast cancer, independent of molecular subtype and other clinical factors, including nodal status. This includes triple negative (TNC), and HER2-positive breast cancer patients, for whom there are no clinically available diagnostic assays. The MenaCalc™ test is also intended for all patients with early stage squamous cell carcinoma of the lung.

The MenaCalc™ assay is a tissue-based QIF assay which measures expression levels of the Mena protein and the non-invasive isoform $Mena^{11a}$. The Mena protein and its isoforms are key potentiators and modulators of cellular phenotype and behavior, including increasing cell chemotaxis, motility, migration and invasiveness and are central to the metastatic cascade. Mena is expressed in multiple isoforms, including $Mena^{INV}$ and $Mena^{11a}$. Overexpression of $Mena^{INV}$ and down regulation of $Mena^{11a}$ in tumor cells correlate with increased metastatic potential and decreased overall survival.

MenaCalc™ Clinical Studies

In September 2012, the positive results of a combined 797 (cohort 1 with 501 and cohort 2 with 296) breast cancer patient clinical study using the MenaCalc™ assay on tissue microarrays (TMAs) were published in *Breast Cancer Research* (Agarwal *et al*., 2012). The prognostic impact of MenaCalc™ using 20-year follow-up for association with risk of disease-specific death was tested. Results showed that relatively high MenaCalc™ scores are associated with poor outcome in two independent cohorts (P=0.0004 for cohort 1 and P=0.0321 for cohort 2). Multivariate analysis on the combined cohorts of 797 patients revealed that high MenaCalc™ scores are associated with poor outcome, independent of age, node status, receptor status and tumor size. MenaCalc™ retained its prognostic value such that patients in the highest quartile had a 60% increase in risk of breast cancer death compared to those in the lowest three quartiles [HR=1.597 (95% CI = 1.2-2.13); P=0.0015]. The linear trend in risk across MenaCalc™ scores was statistically significant [HR=1.211 (95% CI = 1.08-2.36); P=0.00164]. The conclusion from this study is that MenaCalc™ can be used successfully to stratify patients into high and low-risk for developing metastasis and may have value in node-positive and ER-negative breast cancer patients.

In April 2015, we presented positive results from a clinical study of 201 patients demonstrating MenaCalc™ as an independent prognostic factor and predictor of metastasis in patients with early stage NSCLC at the American Association for Cancer Research (AACR) Annual Meeting 2015. Results from this study demonstrated that MenaCalc™ scores were significantly (p=0.001) higher in patients with Squamous Cell Carcinoma (N=32) as compared to other subtypes. High MenaCalc™ scores were associated (10% significance level) with decrease 5-year disease specific survival in all patients [HR=1.78 (95% CI: 0.92-3.43); P=0.08], and were significantly associated with survival when either corrected for histological subtype [HR=2.10 (95% CI: 1.04-4.26); P=0.04] or in the squamous-only population [HR=6.60 (95% CI: 1.22-53.75); P=0.04].

In June 2015, positive results from a clinical study of MenaCalc™ in patients with axillary node negative (ANN) invasive breast cancer was published in *BMC Cancer* (Forse *et al.*, 2015). Data from this study confirmed earlier results that MenaCalc™ scores are a strong predictor of disease-specific overall survival in patients with node-negative invasive breast cancer (P=0.0199), and had good performance in a subset of patients who did not receive hormone or chemotherapy (P=0.0052). This clinical study of 403 patients, compared 261 women who received adjuvant treatment (chemotherapy and/or hormone therapy) to 142 patients did not received adjuvant treatment. Women who had high MenaCalc™ scores had a 2.2-fold greater risk of death compared to patients with low MenaCalc™ scores (P=0.0199) when controlled for other traditional clinical factors. A similar association was found with the subgroup who did not receive adjuvant treatment P=0.0353; n=142), but as expected, the association with patients who received adjuvant treatment was not significant, providing preliminary evidence that patients with high MenaCalc™ scores may benefit from added therapy.

In January 2016, we announced positive results from the analytic validation study of our fully-automated commercial MenaCalc™ assay, which confirmed the test's overall assay performance and precision. In this study, we assessed the overall assay performance, imaging, and scoring performance of our commercial MenaCalc™ test using FFPE tissue samples (n=28) from patients with invasive breast cancer. The MenaCalc™ test demonstrated strong assay performance (day-to-day reproducibility) as measured by linear regression analysis showing Pearson's R greater than 0.85 and linear slopes greater than 0.98 with a mean %CV of 2.3% (Range 0.07-6.95). Further, imaging and scoring performance (run-to-run precision) was also highly precise with Pearson's R and linear slopes greater than 0.99 as well as %CV of 0.45% (Range 0.02-2.32).

MetaSite Breast™ Assay

The MetaSite *Breast*™ test has been analytically validated under CLIA, tested in 6 clinical studies in over 1,700 patients, and is available for clinical use in most states. The MetaSite *Breast*™ test is a tissue-based immunohistochemistry, or IHC assay performed on formalin-fixed paraffin-embedded, or FFPE tissue from a biopsy that directly identifies and quantifies the active sites of the metastatic process. The MetaSite *Breast*™ test is intended for patients with early stage (stage 1-3) invasive breast cancer who have node-negative or node-positive (1-3), ER-positive, HER2-negative disease.

Mechanism of action for use as a prognostic diagnostic to predict risk of cancer metastasis

In order for breast cancer tumor cells to enter a blood vessel (intravasate), three types of cells must self-assemble in apposition to each other in individual three-cell structures. This structure termed a "MetaSite™", is composed of an endothelial cell (cells that lines blood vessels), a perivascular macrophage (a type of immune cell), and a tumor cell that expresses the Mena protein. We have demonstrated in clinical studies that the number of MetaSites™ correlates with increased risk of cancer metastasis.

MetaSite Breast™ Clinical Studies

In April 2009, the positive results of a clinical study using the MetaSite *Breast*™ assay on patient tumor samples with invasive breast cancer was published in *Clinical Cancer Research* (Robinson*, et al.*, 2009). In this case-controlled 5-year retrospective study, a cohort of 60 patients with invasive ductal breast carcinoma, including 30 patients who developed metastatic disease was studied using the MetaSite *Breast*™ assay. The results from this study demonstrated MetaSite™ score density was statistically significantly greater in patients who subsequently developed systemic metastasis compared with the patients who had only localized breast cancer (median, 105 vs. 50, respectively; P=0.00006). For every 10-unit increase in MetaSites™ the odds ratio of systemic metastasis increased by 1.9 (95% confidence interval, 1.1-3.4). The number of MetaSites™ observed per patient ranged from 12 to 240 and the odds of metastasis nearly doubled for every increase of 10 MetaSites™. Importantly, the MetaSite™ score density was not correlated with tumor size, lymph node metastasis, lymphovascular invasion, or hormone receptor status.

In August 2014, the positive results of a 481-patient clinical study demonstrating the prognostic utility of the MetaSite *Breast*™ assay was published in the *Journal of the National Cancer Institute* (Rohan *et al.*, 2014) In a case-controlled nested prospective-retrospective study, a cohort of 3,760 patients was examined with invasive ductal breast carcinoma diagnosed between 1980 and 2000 and followed through 2010. The association between the MetaSite™ score from the MetaSite *Breast*™ assay and risk of distant metastasis was prospectively examined. A total of 481 blocks representing 259 case-controlled pairs were usable and selected for inclusion in this study. Control and case subjects had very similar distributions with respect baseline characteristics such as age and tumor size. Results from this study demonstrated a statistically significant association between increasing MetaSite™ score and risk of metastasis in the ER-positive, HER2-negative subpopulation (N=295) (OR high vs. low tertile = 2.70, 95% CI=1.39 to 5.26, Ptrend 0.004; OR per 10-unit increase in MetaSite™ score = 1.16, 95% CI = 1.03 to 1.30). The absolute risk of distant metastasis for the low, medium and high-risk groups was estimated to be 5.9% (95% CI=5.1-6.9%), 14.1% (95% CI=13.0-15.0%), and 30.3% (95% CI=26.1-35.4%), respectively. Statistical significance was not achieved in the triple negative (TNC) (N=98) or HER2-positive subpopulations (N=75). The conclusion from this study was the MetaSite™ score predicted the risk of distant metastasis in ER-positive, HER2-negative breast cancer patients independently of traditional clinicopathologic features such as age and tumor size.

In September 2015, we announced topline data from a prospectively defined case-controlled nested cohort of 3,760 patients with invasive ductal carcinoma of the breast diagnosed between 1980 and 2000 followed through 2010 from the Kaiser Permanente Northwest health care system. Of the 3,760 patients treated in this cohort, we received 573 breast cancer tissue blocks of which 481, representing 259 case-controlled pairs, were usable and included in the study. In this study, the MetaSite *Breast*™ Score was found to be significantly and directly associated with increased risk of distant metastasis in ER-positive, HER2-negative invasive breast cancer for both high (>35 MetaSites™) versus low (<12 MetaSites™) MetaSite™ scores (OR = 3.4; 95% CI = 2.8-4.1; P=0.0002) as well as between intermediate (12-35 MetaSites™) and low MetaSite™ scores (OR=3.24; 95% CI = 2.6-3.9; P=0.0006). This study demonstrated the MetaSite *Breast*™ Score predicted risk of distant metastasis in ER-positive, HER2-negative early stage invasive breast cancer independent of traditional clinical factors. Data from this study was presented at the San Antonio Breast Cancer Symposium (SABCS) in December 2016.

In December 2015, we presented results from the analytic validation study of our fully-automated commercial MetaSite *Breast*™ assay at the Tumor Metastasis meeting of the American Associations for Cancer Research (AACR). The reliability of our commercial MetaSite *Breast*™ test was supported by confirming the test's analytical accuracy, reproducibility, and precision. Reproducibility across operators, instruments and different sections of a tumor sample ranged from 91% to 97% and analytical precision was found to be greater than 97% with a mean percent coefficient of variation (%CV) of 6.6% (n=35). Our commercial MetaSite *Breast*™ assay showed a high degree of analytical accuracy with the reference standard with AUCs of 0.84 and 0.90 for low and high risk cut-points, respectively. The gold standard method was originally developed at AECOM, where results from their study published in August 2014 in the *Journal of the National Cancer Institute* (Rohan *et al*., 2014) demonstrated the number of MetaSites™ in tumors was predictive of metastatic disease in ER-positive breast cancer.

In December 2016, Dr. Joseph Sparano, principal investigator for MetaStat's ECOG 2197 Cohort Study, presented study results at the 39th annual San Antonio Breast Cancer Symposium (SABCS). In this study, MetaSite *Breast*™ test was prognostic for distant metastatic recurrence within 5 years and provided complementary prognostic and potentially clinically actionable information to the low/mid-range Recurrence Score from Genomic Health's Oncotype DX, breast cancer test. The ECOG 2197 Cohort Study is a prospectively designed retrospective study (n=600) in an independent cohort of ESBC patients treated with surgery, 4 cycles of adjuvant chemotherapy (doxorubicin 60 mg/m2 and cyclophosphamide 600 mg/m2 (AC) or docetaxel 60 mg/m2 (AT)) and endocrine therapy. Results from this study revealed a significant positive association between continuous MetaSite Score and distant recurrence-free interval (DRFI) p=0.001 and recurrence-free interval (RFI) p=0.00006 in HR-positive HER2-negative disease in years 0-5 and by MetaSite Score tertiles for DRFI (p=0.04) and RFI (p=0.01). Proportional hazards models including clinical covariates (N0 vs. N1; T1 vs. T2; high vs. int. vs. low grade) also revealed significant positive associations for continuous MetaSite Score with RFI (p=0.04), and borderline association with DRFI (p=0.08). Importantly, MetaSite *Breast*™ provided useful prognostic information beyond the Genomic Health's Oncotype DX Recurrence Score. Patients with high MetaSite Score (MS>17) and low Recurrence Score (RS<18) results had 9.7-fold greater risk (HR=9.7, 95%CI 1.8-54.1) of distant metastasis compared to patients with low MetaSite Score (MS<6) results. Patients with intermediate MetaSite Score (MS=6-17) and low Recurrence Score (RS<18) results had approximately 4.7-fold greater risk (HR=4.7, 95%CI=0.9-24.2) of distant metastasis compared to patients with low MetaSite Score (MS<6) results.

In December 2016, we presented results from the Kaiser Permanente Cohort Study conducted by MetaStat, that demonstrated MetaSite Score was a statically significant predictor of distant metastasis and a binary cutpoint was able to discriminate high and low risk patient groups when adjusted for clinical factors. Independent verification and clinical validation of MetaStat's fully automated and analytically validated tissue-based MetaSite *Breast*™ test for risk of cancer metastasis in HR-positive HER2-negative ESBC. The Kaiser Permanente Cohort Prognostic Study is a case-control nested cohort of 3,760 patients diagnosed with ESBC from the Kaiser Permanente Northwest Health Care System in which 464 tumor samples were tested using the MetaSite *Breast*™ assay. MetaSite Score was a statistically significant predictor of distant metastasis (p=0.039) in patients with HR-positive HER2-negative disease. Using predefined cutpoints based on tertiles for the control group in the overall study population (n=282), MetaSite Score was significantly associated with distant metastasis for the high (MS>41) versus low (MS<13) score tertiles (OR=2.94; 95%CI=1.62-5.41, P=0.0005) and the intermediate (MS=13-41) versus low score tertiles (OR=2.24; 95%CI=1.23-4.13, P=0.009). A binary cut-point for the high-risk group (MS>14) was significant with a 2-fold higher risk (OR=2.1, 95%CI=1.06-3.96) of distant metastasis versus the low risk group and adjusted for clinical covariates (P=0.036).

Competition

The life sciences, biotechnology and molecular diagnostic industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary technologies and products. Any therapeutic, companion diagnostic and prognostic diagnostic product candidates that we are able to successfully develop and commercialize will compete with both existing therapies and diagnostics and new therapies and diagnostics that may become available in the future. While we believe that our technology and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical, specialty pharmaceutical and biotechnology companies, both large and small molecular diagnostic companies, academic institutions and governmental agencies and public and private research institutions, among others.

We plan to compete in segments of the pharmaceutical, biotechnology and other related markets that pursue personalized medicine approaches to treating cancer. There are many companies presently developing therapies for cancer in the field of precision medicines, including divisions of large pharmaceutical companies, specialty pharmaceutical and biotechnology companies of various sizes, including Pfizer Inc., Merck & Co., Inc., Novartis Pharmaceuticals Corp., F. Hoffmann-La Roche Ltd, Bristol-Myers Squibb Company, Eli Lilly and Company, AstraZeneca, PLC, Amgen, Inc., Biogen, Inc., Genentech, Inc., Celgene Corp., Bayer AG, Takeda Pharmaceutical Company Limited, through its wholly owned subsidiary ARIAD Pharmaceuticals, Inc., Clovis Oncology, Inc., Ignyta, Inc., and Deciphera Pharmaceuticals LLC, among many others.

We believe our main diagnostic competition will be from a number of private and public companies that offer molecular diagnostic tests, including gene profiling and expression in multiple cancers indications, including companies such as Genomic Health, Inc., Agendia Inc., BioTheranostics, Inc., Exact Sciences, Inc. GenomeDx Biosciences Inc., Hologic Inc., Myriad Genetics, Inc., NanoString Technologies Inc., NeoGenomics, Inc., Novartis AG, Qiagen N.V., Roche Diagnostics, a division of Roche Holding, Ltd, Siemens AG, Veridex LLC, a Johnson & Johnson company, Celera Corporation, and GE Healthcare, a business unit of General Electric Company, as well as others. Commercial laboratories, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, with strong distribution networks for diagnostic tests, may also compete with us. We may also face competition from Illumina, Inc. and Thermo Fisher Scientific Inc., both of which have announced their intention to enter the clinical diagnostics market as well as other companies and academic and research institutions. We may also face completion from companies focused on liquid biopsies and pan-cancer clinical diagnostics, such as Danaher Corporation and its Cepheid, Inc. subsidiary, Foundation Medicine, Inc., Guardant Health, MDxHealth, Inc., Metamark Inc., Natera Inc. and Response Genetics, Inc., among many others.

Our competitors may develop and market therapeutic, companion diagnostic and prognostic diagnostic products or other novel technologies that are more effective, safer, more convenient or less costly than any that may be commercialized by us, or may obtain regulatory approval for their products more rapidly than we may obtain approval for ours. Many of our present and potential competitors have widespread brand recognition, distribution and substantially greater financial and technical resources and development, production and marketing capabilities than we do. If we are unable to compete successfully, we may be unable to gain market acceptance and therefore revenue from our therapeutics and diagnostics may be limited.

Patents and Intellectual Property

We believe that clear and extensive patent coverage and protection of the proprietary nature of our technologies is central to our success. Our intellectual property strategy is intended to develop and maintain a competitive position and long-term value through a combination of patents, patent applications, copyrights, trademarks, and trade secrets. We have invested and will continue to invest in our intellectual property portfolio, which has been partially accomplished in conjunction with the resources of our Licensors. This applies to both domestic and international patent coverage.

Three (3) patents and allowance of claims pursuant to a divisional patent application in the United States, and three (3) international patents have been issued covering key aspects of our core driver-based biomarker technologies for epithelial-based solid tumors including breast, lung, prostate and colorectal. The issued patents are listed below:

1. U.S. Patent No. 8,642,277, entitled "Tumor Microenvironment of Metastasis (TMEM) and Uses Thereof in Diagnosis, Prognosis, and Treatment of Tumors;" Inventors: Frank Gertler, John Condeelis, Thomas Rohan, and Joan Jones; assigned to MIT, Cornell and AECOM;

2. U.S. Patent No. 8,603,738, entitled "Metastasis specific splice variants of Mena and uses thereof in diagnosis, prognosis and treatment of tumors;" Inventors: John Condeelis, Sumanta Goswami, Paola Nistico, and Frank Gertler; assigned to AECOM, IFO and MIT;

3. U.S. Patent No. 8,298,756 entitled "Isolation, Gene Expression, And Chemotherapeutic Resistance of Motile Cancer Cells;" Inventor: John S. Condeelis;

4. U.S. Divisional Application No. 14/074,089, entitled "Metastasis specific splice variants of Mena and uses thereof in diagnosis, prognosis and treatment of tumors;" Inventors: John Condeelis, Sumanta Goswami, Paola Nistico, and Frank Gertler; assigned to AECOM, IFO and MIT;

5. European Patent No. 1784646 entitled "Methods for Identifying Metastasis in Motile Cells;" Inventor: John S. Condeelis;

6. European Patent No. 2126566 B1 entitled "Metastasis specific splice variants of Mena and uses thereof in diagnosis, prognosis and treatment of tumors;" Inventors John S. Condeelis, Sumanta Goswami, Frank Gertler, and Paola Nisticò.

7. Canadian Patent No. 2,676,179 entitled "Metastasis specific splice variants of Mena and uses thereof in diagnosis, prognosis and treatment of tumors;" Inventors: John Condeelis, Sumanta Goswami, Paola Nistico, and Frank Gertler; assigned to AECOM, IFO and MIT.

These patents expire between 2028 and 2031.

We have and intend to continue to file additional patent applications to strengthen our therapeutic and diagnostic intellectual property rights, as well as seek to add to our intellectual property portfolio through licensing, partnerships, joint development and joint venture agreements.

Our employees and key technical consultants working for us are required to execute confidentiality and assignment agreements in connection with their employment and consulting relationships. Confidentiality agreements provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship shall be kept confidential except in specified circumstances. Additionally, our employment agreements provide that all inventions conceived by such employee while employed by us are our exclusive property. We cannot provide any assurance that employees and consultants will abide by the confidentiality and assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our technology or obtain and use information that we regard as proprietary.

License Agreements

In August 2010, we entered into a License Agreement (the "License Agreement") with AECOM, MIT, Cornell and IFO-Regina. The License Agreement covers patents and patent applications, patent disclosures, cell lines and technology surrounding discoveries in the understanding of the underlying mechanisms of systemic metastasis in solid epithelial cancers, including our core diagnostic technologies, including the MetaSite *Breast*™ and MenaCalc™ assays. The License Agreement calls for certain customary payments such as a license signing fee, reimbursement of patent expenses, annual license maintenance fees, milestone payments, and the payment of royalties on sales of products or services covered under the agreement. See "Contractual Obligations" in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section for more information regarding our financial obligations related to the License Agreement.

Effective March 2012, we entered into a second license agreement (the "Second License Agreement") with AECOM. The Second License Agreement covers patent and patent applications, patent disclosures, and other technology surrounding discoveries in the understanding of the underlying mechanisms of systemic metastasis in solid epithelial cancers, including the isolation (capture of), gene expression profile (the "Human Invasion Signature") and chemotherapeutic resistance of metastatic cells. The Second License Agreement requires certain customary payments such as a license signing fee, reimbursement of patent expenses, annual license maintenance fees, milestone payments, and the payment of royalties on sales of products or services covered under such agreements. See "Contractual Obligations" in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section for more information regarding our financial obligations related to the Second License Agreement.

Pursuant to both the License Agreement and the Second License Agreement, we have the right to initiate legal proceedings on our behalf or in the Licensors' names, if necessary, against any infringer, or potential infringer, of a licensed intellectual property who imports, makes, uses, sells or offers to sell products. Any settlement or recovery received from any such proceeding shall be divided eighty percent (80%) to us and twenty percent (20%) to the Licensors after we deduct from any such settlement or recovery our actual counsel fees and out-of-pocket expenses relative to any such legal proceeding. If we decide not to initiate legal proceedings against any such infringer, then the Licensors shall have the right to initiate such legal proceedings. Any settlement or recovery received from any such proceeding initiated by the Licensors shall be divided twenty percent (20%) to us and eighty percent (80%) to the Licensors after the Licensors deduct from any such settlement or recovery their actual counsel fees and out-of-pocket expenses relative to any such legal proceeding.

Effective December 2013, we entered into two separate worldwide exclusive license agreements with MIT and its David H. Koch Institute for Integrative Cancer Research at MIT and its Department of Biology, AECOM, and Montefiore Medical Center ("Montefiore" and, together with MIT and AECOM, the "Alternative Splicing Licensors"). The diagnostic license agreement (the "Alternative Splicing Diagnostic License Agreement") and the therapeutic license agreement (the "Alternative Splicing Therapeutic License Agreement" and, together with the Diagnostic License Agreement, the "2014 Alternative Splicing License Agreements") covers pending patent applications, patent disclosures, and technology surrounding discoveries of alternatively spliced mRNA and protein isoform markers for the treatment and/or prevention of cancer through the epithelial-mesenchymal transition (EMT) in epithelial solid tumor cancers. The 2014 Alternative Splicing License Agreements call for certain customary payments such as a license signing fee, reimbursement of patent expenses, annual license maintenance fees, milestone payments, and the payment of royalties on sales of products or services covered under the agreement. See "Contractual Obligations" in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section for more information regarding our financial obligations related to the Alternative Splicing License Agreements.

Further, pursuant to the 2014 Alternative Splicing License Agreements, we have the right to initiate legal proceedings on our behalf or in the Licensors' names, if necessary, against any infringer, or potential infringer, of any licensed intellectual property who imports, makes, uses, sells or offers to sell products. Any settlement or recovery received from any such proceeding shall be divided 80% to us and 20% to the Licensors after we deduct from any such settlement or recovery our actual counsel fees and out-of-pocket expenses relative to any such legal proceeding. If we decide not to initiate legal proceedings against any such infringer, then the Licensors shall have the right to initiate such legal proceedings. Any settlement or recovery received from any such proceeding initiated by the Licensors shall be divided 20% to us and 80% to the Licensors after the Licensors deduct from any such settlement or recovery their actual counsel fees and out-of-pocket expenses relative to any such legal proceeding.

Effective June 2014, we entered into a License Agreement (the "Antibody License Agreement") with MIT. The Antibody License Agreement covers proprietary technology and know-how surrounding monoclonal and polyclonal antibodies specific to the Mena protein and its isoforms. The Antibody License Agreement calls for certain customary payments such as a license signing fee, reimbursement of patent expenses, annual license maintenance fees, milestone payments, and the payment of royalties on sales of products or services covered under the agreement. See "Contractual Obligations" in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section for more information regarding our financial obligations related to the Antibody License Agreement.

As part of our intellectual property strategy, we have terminated certain license agreements and patent applications related to non-core technologies.

Partnerships and Collaborations

In connection with our business strategy, we may enter into exclusive and/or non-exclusive research and development and other collaboration or partnership agreements.

Celgene Corporation

On August 22, 2016, we executed a pilot materials transfer agreement (the "MTA") with Celgene Corporation ("Celgene") to conduct a mutually agreed upon pilot research project (the "Pilot Project"). On September 29, 2016, we entered into an amendment (the "Amendment") to the MTA (the "Amendment," and together with the MTA, the "Research Agreement"), which provided for milestone payments to MetaStat of up to approximately $973,000. Under the terms of the Research Agreement, Celgene will provide certain proprietary materials to MetaStat and MetaStat will evaluate Celgene's proprietary materials in its metastatic cell line and animal nonclinical models. See Note 11 for accounting treatment related to the Research Agreement.

Albert Einstein College of Medicine and Montefiore Medical Center

Effective January 9, 2015, we executed a collaboration agreement (the "Collaboration Agreement") with AECOM and Montefiore Medical Center ("Montefiore," and together with AECOM, the "Institutions") to collaborate on research projects (the "Research Projects") including conducting studies that establish the clinical validity and clinical utility of MetaStat's prognostic diagnostic tests, including the MetaSite *Breast*™ test, the MenaCalc™ test, and a combined MetaSite *Breast*™ and MenaCalc™ test. The term of the Collaboration Agreement is five years, which may be terminated by either party with thirty days written notice.

National Institutes of Health, National Cancer Institute

Effective September 21, 2016, we executed an agreement with the National Institutes of Health, National Cancer Institute (the "NCI"), whereby the NCI will contract with MetaStat to perform the MetaSite *Breast*™ and MenaCalc™ analysis of breast cancer tumor tissue as part of a clinical study. In addition, MetaStat will collaborate with the Department of Cancer Epidemiology and Genetics (DCEG) at the NCI on interpretation of the study analysis and dissemination of results.

Government Regulations

Regulation by governmental authorities in the United States, at the federal, state and local level, and in and other countries is a significant factor in the research and development, manufacture, commercialization and marketing of both diagnostic tests and pharmaceuticals.

Diagnostic Regulation

The United States Food and Drug Administration, or the FDA, regulates the sale or distribution, in interstate commerce, of medical devices, including *in vitro* diagnostic test kits or IVDs, such as our companion diagnostics. Devices subject to FDA regulation must undergo pre-market review prior to commercialization unless the device is of a type exempted from such review. Additionally, medical device manufacturers must comply with various regulatory requirements under the Federal Food, Drug and Cosmetic Act, or FDCA, and regulations promulgated under that Act, including quality system review regulations, unless exempted from those requirements for particular types of devices. Entities that fail to comply with FDA requirements can be liable for criminal or civil penalties, such as recalls, detentions, orders to cease manufacturing and restrictions on labeling and promotion.

Clinical laboratory services, such as our prognostic diagnostic tests are currently not subject to FDA regulation, but IVDs and analyte-specific reagents and equipment used by these laboratories may be subject to FDA regulation. Clinical laboratory tests that are developed and validated by a laboratory for use in examinations the laboratory performs itself are called "home brew" tests or more recently, Laboratory Developed Tests, or LDTs. LDTs are subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA.

Beginning in January 2006, the FDA began indicating its belief that LDTs were subject to FDA regulation as devices and issued a series of guidance documents intending to establish a framework by which to regulate certain laboratory tests. In September 2006, the FDA issued draft guidance on a new class of tests called "In Vitro Diagnostic Multivariate Index Assays", or IVDMIAs. Under this draft guidance, specific tests could be classified as either a Class II or a Class III medical device, which may require varying levels of FDA pre-market review depending on intended use and the level of control necessary to assure the safety and effectiveness of the test. In July 2007, the FDA posted revised draft guidance that addressed some of the comments submitted in response to the September 2006 draft guidance. In May 2007, the FDA issued a guidance document "Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis." This guidance document was developed to support the classification of gene expression profiling test systems for breast cancer prognosis into Class II. In addition, the Secretary of the Department of Health and Human Services, or HHS, requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetics testing. A final report was published in April 2008. In June 2010, the FDA announced a public meeting to discuss the agency's oversight of LDTs prompted by the increased complexity of LDTs and their increasingly important role in clinical decision making and disease management. The FDA indicated that it is considering a risk-based application of oversight to LDTs. The public meeting was held in July 2010 and further public comments were submitted to the FDA in September 2010. In June 2011, the FDA issued draft guidance regarding "Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only," which was finalized in November 2013.

In October 2014, the FDA published two draft guidance documents that, if finalized, would implement a regulatory approach for most

LDTs. In the draft guidance documents, the FDA stated that it had serious concerns regarding the lack of independent review of the evidence of clinical validity of LDTs and asserted that the requirements under CLIA do not address the clinical validity of any LDT. The draft guidance documents proposed to impose a risk-based, phased-in approach for LDTs similar to the existing framework for *in vitro* diagnostic devices. On November 18, 2016, the FDA announced that it would not finalize the draft guidance documents for LDTs prior to the end of the Obama administration. The decision of whether and how to proceed with the draft guidance will be left to the Trump administration, which began on January 20, 2017.

In January 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining a possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. In the discussion paper, the FDA states that there is "a growing consensus that additional oversight of LDTs is necessary." Similar to the FDA's 2014 draft guidance, the FDA's discussion paper proposes a risk-based framework that would require most LDTs to comply with most of the FDA's regulatory requirements for medical devices. Unlike the draft guidance, however, the discussion paper proposes to exempt currently marketed LDTs from premarket review, requiring only new or modified tests to be approved or cleared by the agency. In addition, the FDA proposed requiring LDTs to comply with only a subset of the medical device Quality System Regulation, or QSRs and proposed other changes from the 2014 draft guidance. We cannot predict whether the FDA will take action to regulate LDTs under the new administration or what approach the FDA will seek to take.

Legislative proposals have been introduced in Congress or publicly circulated, each of which would implement differing approaches to the regulation of LDTs. We cannot predict the ultimate form of any such guidance or regulation and the potential impact on our prognostic diagnostic tests or materials used to perform our prognostic diagnostic tests. If pre-market review is required, our business could be negatively impacted until such review is completed and clearance to market or approval is obtained. FDA could require we seek pre-market clearance or approval for tests currently under development delaying product commercialization or following product launch to require that we stop selling our tests. If our tests are allowed to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are limited, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance notice or filing a pre-market application, or PMA with the FDA. If pre-market review is required by the FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by the FDA and to the requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

While we expect all materials used in our tests to qualify according to CLIA regulations, we cannot be certain that the FDA might not enact rules or guidance documents which could impact our ability to purchase materials necessary for the performance of our tests. Should any of the reagents obtained by us from vendors and used in conducting our tests be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

Regulation of Medical Devices and In Vitro Diagnostic Devices (IVDs) – Companion Diagnostics

We may seek to develop or seek to partner with third parties to develop *in vitro* companion diagnostics for use in selecting the patients that we believe will respond to certain drugs. We expect our Mena protein isoform companion diagnostic tests will be regulated by the FDA as an IVD, companion diagnostic. As defined by the FDA, an IVD companion diagnostic is a medical device that provides information that is essential for the safe and effective use of a corresponding drug or biological product. An IVD companion diagnostic helps a health care professional determine whether a therapeutic product's benefits to patients will outweigh any potential side effects or risks.

In August 2014, the FDA issued guidance that addresses issues critical to developing *in vitro* companion diagnostics. The guidance states that if safe and effective use of a therapeutic product depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the drug therapeutic and *in vitro* companion diagnostic device on issues related to co-development of the products. The FDA generally requires *in vitro* companion diagnostics intended to select the patients intended to receive a cancer treatment to obtain approval of a PMA approval, for that diagnostic simultaneously with approval of the drug.

To be commercially distributed in the United States, a medical device, including IVDs, must receive either 510(k) clearance, de novo authorization, or PMA approval from the FDA prior to marketing. There are three classes of medical devices recognized by the FDA, Class I (low risk), Class II (moderate risk), and Class III (high risk).

Class I devices are those for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR, requirements, facility registration and product listing; reporting of adverse medical events or AEs; and appropriate, truthful, and non-misleading labeling, advertising and promotional materials. Many Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) premarket notification process discussed below.

Class II devices are subject to the FDA's general controls, and any other special controls, such as performance standards, post-market surveillance, and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for Class II devices are accomplished through the 510(k) premarket notification procedure, although some Class II devices are exempt from the 510(k) requirements. Premarket notifications are subject to user fees, unless a specific exemption applies. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device, which is a previously cleared 510(k) device or a preamendment device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of a PMA. In determining substantial equivalence, the FDA assesses whether the proposed device has the same intended use and technical characteristic as the predicate device, or whether the proposed device has different technological characteristics, but the information submitted in the premarket notification demonstrates the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device. The FDA may request additional information, including clinical data. Under the FDCA, a manufacturer must submit a premarket notification at least 90 days before introducing a device into interstate commerce, but the FDA's review of the premarket notification can take significantly longer. If the FDA determines that the device is substantially equivalent to the predicate device(s), the subject device may be marketed. However, if the FDA determines that a device is not substantially equivalent to the predicate device(s), then the device would be regulated as a Class III device, discussed below. If a manufacturer obtains a 510(k) clearance for its device and then makes a modification that could significantly affect the device's safety or effectiveness, a new premarket notification must be submitted to the FDA.

Class III devices are those deemed by the FDA to pose the greatest risk, such as those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above and that are life-sustaining or life-supporting. Some preamendment Class III devices for which the FDA has not yet required a PMA require the FDA's clearance of a premarket notification in order to be marketed. However, most Class III devices are required to undergo the PMA process in which the manufacturer must demonstrate reasonable assurance of the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must provide valid scientific evidence, typically extensive preclinical and clinical trial data, and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. PMA applications (and supplemental PMA applications) are subject to significantly higher user fees than 510(k) premarket notifications. Some PMA applications are exempt from a user fee, for example, a small business's first PMA.

A PMA for an IVD typically includes data from preclinical studies and well-controlled clinical trials. Preclinical data for an IVD includes many different tests, including how reproducible the results are when the same sample is tested multiple times by multiple users at multiple laboratories. The clinical data need to establish that the test is safe and effective for the proposed intended use in the indicated population. In addition, the PMA must include information regarding the test's clinical utility, meaning that an IVD provides information that is clinically meaningful. Such information must be provided even if the clinical significance of the biomarker is obvious. The applicant may also rely upon published literature or submit data to the FDA to show clinical utility.

A PMA also must provide information about the device and its components regarding, among other things, device design, manufacturing and labeling. The sponsor must pay an application fee to the FDA upon submission of a PMA, which is approximately $250,000 for 2017.

As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose elaborate testing, control, documentation and other quality assurance procedures.

Upon submission, the FDA determines if the PMA is sufficiently complete to permit a substantive review, and, if so, the FDA accepts the application for filing. The FDA then commences an in-depth review of the PMA. The entire process can typically take multiple years from submission of the PMA to approval, but may take longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided. The FDA also may respond with a not approvable determination based on deficiencies in the PMA application and require additional clinical trial or other data that are often expensive and time-consuming to generate and can substantially delay approval.

During the review period, an FDA advisory committee, typically a panel of clinicians, may be convened to review the PMA application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision-making process.

If the FDA's evaluation of the PMA is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA approval for the approved indications, which can be more limited than those originally sought by the applicant. The PMA approval can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in an enforcement action, including the loss or withdrawal of the approval.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to the information needed to support the proposed change from the product covered by the original PMA.

After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. The FDA also may convene an advisory panel of outside experts to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA generally will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR. The FDA can delay, limit, or deny approval of a PMA application for many reasons.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: public warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of products, operating restrictions, partial suspension or total shutdown of production, delays in or denial of 510(k) clearance or PMA applications for new products, challenges to existing 510(k) clearances or PMA applications, and a recommendation by the FDA to disallow a device manufacturer from entering into government contracts. The FDA also has the authority to request repair, replacement, or refund of the cost of any device manufactured or distributed. In the event that a supplier fails to maintain compliance with a device manufacturer's quality requirements, the manufacturer may have to qualify a new supplier and could experience manufacturing delays as a result.

We believe that products we may develop in the future for use as companion diagnostic tests are likely to be regulated as Class III devices requiring PMA approval.

Clinical Trials and IDEs

A clinical trial is almost always required to support a PMA. For significant risk devices, the FDA regulations require that human clinical investigations conducted in the U.S. be approved via an Investigational Device Exemption, or IDE, which must be approved before clinical testing may commence. In some cases, one or more smaller IDE studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device. A 30-day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. The FDA may disapprove, or approve with conditions, the IDE within the 30-day period. If disapproved, the clinical trial may not begin until the deficiencies noted by the FDA are addressed, and another IDE is submitted to the FDA for approval. If approved with conditions, the sponsor must address the conditions prior to commencement of the trial. If the FDA does not respond to the sponsor within the 30-day period, the IDE is deemed approved and the clinical study may commence.

IVD trials usually do not require an IDE approval, so long as, among other things, the results of the IVD test are not used diagnostically without confirmation of the test results by another, medically established diagnostic product or procedure. For a trial where the IVD result directs the therapeutic care of patients with cancer, we believe that the FDA would likely consider the investigation to require an IDE application.

An IDE application must be supported by appropriate data, such as laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. The FDA typically grants IDE approval for a specified number of patients. All clinical studies of investigational devices, regardless of whether IDE approval is required, require approval from an institutional review board, or IRB.

During the clinical trial, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and record keeping requirements. These IDE requirements apply to all investigational devices, whether considered significant or nonsignificant risk. Prior to granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA for compliance with applicable requirements.

Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at a study site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Investigational IVDs may only be distributed for use in an investigation, and the labeling must prominently contain the statement "For Investigational Use Only. The performance characteristics of this product have not been established."

Expedited Access Pathway Program

In April 2015, the FDA issued a final guidance document establishing the Expedited Access Pathway, or EAP program. The EAP program is intended to speed patient access to devices (including companion diagnostics) that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions and are subject to PMA approval or de novo authorization. In order to be accepted into the EAP program, a sponsor must demonstrate to the FDA's satisfaction that the device is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition and that it addresses an unmet need. The sponsor must also submit an acceptable draft Data Development Plan. Once accepted into the program, the FDA intends to engage with sponsors of EAP devices earlier and more interactively during the device's development, assessment, and review. The FDA will also work with the device sponsor to try to reduce the time and cost from development to an approval decision. Elements of the EAP program may include priority review, interactive review, senior management involvement, and assignment of a case manager.

Post-Market Device Regulation

After a device obtains FDA approval and is on the market, numerous regulatory requirements apply. These requirements include the QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off-label" uses, the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur, and the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA.

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines, injunctions and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for PMA approval of new products; withdrawing PMA approvals already granted; and criminal prosecution.

Clinical Laboratory Improvement Amendments of 1988, or CLIA – Prognostic Diagnostics

LDTs, such as our prognostic diagnostic tests, are subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and are not currently regulated as medical devices under the FDCA. Under CLIA, a laboratory is any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. We have a current certificate of accreditation under CLIA to perform high complexity testing of our prognostic diagnostic tests for breast cancer, including the MetaSite *Breast*™ and MenaCalc™ assays.

As a clinical reference laboratory as defined under CLIA, we are required to hold a certificate applicable to the type of work we perform and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring they be certified by the federal government and comply with various operational, personnel, facilities administration, quality, and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable, and timely. Laboratories must register and list their tests with The Centers for Medicare & Medicaid Services, or CMS, the agency that oversees CLIA. CLIA compliance and certification is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries and for many private payors. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey cost.

To renew our CLIA certificate, we will be subject to survey and inspection every two years to assess compliance with program standards and may be subject to additional inspections without prior notice. The standards applicable to the testing which we perform may change over time. We cannot assure that we will be able to operate profitably should regulatory compliance requirements become substantially costlier in the future.

If our clinical reference laboratory falls out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. Additionally, we must maintain CLIA compliance and certification to be eligible to bill for tests provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanction, our business would be harmed.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require that laboratories meet certain personnel qualifications, specify certain quality control procedures, meet facility requirements, or prescribe record maintenance requirements.

If regulated by the FDA, we believe that our LDTs would likely be regulated as either Class II or Class III devices. Accordingly, premarket review—either a 510(k), de novo application, or a PMA—would likely be required for our tests if the FDA no longer applies its enforcement discretion to LDTs and our tests do not qualify as grandfathered tests that are exempted from premarket review. While the data requirements are typically greater for Class III devices, the data required for Class II devices has increased, and it is likely that some amount of clinical data (retrospective or prospective or both) would be required for any type of submission to the FDA. Ongoing compliance with FDA regulations would increase the cost of conducting our business, subject us to inspection by the FDA and to the requirements of the FDA and penalties for failure to comply with the requirements of the FDA. We cannot assure you that our current prognostic diagnostic products and other future products will not require 510(k) clearance or PMA approval in the future, or, in such an event, that such approval or clearance would be forthcoming. Should any of the clinical laboratory device reagents obtained by us from vendors and used in conducting our home brew test be affected by future regulatory actions, we could be adversely affected by those actions, including increased cost of testing or delay, limitation or prohibition on the purchase of reagents necessary to perform testing.

Massachusetts and Other States' Laboratory Testing

Our clinical reference laboratory is located in Boston, Massachusetts. Accordingly, we are required to be licensed by Massachusetts, under Massachusetts laws and regulations, as well as CLIA under CMS regulations, which both establish standards for:

- Day-to-day operation of a clinical laboratory, personnel standards including training and competency of all laboratory staff;
- Physical requirements of a facility, including, policies and procedures; and safety;
- Equipment; and
- Quality control, including quality assurance; and proficiency testing.

In 2015, we received the necessary certifications and licenses from both CLIA and Massachusetts for our clinical reference laboratory to perform testing services of our prognostic diagnostic breast cancer tests.

If a laboratory is not in compliance with Massachusetts statutory or regulatory standards, or CLIA regulations as mandated by CMS, the Massachusetts State Department of Health and/or CMS may suspend, limit, revoke or annul the laboratory's Massachusetts license, and CLIA certification, censure the holder of the license or assess civil money penalties. Additionally, statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor. In the event that we should be found not to be in compliance with Massachusetts or CLIA laboratory requirements, we could be subject to such sanctions, which could harm our business.

California, New York, Florida, Maryland, Pennsylvania and Rhode Island require out-of-state laboratories, which accept specimens from those states to be licensed in each state. We have received licensing from Massachusetts, California, Florida, Pennsylvania and Rhode Island and are currently seeking licensing from New York and Maryland.

From time to time, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

Therapeutic Regulation

United States Drug Approval Process

In the United States, the FDA regulates drugs under the FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applying company to a variety of administrative or judicial sanctions.

Before a drug may be marketed in the U.S., the FDA generally requires the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with good laboratory practice, or GLP, regulations;
- submission of an Investigational New Drug or IND application to the FDA, which must become effective before human clinical trials may begin;
- approval of each phase of the proposed clinical trials and related informed consents by an IRB, at each clinical site where such trial will be performed;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, standards and regulations to establish the safety and efficacy of the proposed drug for each indication;
- submission of a New Drug Application, or NDA to the FDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical Studies and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for AEs and, in some cases, to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the safety and effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. In addition, a sponsor must provide information regarding most clinical trials to be disclosed on http://clinicaltrials.gov, a website maintained by the National Institutes of Health.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness;

- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage; and

- Phase 3: The drug is administered to an expanded patient population in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the efficacy and safety of the product for approval for specified indications, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and more frequently if serious adverse events, or AEs occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Pursuant to the 21st Century Cures Act, which was enacted on December 13, 2016, the manufacturer of an investigational drug for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access. This requirement applies on the later of 60 days after the date of enactment or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is subject to a substantial application user fee.

The FDA generally conducts a preliminary review of all NDAs to determine if they are sufficiently complete to permit substantive review within the first 60 days after submission before accepting them for filing. The FDA may request additional information in connection with this preliminary review rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is subject to further review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs. Under these goals, the FDA has committed to review most such applications for non-priority products within 10 months, and most applications for priority review products, that is, drugs that the FDA determines represent a significant improvement over existing therapy, within six months. The FDA may also refer applications for novel drugs or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA is not required to adhere its review time goals, and its review could experience delays that cause those goals to not be met.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval process for each product candidate requires substantial time, effort and financial resources, and each may take many years to complete. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an application for a product candidate on a timely basis, or at all. Further, applicants often encounter difficulties or unanticipated costs in their efforts to develop product candidates and secure necessary governmental approvals, which could delay or preclude the marketing of those products.

After the FDA's evaluation of the NDA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA may then issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the NDA.

Programs for Expedited Review and Approval

The FDA has developed certain programs and designations that enable NDAs for product candidates meeting specified criteria to be eligible for certain expedited review and approval processes such as fast track designation, priority review, accelerated approval, and breakthrough therapy designation. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. These include Fast Track Designation, Priority Review, Accelerated Approval, and Breakthrough Therapy Designation.

In addition to the expedited review and approval programs and designations, the FDA also recognizes certain other designations and alternative approval pathways that afford certain benefits, such as the orphan drug designation and alternative types of NDAs under the Hatch-Waxman Act.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product and for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity, such that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Combination Products

The FDA regulates combinations of products that cross FDA centers, such as drug, biologic or medical device components that are physically, chemically or otherwise combined into a single entity, as a combination product. The FDA center with primary jurisdiction for the combination product will take the lead in the premarket review of the product, with the other center consulting or collaborating with the lead center. The 21st Century Cures Act, or Cures Act, amended the provisions of the FDCA relating to the regulation of combination products to, among other things, require the FDA to conduct the premarket review of any combination product under a single application whenever appropriate.

In practice, the FDA's Office of Combination Products, or OCP, determines which center will have primary jurisdiction for the combination product based on the combination product's "primary mode of action." A mode of action is the means by which a product achieves an intended therapeutic effect or action. The primary mode of action is the mode of action that provides the most important therapeutic action of the combination product, or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

It is often difficult for the OCP to determine with reasonable certainty the most important therapeutic action of the combination product. In those difficult cases, the OCP will consider consistency with other combination products raising similar types of safety and effectiveness questions, or which center has the most expertise to evaluate the most significant safety and effectiveness questions raised by the combination product.

If a combination product sponsor disagrees with OCP's primary mode of action determination, the Cures Act permits the sponsor to request that the FDA provide a substantive rationale for its determination. The sponsor can then propose one or more studies to establish the relevance of the chemical action in achieving the product's primary mode of action and the FDA and the sponsor will collaborate to reach agreement on the design of such studies within 90 calendar days. If the sponsor conducts the agreed-upon studies, the FDA must consider the resulting data when reevaluating the product's primary mode of action.

Post-Market Drug Regulation

If the FDA approves a drug product for commercial marketing, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety and/or other factors after approval, require testing and surveillance programs to monitor the product after commercialization and/or patients using the product for observation of the product's long-term effects, or impose other conditions, including distribution restrictions or other risk management mechanisms, including Risk Evaluation and Mitigation Strategies, or REMS, which can materially affect the potential market and profitability of the product. Any approved product is also subject to requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, labeling, and reporting of adverse experiences with the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and re-approval.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon drug developers and their manufacturers. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences of a failure to comply with regulatory requirements during or after the FDA approval process include, among other things:

- restrictions on the marketing or manufacturing of the product, product recalls or complete withdrawal of the product from the market;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- consent decrees, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Additional Regulations and Environmental Matters

Health Insurance Portability and Accountability Act (HIPAA) and HITECH

Under the administrative simplification provisions the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, the United States Department of Health and Human Services (HHS) issued regulations that establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of protected health information used or disclosed by health care providers and other covered entities, such as MetaStat. Three principal regulations with which we are required to comply have been issued in final form under HIPAA: privacy regulations, security regulations, and standards for electronic transactions, which establish standards for common health care transactions. The privacy and security regulations were extensively amended in 2013 to incorporate requirements from the HITECH Act.

The privacy regulations cover the use and disclosure of protected health information by health care providers and other covered entities. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a health care provider, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored.

The HITECH Act, among other things, established certain protected health information security breach notification requirements. A covered entity must notify affected individual(s) and the HHS when there is a breach of unsecured protected health information. The HIPAA privacy and security regulations establish a uniform federal “floor” that health care providers must meet and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents that is more prescriptive than HIPAA.

These laws contain significant fines and other include civil and criminal penalties for wrongful use or disclosure of protected health information. Additionally, to the extent that we submit electronic health care claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and the HITECH Act, payments to us may be delayed or denied.

We have policies and procedures to comply with these regulations. The requirements under these regulations may change periodically and could have an adverse effect on our business operations if compliance becomes substantially costlier than under current requirements.

In addition to federal privacy regulations, there are a number of state and international laws governing confidentiality of health information that may be applicable to our operations. The United States Department of Commerce, the European Commission and the Swiss Federal Data Protection and Information Commissioner have agreed on a set of data protection principles and frequently asked questions (the "Safe Harbor Principles") to enable U.S. companies to satisfy the requirement under European Union and Swiss law that adequate protection is given to personal information transferred from the European Union or Switzerland to the United States. The European Commission and Switzerland have also recognized the Safe Harbor Principles as providing adequate data protection.

New laws governing privacy may be adopted in the future as well. We have taken steps to comply with health information privacy requirements to which we are aware that we will be subject. However, we can not provide assurance that we will be in compliance with diverse privacy requirements in all of the jurisdictions in which we do business. Failure to comply with privacy requirements could result in civil or criminal penalties, which could have a materially adverse impact on our business.

Federal and State Physician Self-referral Prohibitions

We will be subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, and to similar state restrictions such as the California's Physician Ownership and Referral Act, or PORA. Together these restrictions generally prohibit us from billing a patient or any governmental or private payer for any test when the physician ordering the test, or any member of such physician's immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition. Both the Stark Law and PORA contain an exception for compensation paid to a physician for personal services rendered by the physician. We would be required to refund any payments we receive pursuant to a referral prohibited by these laws to the patient, the payer or the Medicare program, as applicable.

Both the Stark Law and certain state restrictions such as PORA contain an exception for referrals made by physicians who hold investment interests in a publicly traded company that has stockholders' equity exceeding $75 million at the end of its most recent fiscal year or on average during the previous three fiscal years, and which satisfies certain other requirements. In addition, both the Stark Law and certain state restrictions such as PORA contain an exception for compensation paid to a physician for personal services rendered by the physician.

However, in the event that we enter into any compensation arrangements with physicians, we cannot be certain that regulators would find these arrangements to be in compliance with Stark, PORA or similar state laws. In such event, we would be required to refund any payments we receive pursuant to a referral prohibited by these laws to the patient, the payer or the Medicare program, as applicable.

Sanctions for a violation of the Stark Law include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to $15,000 for each service arising out of the prohibited referral;
- possible exclusion from federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty of up to $100,000 against parties that enter into a scheme to circumvent the Stark Law's prohibition.

These prohibitions apply regardless of the reasons for the financial relationship and the referral. No finding of intent to violate the Stark Law is required for a violation. In addition, under an emerging legal theory, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act.

Further, a violation of PORA is a misdemeanor and could result in civil penalties and criminal fines. Finally, other states have self-referral restrictions with which we have to comply that differ from those imposed by federal and California law. It is possible that any financial arrangements that we may enter into with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide assurance that we will be found to be in compliance with these laws following any such regulatory review.

Federal, State and International Anti-kickback Laws

The Federal Anti-kickback Law makes it a felony for a provider or supplier, including a laboratory, to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal health care program. A violation of the Anti-kickback Law may result in imprisonment for up to five years and fines of up to $250,000 in the case of individuals and $500,000 in the case of organizations. Convictions under the Anti-kickback Law result in mandatory exclusion from federal health care programs for a minimum of five years. In addition, HHS has the authority to impose civil assessments and fines and to exclude health care providers and others engaged in prohibited activities from Medicare, Medicaid and other federal health care programs.

Actions which violate the Anti-kickback Law or similar laws may also involve liability under the Federal False Claims Act, which prohibits the knowing presentation of a false, fictitious or fraudulent claim for payment to the United States Government. Actions under the Federal False Claims Act may be brought by the Department of Justice or by a private individual in the name of the government.

Although the Anti-kickback Law applies only to federal health care programs, a number of states have passed statutes substantially similar to the Anti-kickback Law pursuant to which similar types of prohibitions are made applicable to all other health plans and third-party payers.

Federal and state law enforcement authorities scrutinize arrangements between health care providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals and opportunities. The law enforcement authorities, the courts and the United States Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between health care providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the Anti-kickback Law, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce future referrals.

In addition to statutory exceptions to the Anti-kickback Law, regulations provide for a number of safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-kickback Law. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection.

Among the safe harbors that may be relevant to us is the discount safe harbor. The discount safe harbor potentially applies to discounts provided by providers and suppliers, including laboratories, to physicians or institutions where the physician or institution bills the payer for the test, not when the laboratory bills the payer directly. If the terms of the discount safe harbor are met, the discounts will not be considered prohibited remuneration under the Anti-kickback Law. We anticipate that this safe harbor may be potentially applicable to any agreements that we enter into to sell tests to hospitals where the hospital submits a claim to the payer.

The personal services safe harbor to the Anti-kickback Law provides that remuneration paid to a referral source for personal services will not violate the Anti-kickback Law provided all of the elements of that safe harbor are met. One element is that, if the agreement is intended to provide for the services of the physician on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals. Failure to meet the terms of the safe harbor does not render an arrangement illegal. Rather, such arrangements must be evaluated under the language of the statute, taking into account all facts and circumstances.

In the event that we enter into relationships with physicians, hospitals and other customers, there can be no assurance that our relationships with those physicians, hospitals and other customers will not be subject to investigation or a successful challenge under such laws. If imposed for any reason, sanctions under the Anti-kickback Law or similar laws could have a negative effect on our business.

Other Federal and State Fraud and Abuse Laws

In addition to the requirements that are discussed above, there are several other health care fraud and abuse laws that could have an impact on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal health care programs substantially in excess of its usual charges for its services. The terms "usual charge" and "substantially in excess" are ambiguous and subject to varying interpretations.

Further, the Federal False Claims Act prohibits a person from knowingly submitting a claim, making a false record or statement in order to secure payment or retaining an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in fines, imprisonment or both, and possible exclusion from Medicare or Medicaid programs.

Corporate Practice of Medicine

Numerous states have enacted laws prohibiting business corporations, such as MetaStat, from practicing medicine and employing or engaging physicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings. Typically, such laws are only applicable to entities that have a physical presence in the state.

Compliance with Environmental Laws

We expect to be subject to regulation under federal, state and local laws and regulations governing environmental protection and the use, storage, handling and disposal of hazardous substances. The cost of complying with these laws and regulations may be significant. Our planned activities may require the controlled use of potentially harmful biological materials, hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have.

Other Regulations

The U.S. Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

Foreign Regulation

To obtain marketing approval of a drug under European Union regulatory systems, we may submit marketing authorization applications, or MAAs, either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, and optional for those products that are highly innovative or for which a centralized process is in the interest of patients. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Scientific Advice Working Party of the Committee of Medicinal Products for Human Use, or the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria comprising the seriousness of the disease, such as heavy disabling or life-threatening diseases, to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, the European Medicines Agency, or EMA, ensures that the opinion of the CHMP is given within 150 days.

The EMA grants orphan drug designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the European Union. In addition, orphan drug designation can be granted if the drug is intended for a life threatening, seriously debilitating or serious and chronic condition in the European Union and without incentives it is unlikely that sales of the drug in the European Union would be sufficient to justify developing the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the European Union of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free protocol assistance, fee reductions for access to the centralized regulatory procedures before and during the first year after marketing authorization and between 6 and 10 years of market exclusivity following drug approval.

The decentralized procedure for submitting an MAA provides an assessment of an application performed by one member state, known as the reference member state, and the approval of that assessment by one or more other member states, known as concerned member states. Under this procedure, an applicant submits an application, or dossier, and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states. Prior to submitting an MAA for use of drugs in pediatric populations, the EMA requires submission of, or a request for waiver or deferral of, a Pediatric Investigation Plan.

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from assessing a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted but not approved for two years. Even if a compound is considered to be a new chemical entity and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the drug if such company can complete a full MAA with a complete human clinical trial database and obtain marketing approval of its product.

Healthcare Reform

Containing healthcare expenditures is a major trend in the U.S. and the rest of the world. Both government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products, including therapeutics and diagnostics, implementing reductions in Medicare and other healthcare funding, and applying new payment methodologies. For example, in March 2010, the Affordable Care Act was enacted, which, among other things, subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; creation of the Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs; and establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. There is uncertainty with respect to the impact the new presidential administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have also been proposed and adopted in the U.S. to reduce healthcare expenditures. These changes include aggregate reductions of Medicare payments to providers of 2% per fiscal year that, due to subsequent legislative amendments, will remain in effect through 2025 unless additional action is taken by Congress. The American Taxpayer Relief Act of 2012 was signed into law in January 2013, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers to five years from three. Recently there has been heightened scrutiny over the manner in which manufacturers set prices for their marketed products.

Reimbursement

Sales of any of our therapeutic and companion diagnostic product candidates that may be approved will depend, in part, on the extent to which the cost of the products will be covered by government and third party payers. Third party payers may limit coverage to an approved list of products, or formulary, which might not include all drug products approved by the FDA for an indication. Any product candidates for which we obtain marketing approval may not be considered medically necessary or cost-effective by third party payers, and we may need to conduct expensive pharmacoeconomic studies in the future to demonstrate the medical necessity and/or cost effectiveness of any such product.

The reimbursement environment is evolving as regulators and payors try to establish new rules and frameworks for the reimbursement of molecular diagnostic tests. There has been an increased interest in implementing cost containment programs to limit government-paid health care costs, including price controls and restrictions on reimbursement. Continued interest in and adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for product candidates we are developing.

Our prognostic diagnostic tests are expected to be offered as a clinical laboratory service. Revenue for clinical laboratory diagnostics may come from several sources, including commercial third-party payers, such as insurance companies and health maintenance organizations (HMOs), government payers, such as Medicare and Medicaid in the United States, patient self-pay and, in some cases, from hospitals or referring laboratories who, in turn, may bill third-party payers.

The proportion of private payers compared to government payers such as Medicaid/Medicare will impact the average selling price (discounting), length of payables, and losses due to uncollectible accounts receivable. Working with relevant medical societies and other appropriate constituents to obtain appropriate reimbursement amounts by all payers will be key. The objective of this effort will be to ensure the amount paid by Medicare and other payers for our assays accurately reflects the technology costs, the benefit that the analysis brings to patients, and its positive impact on healthcare economics. In order to gain broad reimbursement coverage, we expect substantial resources will need to be devoted to educating payers such as Kaiser Permanente, Aetna, United Healthcare, and others on the following attributes of our prognostic diagnostic assays, including, but not limited to:

- test performance (specificity, selectivity, size of the risk groups);
- clinical utility and effectiveness;
- peer-reviewed publication and consistent study outcomes;
- patient and physician demand; and
- improved health economics.

Billing codes are the means by which Medicare and private insurers identify certain medical services that are provided to patients in the United States. CPT codes are established by the American Medical Association (AMA). The amounts reimbursed by Medicare for the CPT codes are established by the Centers for Medicare & Medicaid Services (CMS) using a relative value system, with recommendations from the AMA's Relative Value Update Committee and professional societies representing the various medical specialties.

Reimbursement for our prognostic diagnostic tests, including MetaSite *Breast*™ and MenaCalc™ will be based on:

- eligibility for reimbursement under well-established medical billing CPT code 88361;
- reimbursement under the CPT miscellaneous procedure code; or
- qualification under any applicable new molecular diagnostic codes currently under consideration.

As part of our longer-term reimbursement strategy, we or any potential partners may choose to apply for a unique CPT code once our prognostic diagnostic assays are commercially available and health economic data have been established.

Well-established medical billing CPT code 88361

CPT code 88361 is specific to computer-assisted image analysis and went into effect in 2004. Our prognostic diagnostic tests involve both a technical and professional component. The technical component involves preparation of the patient sample and scanning the image, while the professional component involves the physician's reading and evaluation of the test results. Since our prognostic diagnostic tests will be billed as a service, we anticipate payments for both the professional and technical components. The actual payment varies based upon a geographic factor index for each state and may be higher or lower than the Medicare national amounts in particular cases based on geographic location.

CMS coding policy defines the unit of service for each IHC stain charge is one unit per different antigen tested and individually reported, per specimen. Medicare contractors cannot bill for multiple service units of CPT code 88361 (Immunohistochemistry, each antibody) for “cocktail” stains containing multiple antibodies in a single “vial” applied in a single procedure, even if each antibody provides distinct diagnostic information. We believe this CMS policy is not applicable to our procedure because our multiple stain reaction involves multiple separate steps of multiple primary antibodies binding followed by counterstaining.

CPT Miscellaneous Procedure Code

Tests that are billed under a non-specific, unlisted procedure code are subject to manual review of each claim. Claims are paid at a rate established by the local Medicare carrier in Massachusetts and based upon the development and validation costs of developing the assays, the costs of conducting the tests, the reimbursement rates paid by other payers and the cost savings impact of the tests. Because there is no specific code or national fee schedule rate for the test, payment rates established by the local Medicare contractor may be subject to review and adjustment at any time.

Sales and Marketing

We have not yet established a sales and marketing infrastructure. For any of our therapeutic or companion diagnostic product candidates for which we may in the future receive marketing approvals, we may seek to commercialize the product ourselves or through one or more strategic commercialization collaborations.

Our prognostic diagnostic tests are expected to be offered as a clinical laboratory service through our CLIA-certified laboratory located in Boston, Massachusetts. We plan to implement a de-risked commercialization strategy based on non-exclusive agreements with strategic distribution partners and/or CSOs in the U.S. and distributors in Europe and throughout the rest-of-world.

We aim to enter into agreements with commercialization or strategic partners that have existing commercialization infrastructure, established distribution channels, and strong relationships with our target audience in the medical community. We aim to avoid the cost and risk associated with building a new sales and marketing infrastructure.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We expect to rely on third parties for the manufacture of any therapeutic product candidates for preclinical and clinical testing, as well as for commercial manufacture of any products that we may commercialize. We generally expect to rely on third parties for the manufacture of our companion diagnostics, including Mena protein isoform Mabs.

Our state-of-the-art CLIA-certified reference laboratory is located at 27 Drydock Avenue in Boston, MA. Our CLIA-certified laboratory is our primary location for prognostic diagnostic testing and data analysis of patient tumor samples. Although the science behind our prognostic diagnostic technology is cutting edge and sophisticated, a key competitive advantage of our approach is that we have simplified our testing methods and procedures based on established immunohistochemical, or IHC, and quantitative immunofluorescence, or QIF techniques and utilize common inexpensive materials.

The MetaSite *Breast*™ assay uses widely available IHC dyeing techniques to identify individual cell types. This staining technique uses antibodies that recognize individual cell types. By attaching different dye colors to different antibody types, the operator can view different cell types on a single slide. We believe this approach to diagnosis and prognosis of cancer is more cost effective than many genomic-based approaches currently on the market. We believe the most economical way to enter the market with the MetaSite *Breast*™ test will be through contract manufacturing for these IHCs.

The MenaCalc™ and Mena^{INV} assays use widely available QIF techniques to identify individual cell types, allowing the test to interrogate tumor cells separately within tumor microenvironment rather than measuring homogenous biopsies containing tumor and non-tumor cell types. This staining technique uses antibodies that recognize or detect the different protein variants of Mena. The antibodies used are detected by labeling the different antibody types different fluorescent dyes that allow the operator to measure and quantify the levels selectively within the tumor cells on the slide. We believe this approach to diagnosis and prognosis of cancer is more cost effective than many genomic-based approaches currently on the market that utilize heterogeneous mixtures of tumor and stromal cells in patient samples.

Employees

We currently have six full-time employees. In addition, we utilize outside consultants to support certain elements of our research and development, information technology, and commercial operations. From time to time we have also engaged several consulting firms involved with public relations, investor relations and other functions.

Insurance

We have general and umbrella liability insurance, employment practices liability insurance as well as directors and officers (D&O) insurance in amounts that we believe comply with industry standards.

Legal Proceedings

We are not engaged in any material litigation, arbitration or claim, and no material litigation, arbitration or claim is known by our management to be pending or threatened by or against us that would have a material adverse effect on our results from operations or financial condition.

Corporate Structure

We were incorporated on March 28, 2007 under the laws of the State of Nevada. From inception until November of 2008, our business plan was to produce and market inexpensive solar cells and in November 2008, our board of directors determined that the implementation of our business plan was no longer financially feasible. At such time, we discontinued the implementation of our prior business plan and pursued an acquisition strategy, whereby we sought to acquire a business. Based on these business activities, until February 27, 2012, we were considered a "blank check" company, with no or nominal assets (other than cash) nor operations.

MetaStat BioMedical, Inc. (“MBM”) (formerly known as MetaStat, Inc.), our wholly owned Delaware subsidiary, was incorporated in the State of Texas on July 22, 2009 and re-incorporated in the State of Delaware on August 26, 2010. MBM was formed to allow cancer patients to benefit from the latest discoveries in how cancer spreads to other organs in the body. The Company’s mission is to become an industry leader in the emerging field of personalized cancer therapy.

On February 27, 2012 (the “Closing Date”), we consummated a share exchange as more fully described below, whereby we acquired all the outstanding shares of MBM and, MBM became our wholly owned subsidiary. From and after the share exchange, our business is conducted through our wholly owned subsidiary, MBM, and the discussion of our business is that of our current business which is conducted through MBM.

Prior to April 9, 2012, our company name was Photovoltaic Solar Cells, Inc. For the sole purpose of changing our name, on April 9, 2012, we merged with a newly-formed, wholly owned subsidiary incorporated under the laws of Nevada called MetaStat, Inc. As a result of the merger, our corporate name was changed to MetaStat, Inc. In May 2012, we changed the name of our Delaware subsidiary to MetaStat BioMedical, Inc. from MetaStat, Inc.

Share Exchange

On the Closing Date, we entered into a Share Exchange Agreement (the “Exchange Agreement”) by and among us, MBM, the holders of all outstanding shares of MBM (the “MBM Shareholders”) and Waterford Capital Acquisition Co IX, LLC, our principal shareholder (the “Company Principal Shareholder”), whereby we acquired all of the outstanding shares of MBM (the “MBM Shares”) from the MBM Shareholders. In exchange, we issued to the MBM Shareholders an aggregate of 1,224,629 shares of our common stock (the “Exchange Shares”), equal to 95.6% of our outstanding shares of common stock after such issuance. As a result of the transactions contemplated by the Exchange Agreement (collectively, the “Share Exchange”), MBM became our wholly owned subsidiary. Pursuant to the Exchange Agreement, we assumed warrants to purchase up to 52,035 shares of MBM’s common stock, with exercise prices ranging between $22.50 and $30.00 per share on a 2.2-for-1 basis, equivalent to 114,475 shares of our common stock with exercise prices ranging from $10.20 to $13.65 per share. Immediately prior to the Share Exchange, we converted approximately $336,075 of debt owed to the Company Principal Shareholder into 20,640

shares of our common stock (the "Debt Conversion") and issued an aggregate of 2,400 shares of our common stock to certain of our officers, directors and consultants in consideration for services rendered to us, leaving 56,000 shares of our common stock outstanding immediately prior to the issuance of the Exchange Shares. Additionally, immediately prior to the Share Exchange, we issued five-year warrants to purchase up to an aggregate of 23,334 shares of our common stock at an exercise price of $21.00 per share, of which warrants to purchase 22,500 shares were issued for a purchase price of $21,000 and warrants to purchase 834 shares were issued for services rendered to us prior to the Share Exchange (the "Warrant Financing"). We used the proceeds of the Warrant Financing to pay off all of our liabilities prior to the Share Exchange.

On the Closing Date, we assumed MBM's 2012 Omnibus Securities and Incentive Plan (the "2012 Incentive Plan") and reserved 74,453 shares of our common stock for the benefit of our employees, nonemployee directors and consultants. All 33,834 options outstanding under the 2012 Incentive Plan were converted, on a 2.2-for-1 basis, into the right to receive options to purchase up to 74,434 shares of our common stock with an exercise price of $10.20 per share.

Principal Executive Offices

Our principal executive office and clinical reference laboratory are located at 27 Drydock Ave., 2nd Floor, Boston, Massachusetts 02210, We have additional executive offices at 401 Park Ave. South, 8th Floor, New York, New York 10016. Our corporate telephone number is (617) 531-6500 and our website is *http://www.metastat.com*. Information contained on our website does not constitute part of, and is not deemed incorporated by reference into, this Form 10-K.

Item 1A. RISK FACTORS

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, prospects, results of operations, financial condition and cash flows, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Relating to Our Financial Condition and Capital Resources

If we are unable to continue as a going concern, our securities will have little or no value.

The report of our independent registered public accounting firm that accompanies our audited consolidated financial statements for the years ended February 28, 2017 and February 29, 2016 contain a going concern qualification in which such firm expressed substantial doubt about our ability to continue as a going concern. As of February 28, 2017, and February 29, 2016, we had an accumulated deficit of approximately $26.3 million and $23.4 million, respectively. At February 28, 2017, we have a negative working capital. We currently anticipate that our cash and cash equivalents will not be sufficient to fund our operations for the next twelve months, without raising additional capital. Our continuation as a going concern is dependent upon continued financial support from our shareholders, the ability of us to obtain necessary equity and/or debt financing to continue operations, and the attainment of profitable operations. These factors raise substantial doubt regarding our ability to continue as a going concern. Although we are actively working to obtain additional funding, we cannot make any assurances that additional financings will be available to us and, if available, completed on a timely basis, on acceptable terms or at all. If we are unable to complete an equity or debt offering, or otherwise obtain sufficient financing when and if needed, it would negatively impact our business and operations, which would likely cause the price of our common stock to decline. It could also lead to the reduction or suspension of our operations and ultimately force us to cease our operations.

We are at an early stage of development as a company and do not have, and may never have, any products that generate revenue.

We are a pre-commercial biotechnology company. At this time, we do not have any commercial products or laboratory services that generate revenue. Our business has evolved to an integrated Rx/Dx company focused on developing and commercializing therapeutics and companion diagnostics from a pure play prognostic diagnostic company. We are not profitable, and have incurred losses in each year since our inception and expect we expect to continue to incur losses for the foreseeable future.

Our therapeutic and companion diagnostic product candidates are at early stages of development, have not obtained regulatory marketing approval, have never generated any sales and require extensive testing before commercialization. Our limited operating history may adversely affect our ability to implement our business strategy and achieve our business goals, which include, among others, the following activities:

- develop our therapeutic or diagnostic product candidates;
- obtain the human and financial resources necessary to develop, test, commercialize and market our product candidates;
- continue to build and maintain an intellectual property portfolio covering our technology and our product candidates;
- satisfy the requirements of clinical trial protocols, including patient enrollment, establish and demonstrate the clinical efficacy, safety and utility of our product candidates and obtain necessary regulatory approvals;
- commercialize and market our product candidates that receive regulatory approvals to achieve acceptance and use by the medical community in general;
- develop and maintain successful collaboration, strategic and other relationships for the development and commercialization of our product candidates; and
- manage our cash flows and any growth we may experience in an environment where costs and expenses relating to clinical trials, regulatory approvals and commercialization continue to increase.

Additionally, our prognostic diagnostic product candidates will require additional development, analytical validation, clinical evaluation, additional state and CLIA licensing, potential regulatory review, significant sales and marketing efforts and substantial investment or collaboration before they could provide any revenue.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop product candidates, raise capital, generate significant revenue, or any revenue at all, grow our business or continue our operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have a history of net losses, and we expect to incur net losses for the foreseeable future and we expect to continue to incur significant expenses to develop and commercialize our products.

We have incurred substantial net losses since our inception. For the fiscal year ended February 28, 2017 and February 29, 2016, we incurred net losses of approximately $2.9 million and approximately $4.7 million, respectively. From our inception in July 2009 through February 28, 2017, we had an accumulated deficit of approximately $26.3 million. To date, we have not achieved, and we may never achieve, revenue sufficient to offset expenses. We expect to devote substantially all of our resources to research and development and commercialization of our product offerings based on our Rx/Dx strategy. We expect to incur additional losses in the future, and we may never achieve profitability

We expect our losses to continue as a result of costs relating to ongoing research and development primarily for our therapeutic drug discovery and companion diagnostic programs, clinical studies, operational expenses, and other commercialization costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict when we will become profitable, if ever. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We have incurred significant indebtedness under our convertible note with a shareholder.

On January 17, 2017, we issued to a convertible promissory note in the principal amount of $1,000,000 (the "Convertible Note") in exchange for the cancellation of (i) $600,000 principal amount of the Promissory Note plus $96,000 of accrued and unpaid interest, and (ii) $290,400 principal amount of the OID Note. The Convertible Note matures on September 30, 2017, accrues interest at a rate of ten percent (10%) per annum commencing as of January 1, 2017, and may be prepaid upon 10 days' advanced written notice by us at any time prior to the maturity date without penalty or premium. The noteholder has the right to convert the outstanding principal balance of the Convertible Note plus all accrued and unpaid interest thereon into shares of our common stock at a conversion price per share of $2.00.

Our ability to repay or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our indebtedness we may be required to adopt one or more alternatives, such as restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive, or selling assets. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Risks Relating to Our Business and Strategy

We expect to continue to incur significant research and development expenses, which may make it difficult for us to achieve and maintain profitability.

Our operations have consumed substantial amounts of cash since inception. We expect to need substantial additional funding to pursue our development programs and launch and commercialize any product candidates for which we receive regulatory approval, which may include building internal sales and marketing forces to address certain markets.

In recent years, we have incurred significant costs in connection with the development of our prognostic diagnostic tests, including the MetaSite *Breast*™ and MenaCalc™ tests. Our research and development expenses were approximately $1.0 million and $1.4 million for the fiscal years ended February 28, 2017 and February 29, 2016, respectively.

We expect our research and development expenses to increase and remain high for the foreseeable future as we execute our Rx/Dx strategy to develop our driver-based biomarkers primarily for anti-metastatic drugs and companion diagnostics. Additionally, we may not be able to successfully monetize or commercialization our prognostic diagnostic tests. As a result, we will need to generate significant revenue in order to achieve profitability. Our failure to achieve revenue or profitability in the future could cause the market price of our common stock to decline. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our research and development efforts are based on a rapidly evolving area of science, and our approach to development is novel and may never lead to marketable products.

Biopharmaceutical product development is generally a highly speculative undertaking and involves substantial risk. The field of personalized medicine, in which we engage, is an emerging field, and the scientific discoveries that form the basis for our Rx/Dx efforts to develop product candidates are relatively new. Further, the scientific evidence to support the feasibility of developing product candidates based on those discoveries is both preliminary and limited. The failure of the scientific underpinnings of our business model to produce viable product candidates would substantially harm our operations and prospects.

If we are unable to commercialize and generate sales from our products or successfully develop and commercialize other product candidates, our revenue will be insufficient for us to achieve profitability.

We are a pre-commercial biotechnology company. We do not have any commercial products or laboratory services that generate revenue. Our therapeutic and companion diagnostics programs are in an early stage of development. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our therapeutic and companion diagnostic product products resulting from these programs and any others we may develop or acquire in the future, which may never occur.

Before we could generate any revenues from our therapeutic and companion diagnostic product candidates, we must complete the following activities for each of them, any one of which we may not be able to successfully complete:

- conduct substantial preclinical development;
- manage preclinical and clinical activities;
- achieve regulatory approval;
- manage manufacturing activates and establish manufacturing relationships;
- develop our companion diagnostics and conduct clinical testing and achieve regulatory approvals for our companion diagnostics;
- build a commercial sales and marketing infrastructure, if we choose to market any such products ourselves, or enter into a collaboration to access sales and marketing functions;
- develop and implement marketing and reimbursement strategies; and
- invest significant additional cash in each of the above activities.

If we are unable to commercialize and generate sales of our product candidates, or successfully develop, monetize or commercialization our prognostic diagnostic tests, we will not produce sufficient revenue to become profitable.

Our product candidates are in various stages of development and may never be fully developed in a manner suitable for commercialization. If we do not develop commercially successful products, our ability to generate revenue will be limited.

We are a pre-commercial biotechnology company. We do not have any commercial products or laboratory services that generate revenue. All of our product candidates are in various stages of development, and significant research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. If we are unable to develop, receive approval for, or successfully commercialize any of our product candidates, we may be unable to generate meaningful revenue and will incur continued net losses and negative cash flows, which could substantially harm our operations and prospects.

We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our Rx/Dx strategy is to use and expand our driver-based biomarker platform to build a pipeline of therapeutic drug candidates and companion diagnostics, and progress those product candidates through preclinical and clinical development for the treatment of epithelial-based solid tumors. We may not be able to develop product candidates that are safe and effective. Even if we are successful in building a product pipeline, the potential product candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential product candidates fail to produce a pipeline of potentially viable product candidates, then our success as a business will be dependent on the success of fewer potential product candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

We may expend our limited resources to pursue a particular product candidate or indication that does not produce any commercially viable products and may fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and operational resources, we must focus our efforts on particular product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Further, our resource allocation decisions may result in our use of funds for research and development programs and product candidates for specific indications that may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such failure to properly assess potential product candidates could result in missed opportunities and/or our focus on product candidates with low market potential, which would harm our business and financial condition.

Drug development involves a lengthy and expensive process with uncertain outcomes, and any of our preclinical development and clinical trials or studies could produce unsuccessful results or fail at any stage in the testing process.

Preclinical development and clinical testing is expensive and can take many years to complete. The outcomes are inherently uncertain and failure can occur at any time during the preclinical development and clinical trial process. Additionally, any positive results of preclinical studies and early clinical trials of a product candidate may not be predictive of the results of later-stage clinical trials, such that product candidates may reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in earlier studies. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. The results of any preclinical development and clinical trials we conduct may be delayed or unsuccessful for a variety of reasons.

If we experience delays or difficulties in the enrollment of patients in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.

If any of our product candidates enter the clinical development stage, we may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because we are primarily focused on patients with molecularly defined cancers, which may have relatively low incidence rates, our pool of suitable patients may be smaller and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. Additionally, some of our competitors have ongoing clinical trials for product candidates that treat the same indications that our product candidates target, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

The inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon our clinical trials altogether. Enrollment delays in our clinical trials would likely result in increased development costs, and we may not have or be able to obtain sufficient cash to fund such increased costs when needed, which could result in the further delay or termination of the trials.

The approval processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product candidates from applicable regulatory authorities, we will not be able to market and sell those product candidates in those countries or regions and our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. We have not submitted an NDA or similar filing or obtained regulatory approval for any product candidate in any jurisdiction and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including any one or more of the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to hold to previous agreements or commitments;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve our companion diagnostics;
- invest significant additional cash in each of the above activities; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

The time and expense of the approval process, as well as the unpredictability of clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, any of our or future product candidates, which would significantly harm our business, results of operations and prospects.

In order to market and sell our products in any jurisdiction, we or our third-party collaborators must obtain separate marketing approvals in that jurisdiction and comply with its regulatory requirements. The approval procedure can vary drastically among countries, and each jurisdiction may impose different testing and other requirements to obtain and maintain marketing approval. Further, the time required to obtain those approvals may differ substantially among jurisdictions. Approval by the FDA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions. As a result, the ability to market and sell a product candidate in more than one jurisdiction can involve significant additional time, expense and effort to undertake separate approval processes, and could subject us and our collaborators to the numerous and varying post-approval requirements of each jurisdiction governing commercial sales, manufacturing, pricing and distribution of our product candidates. We or any third parties with whom we may collaborate may not have the resources to pursue those approvals, and we or they may not be able to obtain any approvals that are pursued. The failure to obtain marketing approval for our product candidates in foreign jurisdictions could severely limit their potential markets and our ability to generate revenue.

In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with labeling that does not include the claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of the approved labeling, or result in significant negative consequences following marketing approval, if any.

Results of future clinical trials of our product candidates could reveal a high and/or unacceptable severity and frequency of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Further, any observed drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial, or result in potential product liability claims. Any of these occurrences could materially harm our business, financial condition and prospects.

Additionally, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings in the product’s labeling;
- we may be required to create a medication guide for distribution to patients that outlines the risks of such side effects;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product, if approved, and could significantly harm our business, results of operations and prospects.

Failure to successfully validate, develop and obtain regulatory approval for our companion diagnostics could harm our business strategy and operational results.

As one of the central elements of our Rx/Dx business strategy, we seek to identify appropriate patient populations most likely to benefit from our anti-metastatic therapeutic agents or next generation RTK inhibitors and anti-microtubule drugs being developed by potential pharmaceutical and biotechnology partners. In order to assist in identifying those subsets of patients, a companion diagnostic, which is a test or measurement that evaluates the presence of biomarkers in a patient, could be used. We anticipate that the development of companion diagnostics concurrently with our therapeutic agents or with our drugs from potential strategic partners will help us more accurately identify the patients who belong to the target subset, both during the clinical trials and in connection with the commercialization of product candidates.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory clearance or approval prior to their commercialization. We may be dependent on the sustained cooperation and effort of any third-party collaborators with whom we may partner in the future to develop and obtain clearance or approval for these companion diagnostics, and we may not be able to establish arrangements with any such third-party collaborators for the development and production of companion diagnostics when needed or on terms that are beneficial to us, or at all. We and our potential future collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics, including issues relating to the selectivity and/or specificity of the diagnostic, analytical validation, reproducibility, or clinical validation.

Since the FDA generally requires concurrent approval of a companion diagnostic and therapeutic product, any delay or failure by us or our potential future collaborators to develop or obtain regulatory clearance or approval of any companion diagnostics could delay or prevent approval of our related product candidates. The occurrence of any delay or failure could adversely affect and/or delay the development or commercialization of our product candidates.

If we are unable to execute our sales and marketing strategy for our products and are unable to gain market acceptance, we may be unable to generate sufficient revenue to sustain our business.

We are a pre-commercial biotechnology company and have yet to begin to generate revenue from our product candidates. Our therapeutic and companion diagnostic product candidates are in an early stage of development, and, if we obtain marketing approval for any of products in the future, which we anticipate would not occur for several years, if at all. Additionally, we are seeking to monetize or commercialize through strategic partnerships our prognostic diagnostics through our CLIA-certified laboratory, located in Boston, Massachusetts.

Although we believe that our prognostic diagnostics represent a promising commercial opportunity, we may never gain significant market acceptance and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our prognostic diagnostic tests and build that market through physician education, awareness programs and the publication of clinical data. Gaining acceptance in medical communities requires, among other things, publication in leading peer-reviewed journals of results from studies using our current tests and/or our planned cancer tests. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our current tests and our planned tests. Our ability to successfully market our prognostic diagnostic tests that we may develop will depend on numerous factors, including:

- conducting validation studies of such tests in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- conducting clinical utility studies of such tests to demonstrate economic usefulness to providers and payers;
- whether our current or future partners, support our offerings;
- the success of the sales force and marketing effort;

- whether healthcare providers believe such diagnostic tests provide clinical utility;
- whether the medical community accepts that such diagnostic tests are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions; and
- whether private health insurers, government health programs and other third-party payers will cover such diagnostic tests and, if so, whether they will adequately reimburse us.

Failure to achieve significant market acceptance of our products would materially harm our business, financial condition and results of operations.

If third-party payers, including managed care organizations and Medicare, do not provide reimbursement for our products, our commercial success could be compromised.

Physicians and patients may decide not to order our prognostic diagnostic tests unless third-party payers, such as managed care organizations as well as government payers such as Medicare and Medicaid, pay a substantial portion or all of the test's price. There is significant uncertainty concerning third-party reimbursement of any test incorporating new technology, including our prognostic diagnostic tests and any of our future diagnostic tests. Reimbursement by a third-party payer may depend on a number of factors, including a payer's determination that tests using our technologies are:

- not experimental or investigational;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- provide a clinical utility.

Uncertainty surrounds third-party payor coverage and adequate reimbursement of any diagnostic test incorporating new technology, including tests developed using our technologies. Technology assessments of new medical tests conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure. Technology assessments can include evaluation of clinical utility studies, which define how a test is used in a particular clinical setting or situation. Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our cancer diagnostic tests, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our current tests and our planned future tests will be provided in the future by additional third-party payors or that existing agreements, policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. If we cannot obtain coverage and adequate reimbursement from private and governmental payors such as Medicare and Medicaid for our current tests, or new tests or test enhancements that we may develop in the future, our ability to generate revenue could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flows. Further, we may experience delays and interruptions in the receipt of payments from third-party payors due to missing documentation and/or other issues, which could cause delay in collecting our revenue.

In addition, to the extent that our testing is ordered for Medicare inpatients and outpatients, only the hospital may receive payment from the Medicare program for the technical component of pathology services and any clinical laboratory services that we perform, unless the testing is ordered at least 14 days after discharge and certain other requirements are met. We therefore must look to the hospital for payment for these services under these circumstances. If hospitals refuse to pay for the services or fail to pay in a timely manner, our ability to generate revenue could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flows.

Additionally, there is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs and companion diagnostics. Market acceptance and sales of any of our product candidates that obtain regulatory approval in domestic or international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payers and may be affected by existing and future healthcare reform measures.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability for sales of any of our product candidates that are approved for marketing in that country.

Long payment cycles of Medicare, Medicaid and/or other third-party payers, or other payment delays, could hurt our cash flows and increase our need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that we will need to satisfy in order to receive payment, and the programs can be expected to carefully audit and monitor our compliance with these requirements. We will also need to comply with numerous other laws applicable to billing and payment for healthcare services, including, for example, privacy laws. Failure to comply with these requirements may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenue and earnings. In addition, failure by third-party payors to properly process our payment claims in a timely manner could delay our receipt of payment for our products and services, which may have a material adverse effect on our cash flows and business.

We expect to rely on third parties to conduct preclinical and clinical trials of our therapeutic and companion diagnostic product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely, and expect to continue to rely, upon third-party collaborators, including CROs to execute our preclinical development and clinical trials and to monitor and manage data produced by and relating to those trials. However, we may not be able to establish arrangements with collaborators and CROs when needed or on terms that are acceptable to us, or at all, which could negatively affect our development efforts with respect to our drug product candidates and materially harm our business, operations and prospects.

Our research and development and commercialization efforts for our prognostic diagnostics will be hindered if we are not able to contract with third parties for access to clinical samples.

Under standard clinical practice, tumor biopsies removed from patients are typically chemically preserved and embedded in paraffin wax and stored. Our clinical development relies on our ability to secure access to these archived tumor biopsy samples, as well as information pertaining to their associated clinical outcomes. Generally, the agreements under which we gain access to archival samples are nonexclusive. Other companies study archival samples and often compete with us for access. Additionally, the process of negotiating access to archived samples is lengthy since it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are not able to negotiate access to clinical samples with hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed. In addition, access to these clinical samples may be costly, and involve large upfront acquisition costs, which may have a material adverse effect on our cash flows and business.

We may experience delays in our clinical studies that could adversely affect our financial position and our commercial prospects.

Any delays in completing our preclinical development and clinical studies for any of our product candidates may delay our ability to raise additional capital or to generate revenue, and we may have insufficient capital resources to support our operations. Even if we have sufficient capital resources, the ability to become profitable will be delayed if there are problems with the timing or completion of our clinical studies.

We are conducting, and expect to conduct, certain preclinical development, validation studies and clinical studies alone and/or in collaboration with select academic institutions and other third-party institutions through services and collaboration agreements. We may experience delays that are outside of our control in connection with such services and collaboration agreements, including, but not limited to, receiving tissue samples, accompanying medical and clinical data, preparation, review and sign-off of results and/or manuscripts in a timely fashion. Any delays in completing our clinical studies and publishing of results in peer-reviewed journals will delay our commercialization efforts and may materially harm our business, financial condition and results of operations.

If we cannot maintain our current clinical collaborations and enter into new collaborations, our product development could be delayed.

We rely on, and expect to continue to rely on, clinical collaborators, including CROs to perform portions of our clinical trial functions. If any of our collaborators were to breach or terminate its agreement with us or otherwise fail to conduct the contracted activities successfully and in a timely manner, the research, development or commercialization of the products contemplated by the collaboration could be delayed or terminated. If any of our collaboration agreements are terminated, or if we are unable to renew those agreements on acceptable terms, we would be required to seek alternatives. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and these collaborations may not be successful.

Our success in the future depends in part on our ability to enter into agreements with other leading cancer organizations. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can prolong the time it takes to develop, negotiate and implement collaboration. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for products such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that may result from a collaboration.

From time to time we expect to engage in discussions with potential clinical collaborators, which may or may not lead to collaborations. However, we cannot guarantee that any discussions will result in clinical collaborations or that any clinical studies, which may result will be completed in a reasonable time frame or with successful outcomes. If news of discussions regarding possible collaborations become known in the medical community, regardless of whether the news is accurate, failure to announce a collaboration agreement or the entity's announcement of a collaboration with an entity other than us could result in adverse speculation about us, our products or our technology, resulting in harm to our reputation and our business.

Clinical utility studies are important in demonstrating to both customers and payers a test's clinical relevance and value. If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that a product provides clinically meaningful information and value, commercial adoption of such test may be slow, which would negatively impact our business.

Clinical utility studies show when and how to use a clinical test, and describe the particular clinical situations or settings in which it can be applied and the expected results. Clinical utility studies also show the impact of the product results on patient care and management. Clinical utility studies are typically performed with collaborating oncologists or other physicians at medical centers and hospitals, analogous to a clinical trial, and generally result in peer-reviewed publications. Sales and marketing representatives use these publications to demonstrate to customers how to use a clinical test, as well as why they should use it. These publications are also used with payers to obtain coverage for a test, helping to assure there is appropriate reimbursement. We anticipate commencing clinical utility studies for our prognostic diagnostic tests following product launch. We will need to conduct additional studies for our prognostic diagnostic tests, and other tests we plan to introduce, to increase the market adoption and obtain coverage and adequate reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for oncologists and other physicians, adoption of our product could be impaired and we may not be able to obtain coverage and adequate reimbursement for them.

If our sole laboratory facility becomes inoperable, we will be unable to perform our research and development and commercial activities and our business will be harmed.

Our state-of-the-art research and development and commercial laboratory facility located in Boston, Massachusetts received CLIA certification and licensing from Massachusetts, California, Florida, Pennsylvania and Rhode Island. We are seeking licensing from other states including New York and Maryland, in order to process samples from such states, however we cannot guarantee that we will receive the necessary certifications and approvals in a timely fashion. Delays in receiving the necessary state certifications may delay commercialization efforts in these states and may materially harm our business, financial condition and results of operations.

The laboratory facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, fire and power outages, or loss of our commercial lease, which may render it difficult or impossible for us to perform our testing services for some period of time. The inability to perform our research and development and/or commercial activities even for a short period of time, may result in the loss of customers or harm our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

In order to rely on a third party to perform our tests, we could only use another facility with established CLIA certification and state licensure under the scope of which our diagnostic tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified and state-licensed laboratory facility willing to license, transfer or adopt our diagnostic tests and comply with the required procedures, or that such partner or laboratory would be willing to perform the tests for us on commercially reasonable terms.

In order to establish a redundant laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new clinical laboratory facility opened by us would be subject to certification under CLIA, licensing by several states, including New York, California, Florida, Maryland, Pennsylvania and Rhode Island, which can take a significant amount of time and result in delays in our ability to begin operations.

We may experience limits on our revenue if oncologists and other physicians decide not to order our prognostic diagnostic tests or our future tests, we may be unable to generate sufficient revenue to sustain our business.

If medical practitioners do not order our prognostic diagnostic assays or any future tests developed by us, we will likely not be able to create demand for our products in sufficient volume for us to become profitable. To generate demand, we will need to continue to make oncologists, surgeons, pathologists and other health care professionals aware of the benefits, value and clinical utility of our diagnostic tests and any products we may develop in the future through published papers, presentations at scientific conferences and one-on-one education by our sales force. We need to hire or outsource commercial, scientific, technical and other personnel to support this process. Some physicians may decide not to order our test due to its price, part or all of which may be payable directly by the patient if the applicable payer denies reimbursement in full or in part. Even if patients recommend their physicians use our diagnostic tests, physicians may still decide not to order them, either because they have not been made aware of their utility or they wish to pursue a particular course of treatment and/or therapy regardless. If only a small portion of the physician population decides to use our tests, we will experience limits on our revenue and our ability to achieve profitability. In addition, we will need to demonstrate our ability to obtain adequate reimbursement coverage from third-party payers.

We may experience limits on our revenue if patients decide not to use our prognostic diagnostic tests.

Some patients may decide not to order our prognostic diagnostic tests due to its price, part or all of which may be payable directly by the patient if the applicable payer denies reimbursement in full or in part. Even if medical practitioners recommend that their patients use our test, patients may still decide not to use our prognostic diagnostic tests, either because they do not want to be made aware of the likelihood of metastasis or they wish to pursue a particular course of therapy regardless of test results. If only a small portion of the patient population decides to use our test, we will experience limits on our revenue and our ability to achieve profitability.

If we are unable to develop our product candidates to keep pace with rapid technological, medical and scientific change, our operating results and competitive position would be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis, prognosis and treatment of cancer. These advances require us to continuously develop new products and enhance existing products to keep pace with evolving standards of care. Several new cancer drugs have been approved, and a number of new drugs in clinical development may increase patient survival time. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. Our tests could become obsolete unless we continually innovate and expand our products to demonstrate benefit in the diagnosis, monitoring or prognosis of patients with cancer. New treatment therapies typically have only a few years of clinical data associated with them, which limits our ability to develop cancer diagnostic tests based on for example, biomarker analysis related to the appearance or development of resistance to those therapies. If we cannot adequately demonstrate the applicability of our current tests and our planned tests to new treatments, by incorporating important biomarker analysis, sales of our tests could decline, which would have a material adverse effect on our business, financial condition and results of operations.

If we become subject to product liability claims, the damages may exceed insurance coverage levels.

We could be subject to product liability lawsuits based on the use of our product candidates in clinical testing or, if obtained, following marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to cease clinical testing or limit commercialization of our product candidates. We plan to obtain liability insurance for our product candidates as each is entered into clinical studies, large population validation studies and/or any other studies where such liability insurance is needed.

We cannot predict all of the possible harms or side effects that may result from the use of our products and, therefore, the amount of insurance coverage we currently hold, or that we or our collaborators may obtain, may not be adequate to protect us from any claims arising from the use of our products that are beyond the limit of our insurance coverage. If we cannot protect against potential liability claims, we or our collaborators may find it difficult or impossible to commercialize our products, and we may not be able to renew or increase our insurance coverage on reasonable terms, if at all.

The marketing, sale and use of our products and our planned future products could lead to the filing of product liability claims against us if someone alleges that our products failed to perform as designed. We may also be subject to liability for errors in the test results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage. Additionally, any product liability lawsuit could damage our reputation, result in the recall of tests, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

Our dependence on commercialization partners for sales of our prognostic diagnostic tests could limit our success in realizing revenue growth.

We are seeking to monetize or commercialize through the use of distribution and commercialization partners for the sales, marketing and distribution, billing, collection and reimbursement efforts, and to do so we must enter into agreements with these partners to sell, market or commercialize our tests. We may experience launch delays as a result of the timing of clinical data, establishment of a final product profile, and the lead time required to execute commercialization agreements. These agreements may contain exclusivity provisions and generally cannot be terminated without cause during the term of the agreement. We may need to attract additional partners to expand the markets in which we sell tests. These partners may not commit the necessary resources to market and sell our cancer diagnostics tests to the level of our expectations, and we may be unable to locate suitable alternatives should we terminate our agreement with such partners or if such partners terminate their agreement with us. Any relationships we form with commercialization partners are subject to change over time. If current or future commercialization partners do not perform adequately, or we are unable to locate commercialization partners, we may not realize revenue growth.

If we are unable to develop adequate sales, marketing or distribution capabilities or enter into agreements with third parties to perform some of these functions, we will not be able to commercialize our products effectively.

We likely will have a limited infrastructure in sales, marketing and distribution. Initially, we are not planning to directly market and distribute our products. We may not be able to enter into sales, marketing and distribution capabilities of our own or enter into such arrangements with third parties in a timely manner or on acceptable terms.

Our sales force collaborator with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of our products, limiting our potential revenue from the commercialization of these products. Disputes may arise delaying or terminating the commercialization or sales of our diagnostic tests that may result in significant legal proceedings that may harm our business, limit our revenue and our ability to achieve profitability.

We depend on third parties for the supply of tissue samples and other biological materials that we use in our research and development efforts. If the costs of such tissue samples and materials increase or our third-party suppliers terminate their relationship with us, our business may be materially harmed.

We have relationships and plan to enter into new relationships with suppliers and institutions that provide us with tissue samples, tissue microarrays (TMA's), and other biological materials including antibodies that we use in developing and validating our product candidates tests. If one or more suppliers terminate their relationship with us or are unable to meet our requirements for samples, we will need to identify other third parties to provide us with samples and biological materials, which could result in a delay in our research and development activities, clinical studies and negatively affect our business. In addition, as we grow, our research and academic institution collaborators may seek additional financial contributions from us, which may negatively affect our results of operations.

We rely on a limited number of suppliers or, in some cases, a sole supplier, for some of our laboratory instruments and materials and may not be able to find replacements in the event our supplier no longer supplies that equipment.

We expect to rely on several vendors, including, but not limited to Perkin Elmer, ThermoFisher Scientific and VisioPharm AS to supply some of the laboratory equipment and software on which we perform our diagnostic tests. We will periodically forecast our needs for laboratory equipment and software and enter into standard purchase orders or leasing arrangements based on these forecasts. We believe that there are relatively few equipment manufacturers that are currently capable of supplying the equipment necessary for our prognostic diagnostics tests. Even if we were to identify other suppliers, there can be no assurance that we will be able to enter into agreements with such suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing from key vendors the quality and quantity of equipment and software we require for our diagnostic tests, we may need to reconfigure our test process, which would result in delays in commercialization or an interruption in sales. If any of these events occur, our business and operating results could be harmed. Additionally, if key vendors including Perkin Elmer and other vendors deem us to have become uncreditworthy, they have the right to require alternative payment terms from us, including payment in advance. We may also be required to indemnify key vendors including Perkin Elmer and other vendors against any damages caused by any legal action or proceeding brought by a third party against such vendors for damages caused by our failure to obtain required approval with any regulatory agency.

We may also rely on several sole suppliers for certain laboratory materials such as reagents, which we use to perform our diagnostic tests. Although we believe that we will be able to develop alternate sourcing strategies for these materials, we cannot be certain that these strategies will be effective. If we should encounter delays or difficulties in securing these laboratory materials, delays in commercialization or an interruption in sales could occur.

We currently rely, and expect to continue to rely, on third-party suppliers for critical materials needed to perform research and development activities and our prognostic diagnostic tests and our planned future products and any problems experienced by them could result in a delay or interruption of their supply to us.

We currently purchase raw materials, including Mabs for our driver-based biomarkers and testing reagents under purchase orders and do not have long-term commercial contracts with the suppliers of these materials. If suppliers were to delay or stop producing our materials or reagents, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in our research and development efforts and delays in performing our prognostic diagnostic tests while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new materials or reagents and in increased operating costs. Further, any prolonged disruption in a supplier's operations could have a significant negative impact on our ability to perform our prognostic diagnostic tests in a timely manner. Some of the components used in our current or planned products are currently sole-source, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities.

Our success depends on retention of key personnel and the hiring of additional key personnel. The loss of key members of our executive management team could adversely affect our business.

We are dependent on our management team members, including Douglas A. Hamilton, our president and chief executive officer. Our future success also will depend in large part on our continued ability to attract and retain other highly qualified personnel. We intend to recruit and hire other senior executives, scientific, technical and management personnel, as well as personnel with expertise in sales and marketing including reimbursement, clinical testing, and governmental regulation. Such a management transition subjects us to a number of risks, including risks pertaining to coordination of responsibilities and tasks, creation of new management systems and processes, differences in management style, effects on corporate culture, and the need for transfer of historical knowledge.

In addition, Douglas A. Hamilton has not previously been the chief executive officer of a public or private company. While he has had experience as a chief financial officer, chief operating officer and other executive level positions in public companies, a lack of significant experience in being the chief executive officer of a public company could have an adverse effect on our ability to quickly respond to problems or effectively manage issues surrounding the operation of a public company. Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The collective efforts of our executive management and others working with them as a team are critical to us as we continue to develop our technologies, diagnostic tests, research and development efforts and sales and marketing programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of our key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. We do not maintain "key person" life insurance on any of our employees.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

Our operations may involve hazardous materials, and compliance with environmental laws and regulations is expensive.

Our future research and development and commercial activities may involve the controlled use of hazardous materials, including chemicals that cause cancer, volatile solvents, radioactive materials and biological materials including human tissue samples that have the potential to transmit diseases. Our operations may also produce hazardous waste products. We are subject to a variety of federal, state and local regulations relating to the use, handling and disposal of these materials. We generally may contract with third parties for the disposal of such substances and may store certain low level radioactive waste at our facility until the materials are no longer considered radioactive. While we believe that we will comply with then current regulatory requirements, we cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur significant costs associated with civil penalties or criminal fines and in complying with environmental laws and regulations.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities may require the controlled use of potentially harmful biological materials, hazardous materials and chemicals and may in the future require the use of radioactive compounds. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations might be significant and could negatively affect our operating results. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

We expect to along with certain third party vendors that we contract with to collect and store sensitive data, including legally protected health information, credit card information, personally identifiable information about our employees, customers and patients, intellectual property, and our proprietary business information and that of our customers, payers and collaboration partners. We expect to manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information and business and financial information. We face four primary risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure risk and inappropriate modification risk combined with the risk of our being able to identify and audit our controls over the first three risks.

The secure processing, storage, maintenance and transmission of this critical information will be vital to our operations and business strategy. As such we plan to devote significant resources to protecting such information. Although we plan to take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party vendors, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

We depend on our information technology and telecommunications systems, and any failure of these systems could harm our business.

We depend on information technology or IT, and telecommunications systems for significant aspects of our operations. In addition, we expect to outsource aspects of our billing and collections to a third-party provider, whom maybe dependent upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and telecommunications systems will support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and administrative activities. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures we plan to implement, some or all of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we plan on taking to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from processing tests, providing test results to oncologists, pathologists, billing payers, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core Rx/Dx technology and expertise to expand our offerings or distribution. We have minimal experience with acquiring and integrating other companies or assets and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock or securities convertible into shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

We may not be able to support demand for our diagnostic tests or future tests. We may have difficulties managing the evolution of our technology and manufacturing platforms, which could cause our business to suffer.

We anticipate that our diagnostic tests may will be well received by the marketplace, and demand will increase as market acceptance grows. As expected test volumes grow, we will need to increase our testing capacity, increase our scale and related processing, customer service, billing, collection and systems process improvements and expand our internal quality assurance program and technology to support testing on a larger scale. We will also need additional clinical laboratory scientists, pathologists and other scientific and technical personnel to process these additional tests. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. We will also need to add capacity to our information technology infrastructure, which may be costly. As diagnostic tests for additional cancer indications are commercialized, we may need to bring new equipment on line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. Failure to implement necessary procedures or to hire the necessary personnel could result in a higher cost of processing or an inability to meet market demand. We cannot assure you that we will be able to perform tests on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of our test results or that we will respond successfully to the growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for our current tests and our planned future tests, our reputation could be harmed and our future prospects and business could suffer, which may have a material adverse effect on our financial condition, results of operations and cash flows.

Declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over United States health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession. If the economic climate does not improve, or it deteriorates, our business, including our access to patient samples and the addressable market for diagnostic tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party payers, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy contemplates potential international expansion, including partnering with academic and commercial testing partners for research and development and clinical studies, and commercializing our diagnostic tests outside the United States and expanding relationships with international payers and distributors. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- competition from local and regional product offerings;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;

- limits in our ability to penetrate international markets if we are not able to process tests locally;
- lack of intellectual property protection in certain markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our tests and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over the activities of our sales force and distributors that may fall within the purview of the FCPA, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

If we cannot compete successfully with our competitors, we may be unable to generate, increase or sustain revenue or achieve and sustain profitability.

We believe our principal competition for our prognostic diagnostic assays will come from existing diagnostic methods used by pathologists and oncologists. These methods have been used for many years and are therefore difficult to change or supplement. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which potentially facilitates adoption more readily than tests like ours that are performed outside the pathology laboratory.

We also face competition from companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast, lung, prostate and colorectal cancer, including public companies such as Genomic Health Inc., Agendia Inc., GE Healthcare, a business unit of General Electric Company, Hologic Inc., Myriad Genetics Inc., NanoString Technologies Inc., Novartis AG, Qiagen N.V., and Response Genetics Inc., and many other public and private companies. We also face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. We may also face competition from Illumina Inc. and Thermo Fisher Scientific Inc., both of which have announced their intention to enter the clinical diagnostics market. Other potential competitors include companies that develop diagnostic tests such as Roche Diagnostics, a division of Roche Holding Ltd., Siemens AG and Veridex LLC, a Johnson & Johnson company, as well as other companies and academic and research institutions.

Others may invent and commercialize technology platforms such as next generation sequencing approaches that will compete with our test. Projects related to cancer genomics have received government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our tests in countries where we did not apply for patents, where our patents have not been issued or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

The list price of our test may change as well as the list price of our competitor's products. Any increase or decrease in pricing could impact reimbursement of and demand for our tests. Many of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced tests that could be viewed by physicians and payers as functionally equivalent to our tests, or offer tests at prices designed to promote market penetration, which could force us to lower the list prices of our tests and impact our operating margins and our ability to achieve sustained profitability. Some competitors have developed tests cleared for marketing by the FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than our diagnostic test, and that may discourage adoption of and reimbursement for our diagnostic test. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our tests, which could prevent us from increasing or sustaining our revenue or achieving sustained profitability and could cause the market price of our common stock to decline.

Regulatory Risks Relating to Our Business

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and results of operations.

There have been, and may continue to be, legislative and regulatory proposals at the federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. The continuing efforts of the government, insurance companies, managed care organizations and other payers to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our product candidates that obtain marketing approval, which may adversely affect our future profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The Affordable Care Act, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. In May 2017, the House passed legislation to repeal and replace the Affordable Care Act, which will proceed to the Senate for vote. President Trump has also recently issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Affordable Care Act to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. Additionally, on April 1, 2014, the Protecting Access to Medicare Act of 2014, or PAMA, was signed into law, which, among other things, significantly alters the current payment methodology under the CLFS. Under the new law, starting January 1, 2017 and every three years thereafter (or annually in the case of advanced diagnostic lab tests), clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes during a time period to be defined by future regulations. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payer (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Beginning in 2018, the Medicare payment rate for each clinical diagnostic lab test, with some exceptions, will be equal to the weighted median private payer payment for the test, as calculated using data collected by applicable laboratories during the data collection period and reported to CMS during a specified data reporting period. Also under PAMA, CMS is required to adopt temporary billing codes to identify new clinical diagnostic laboratory tests and advanced diagnostic laboratory tests that do not already have unique diagnostic codes, and that have been cleared or approved by the FDA.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our therapeutic and diagnostic products or additional pricing pressures.

If the FDA were to begin regulating our prognostic diagnostic tests, including the* MetaSite *Breast*™ and MenaCalc™ *tests, we could experience significant delays in commercializing our prognostic diagnostics, be forced to stop our sales, experience significant delays in commercializing any future products, incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval as well as experience decreased demand for our prognostic diagnostic tests and demand for reimbursement of our prognostic diagnostic tests.

Clinical laboratory tests, like our prognostic diagnostic tests including the MetaSite *Breast*™ and MenaCalc™ assays, are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as administered through the CMS, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called Laboratory Development Tests, or “LDTs". Most LDTs currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We believe that our prognostic diagnostic tests are not a diagnostic kit and we also believe that they are LDTs. As a result, we believe our prognostic diagnostic tests should not be subject to regulation under established FDA policies.

At various times since 2006, the FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. In October 2014, the FDA issued draft guidance that sets forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. On November 18, 2016, the FDA announced that it would not finalize the draft guidance documents for LDTs prior to the end of the Obama administration. The decision of whether and how to proceed with the draft guidance will be left to the new administration, which began on January 20, 2017. In January 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining a possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. It is unclear at this time if or when the draft guidance will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance. If this draft guidance is finalized as presently written, it includes an oversight framework that would require pre-market review for high and moderate risk LDTs

Legislative proposals addressing oversight of genetic testing and LDTs have been introduced in previous Congresses and we expect that new legislative proposals will be introduced from time to time in the future. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through finalization of guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. If pre-market review is required, our business could be negatively impacted until such review is completed and clearance or approval is obtained, and the FDA could require that we stop selling our tests pending pre-market clearance or approval. If our tests are allowed to remain on the market but there is uncertainty about the regulatory status of our tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are more limited than the claims we currently make, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical studies and submitting a pre-market clearance notice or filing a pre-market approval application with the FDA. If pre-market review is required by the FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by and the regulatory requirements of the FDA, for example registration and listing and medical device reporting, and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

We cannot predict the ultimate timing or form of final FDA guidance or regulations addressing LDTs and the potential impact on our diagnostic tests, our diagnostic tests in development or the materials used to perform our tests. While we expect to qualify all materials used in our tests according to CLIA regulations, we cannot be certain that the FDA will not enact rules or guidance documents which could impact our ability to purchase certain materials necessary for the performance of our tests, such as products labeled for research use only. Should any of the reagents obtained by us from suppliers and used in conducting our tests be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

Testing of potential products may be required and there is no assurance of FDA or any other regulatory approval.

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of both therapeutic and diagnostic biomedical products, through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more and varies substantially based upon the type, complexity, and novelty of the product. The effect of government regulation and the need for FDA approval may be to delay marketing of new products for a considerable period of time, to impose costly procedures upon our activities, and to provide an advantage to larger companies that compete with us. There can be no assurance that FDA or other regulatory approval for any products developed by us will be granted on a timely basis or at all. Any such delay in obtaining, or failure to obtain, such approvals would materially and adversely affect the marketing of any contemplated products and the ability to earn product revenue. Further, regulation of manufacturing facilities by state, local, and other authorities is subject to change. Any additional regulation could result in limitations or restrictions on our ability to

utilize any of our technologies, thereby adversely affecting our operations. Human diagnostic and pharmaceutical products are subject to rigorous preclinical testing and clinical studies and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate United States and foreign statutes and regulations are time-consuming and require the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country. Among the uncertainties and risks of the FDA approval process are the following: (i) the possibility that studies and clinical studies will fail to prove the safety and efficacy of the product, or that any demonstrated efficacy will be so limited as to significantly reduce or altogether eliminate the acceptability of the product in the marketplace, (ii) the possibility that the costs of development, which can far exceed the best of estimates, may render commercialization of the drug marginally profitable or altogether unprofitable, and (iii) the possibility that the amount of time required for FDA approval of a product may extend for years beyond that which is originally estimated. In addition, the FDA or similar foreign regulatory authorities may require additional clinical studies, which could result in increased costs and significant development delays. Delays or rejections may also be encountered based upon changes in FDA policy and the establishment of additional regulations during the period of product development and FDA review. Similar delays or rejections may be encountered in other countries.

If we were required to conduct additional clinical studies prior to marketing our prognostic diagnostic tests, those studies could lead to delays or failure to obtain necessary regulatory approvals and harm our ability to become profitable.

If the FDA decides to regulate our prognostic diagnostic tests, it may require additional pre-market clinical testing before clearing or approving our prognostic diagnostic tests for commercial sales. Such pre-market clinical testing could delay the commencement or completion of clinical testing, significantly increase our test development costs, delay commercialization of any future tests, and potentially interrupt sales of our tests. Although, we plan on performing our future clinical studies at such FDA standards, there is no assurance that such clinical studies will meet certain FDA standards. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical studies may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical studies may be delayed due to access to adequate tissue samples and corresponding clinical data, insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Moreover, the clinical trial process may fail to demonstrate that our breast cancer tests and our planned future tests are effective for the proposed indicated uses, which could cause us to abandon a test candidate and may delay development of other tests.

We may find it necessary to engage CROs to perform data collection and analysis and other aspects of our clinical studies, which might increase the cost and complexity of our studies. We may also depend on clinical investigators, medical institutions, academic institutions and contract research organizations to perform the studies. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical studies may have to be extended, delayed, repeated or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We believe our prognostic diagnostic tests are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Effective October 2015, we received a certificate of accreditation under CLIA to perform testing of our prognostic diagnostic tests for breast cancer. In order to renew the certificate of accreditation, we will be subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our laboratory outside of the renewal process. The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of accreditation, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for tests provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so. Additionally, we will seek to have our laboratory accredited by the College of American Pathologists, or CAP, one of six CLIA-approved accreditation organizations.

In addition, our laboratory is located in Boston, Massachusetts and is required by state law to have a Massachusetts state license; as we expand our geographic focus, we may need to obtain laboratory licenses from additional states.

In addition, we need to have licenses from other states including the states of California, New York, Pennsylvania, Florida, Maryland and Rhode Island among others to test specimens from patients in those states or received from ordering physicians in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions if we seek to expand international distribution of our tests outside the United States.

If we were to lose our CLIA certification or appropriate state license(s), whether as a result of a revocation, suspension or limitation, we would no longer be able to sell our prognostic diagnostic tests, or other diagnostic tests, which would significantly harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states.

We are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, physician payments transparency and health information privacy and security laws. If we are unable to comply with any such laws, we could face substantial penalties.

We are subject to various federal and state fraud and abuse laws, including, without limitation, anti-kickback and false claims statutes. Including, but not limited to:

- Medicare billing and payment regulations applicable to clinical laboratories;
- the federal Medicare and Medicaid Anti-kickback Law and state anti-kickback prohibitions;
- the federal physician self-referral prohibition, commonly known as the Stark Law, and the state equivalents;
- the federal Health Insurance Portability and Accountability Act of 1996;
- the Medicare civil money penalty and exclusion requirements; and
- the federal civil and criminal False Claims Act.

We have and will continue to adopt policies and procedures designed to comply with these laws, including policies and procedures relating to financial arrangements between us and physicians who refer patients to us. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and sales organization may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sales, and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. While we have developed, and instituted a corporate compliance program based on what we believe are the current best practices, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations, we could be subject to a range of regulatory actions, including suspension or termination of clinical studies, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Risks Relating to our Intellectual Property

If we are unable to protect our intellectual property, we may not be able to compete effectively.

We rely upon a combination of patents, patent applications, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies, products and services. Our success will depend in part on our ability to obtain or license patents and enforce patent protection of our products and licensed technologies, as well as the ability of the Licensors to enforce patent protection covering the patents which we license pursuant to the License Agreement, Second License Agreement, the Alternative Splicing License Agreements, and the Antibody License Agreement or other such license agreements we may enter into both in the United States and other countries to prevent our competitors from developing, manufacturing and marketing products based on our technology.

The patent positions of biotechnology and molecular diagnostic companies, such as us, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our licensed technologies are covered by any valid and enforceable patents or are effectively maintained as trade secrets. We could incur substantial costs in seeking enforcement of any eventual patent rights against infringement, and we cannot guarantee that patents that we obtain or in-license will successfully preclude others from using technology that we rely upon. We have applied and intend to apply for patents in the United States and other countries covering our technologies and products as and when we deem appropriate. However, these applications may be challenged or may fail to result in issued patents. We cannot predict the breadth of claims that maybe allowed and issued in patents related to biotechnology applications. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, methods of treating humans are not patentable in many countries outside of the United States.

The coverage claimed in a patent application can be significantly narrowed before a patent is issued, both in the United States and other countries. We do not know whether any of the pending or future patent applications will result in the issuance of patents. Any patents we or the Licensors obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing therapeutic products based on our technology or proprietary therapies. Once any such patents have issued, we cannot predict how the claims will be construed or enforced. Furthermore, others may independently develop similar or alternative technologies or design around our patents.

To the extent patents have been issued or may be issued, we do not know whether these patents will be subject to further proceedings that may limit their scope, provide significant proprietary protection or competitive advantage, or cause them to be circumvented or invalidated. Furthermore, patents that have or may issue on our or the Licensors patent applications may become subject to dispute, including interference, reissue or reexamination proceedings in the United States, or opposition proceedings in foreign countries. Any of these proceedings could result in the limitation or loss of rights.

We may rely on trade secret protection for our confidential and proprietary information. We have taken measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, competitors may independently develop or may have already developed substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

The pending patent applications that we have in-licensed or that we may in-license in the future may not result in issued patents, and we cannot assure you that our issued patents or any patents that might ultimately be issued by the United States Patent and Trademark Office, or USPTO will protect our technology. Any patents that may be issued to us might be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

Inventions, and the intellectual property rights covering them, that are discovered under research, material transfer or other such collaboration agreements may become solely owned by us in some cases, jointly owned by us and the other party to such agreements in some cases, and may become the exclusive property of other party to such agreements in other cases. Under some circumstances, it may be difficult to determine which party owns a particular invention, or whether it is jointly owned, and disputes could arise regarding ownership of those inventions. These disputes could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect or license rights to these inventions.

Unauthorized uses of our proprietary intellectual property by any such research collaborators, and publications by our research collaborators and scientific advisors containing such information, either with our permission or in contravention of the terms of their agreements with us, may limit or harm our ability to obtain patent protection for our product candidates or protect our proprietary information, which could materially harm our business, prospects, financial condition and results of operations.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Litigation or third party claims of intellectual property infringement could impair our ability to develop and commercialize our products successfully.

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be alleged to infringe a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization. Our success will depend in part on our ability to avoid infringing patents and proprietary rights of third parties, and not breaching any licenses that we have entered into with regard to our technologies. A number of pharmaceutical companies, biotechnology companies, independent researchers, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned by or licensed to us. For instance, a number of patents may have issued and may issue in the future on tests and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to rely on licenses from third parties, which may not be available on commercially reasonable terms, or at all.

We have no knowledge of any infringement or patent litigation, threatened or filed at this time. It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a patent holder believes that one of our product candidates infringes on our patent, it may sue we even if we have received patent protection for our technology. Third parties may claim that we are employing our proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes these patents. Regardless of their merit, such claims could require us to incur substantial costs, including the diversion of management and technical personnel, in defending ourselves against any such claims or enforcing our patents. In the event that a successful claim of infringement is brought against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize our products. Although we carry general liability insurance, our insurance may not cover potential claims of this type. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our product candidates or practice our related methods, and our business could materially suffer.

Our rights to use technologies licensed from third parties are not within our control, and we may not be able to develop, commercialize, and sell our products if we lose our existing rights or cannot obtain new rights on reasonable terms.

We license technology necessary to develop certain products from third parties. For example, we license technology from MIT, AECOM, Cornell and IFO-Regina located in Rome, Italy, that we use in certain diagnostic products and that we may use to develop certain additional products. As a result, our current business plans are dependent upon our satisfaction of certain conditions to the maintenance of those license agreements and the rights we license under them. Each of the license agreements provides that we are subject to diligence obligations relating to the development and commercialization of product candidates, milestone payments, royalty payments and other obligations. In addition to these license agreements, we may seek to enter into additional agreements with other third parties in the future granting similar license rights with respect to other potential product candidates. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of any of these license agreements, or any future license agreement we may enter on which our business or product candidates are dependent, the licensor may have the right to assert a claim for damages against us or terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and intellectual property and/or any rights we have acquired to develop and commercialize certain product candidates. If we become liable for material damages under any of these license agreements, this could materially harm our business, prospects, financial condition and results of operations. Similarly, the loss of the rights licensed to us under these license agreements, or any future license agreement that we may enter granting us rights on which our business or product candidates are dependent, would eliminate our ability to further develop the applicable product candidates and would materially harm our business, prospects, financial condition and results of operations.

Our liquidity issues in the past have sometimes caused a delay in payment under our existing license agreements. Our business may suffer if we are unable to meet our obligations, financial or otherwise, under our existing license agreements and if these licenses terminate, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or if we are unable to enter into necessary additional licenses on acceptable terms.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ certain individuals who were previously employed at universities, medical institutions, other diagnostic and biotechnology companies, including potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our licensed patents, or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our licensed patents, future patent applications or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our products or services including clinical studies. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may desire, or be forced, to seek additional licenses to use intellectual property owned by third parties, and such licenses may not be available on commercially reasonable terms or at all.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development or commercialization of our product candidates or to practice our related methods, in which case we would need to obtain a license from that third party or develop a different method relating to the product candidate that does not infringe the applicable intellectual property, which may not be possible. Additionally, we may identify product candidates that we believe are promising and whose composition of matter, use or manufacture are covered by the intellectual property rights of third parties. In such a case, we may desire to seek a license to pursue the development and commercialization of those product candidates. Any license that we may desire to obtain, or that we may be forced to pursue, may not be available when needed on commercially reasonable terms, or at all. Any inability to secure a license that we need or desire could have a material adverse effect on our business, financial condition and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other diagnostic and biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the diagnostic and biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing diagnostic and biotechnology patents is costly, time consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Our collaborators may assert ownership or commercial rights to inventions we develop from our use of the biological materials, which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, universities, medical centers, physicians and researchers in scientific matters and expect to continue to enter into additional collaboration agreements. In certain cases, we do not have written agreements with certain of such collaborators, or the written agreements we have do not cover intellectual property rights. Also, we rely on numerous third parties to provide us with tissue samples and biological materials that we use to develop products. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

We may be involved in lawsuits or administrative proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or potential licensors. We cannot predict if, when or where a third party may infringe one or more of our issued patents. To attempt to stop infringement or unauthorized use, we may need to enforce one or more of our patents, which can be expensive and time-consuming, a significant diversion of employee resources, and distract our management. There is no assurance such action will ultimately be successful in halting third party infringing activities, for example, through a permanent injunction, or that we would be fully or even partially financially compensated for any harm to our business caused by such third-party infringement. Even if such action were initially successful, it could be overturned upon appeal. Even if we are successful in proving in a court of law that a third party is infringing one or more of our issued patents we may be forced to enter into a license or other agreement with the infringing third party on terms less commercially acceptable to us than if the license or agreement were negotiated under conditions between those of a willing licensee and a willing licensor. We may not become aware of a third-party infringer within legal timeframes that would enable us to seek adequate compensation, or at all, thereby possibly losing the ability to be compensated for any harm to our business. Such a third-party may be operating in a foreign country where the infringer is difficult to locate, where we do not have issued patents and/or the patent laws may be more difficult to enforce. If we pursue any litigation, a court may decide that a patent of ours or our licensor's is not of sufficient breath, is invalid, or is unenforceable, or may refuse to stop the other party from using the relevant technology on the grounds that our patents do not cover the technology in question. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, which could reduce the likelihood of success of any infringement proceeding we pursue in any such jurisdiction. An adverse result in any patent litigation could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our pending patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in the applicable jurisdictions.

Certain administrative proceedings may be provoked by third parties before the USPTO and certain foreign patent offices, such as interference proceedings, opposition proceedings, re-examination proceedings, inter partes review, post-grant review, derivation proceedings and pre-grant submissions, in which third parties may challenge the validity or breadth of claims contained in our patents or those of our licensors. An adverse result in any such administrative proceeding could put one or more of our patents at risk of being canceled or invalidated or interpreted narrowly and could put our pending patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in the applicable jurisdictions.

Interference proceedings provoked by third parties or brought by us or the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. Derivation proceedings may be brought by us or a third party to determine whether a patent or application was filed by the true inventor. An unfavorable outcome in an interference or derivation proceeding could require us to cease using the related technology or to attempt to license rights to use it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation, interference, or derivation proceedings may have undesirable outcomes and, even if successful, may result in substantial costs, be a significant diversion of employee resources, and distract our management.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on products and services in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Relating to our Securities

The market price of our common stock may be volatile.

The market price of our common stock has been and will likely continue to be highly volatile, as is the stock market in general and the market for OTC or “bulletin board” quoted stocks in particular. Market prices for securities of early-stage life sciences companies have historically been particularly volatile Some of the factors that may materially affect the market price of our common stock are beyond our control, may include, but are not limited to:

- progress, or lack of progress, in developing and commercializing our current tests and our planned future cancer diagnostic tests;
- favorable or unfavorable decisions about our tests from government regulators, insurance companies or other third-party payers;
- changes in key personnel and our ability to recruit and retain qualified research and development personnel;
- changes in investors’ and securities analysts’ perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- depth of the trading market in our common stock;
- termination of the lock-up agreements or other restrictions on the ability of our existing stockholders to sell shares;

- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section entitled “Risk Factors”; and
- general market and economic conditions.

In addition, the equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities for a number of reasons, including reasons that may be unrelated to our business or operating performance. These broad market fluctuations may result in a material decline in the market price of our common stock and you may not be able to sell your shares at prices you deem acceptable. In the past, following periods of volatility in the equity markets, securities class action lawsuits have been instituted against public companies. Such litigation, if instituted against us, could result in substantial cost and the diversion of management attention.

We cannot assure you that our common stock will become liquid or that it will be listed on a national securities exchange. In addition, there may not be sufficient liquidity in the market for our securities in order for investors to sell their securities.

Currently, our common stock trades on the OTCQB venture stage marketplace for early stage and developing U.S. and international companies. Investors may find it difficult to obtain accurate quotations as to the market value of our common stock. In addition, if we fail to meet the criteria set forth in SEC regulations, by law, various requirements would be imposed on broker-dealers who sell its securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect its liquidity. In addition, there is currently only a limited public market for our common stock and there can be no assurance that a trading market will develop further or be maintained in the future.

We anticipate listing our common stock on a national securities exchange in the future and have applied to list our common stock on the NASDAQ Capital Market, however we cannot make any assurances that we satisfy the listing requirements of such national securities exchange, including, but not limited to:

- closing or bid price requirements;
- stockholders’ equity requirement;
- market value of publicly held shares;
- number of shareholders;
- number of market makers; and
- market value of listed securities.

In order to raise sufficient funds to expand our operations, we may have to issue additional securities at prices which may result in substantial dilution to our shareholders.

If we raise additional funds through the sale of equity or convertible debt, our current stockholders’ percentage ownership will be reduced. In addition, these transactions may dilute the value of our outstanding securities. We may have to issue securities that may have rights, preferences and privileges senior to our common stock. We cannot provide assurance that we will be able to raise additional funds on terms acceptable to us, if at all. If future financing is not available or is not available on acceptable terms, we may not be able to fund our future needs, which would have a material adverse effect on our business plans, prospects, results of operations and financial condition.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of February 28, 2017, we had outstanding 4,707,942 shares of common stock, 3,620,556 of which are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act of 1933, as amended. In addition, as of February 28, 2017, we had outstanding convertible preferred stock, convertible into 1,350,109 shares of common stock, outstanding options to purchase 966,474 shares of our common stock, outstanding warrants to purchase 2,698,694 shares of our common stock, and outstanding convertible debt convertible into 507,946 shares of our common stock. Shares issued upon the exercise of stock options and warrants will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act. The issuance or sale of such shares could depress the market price of our common stock.

In the future, we also may issue our securities if we need to raise additional capital. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock.

Rule 144 Related Risk

The SEC adopted amendments to Rule 144 which became effective on February 15, 2008 that apply to securities acquired both before and after that date. Under these amendments, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell their securities provided that: (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding a sale, (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale and (iii) if the sale occurs prior to satisfaction of a one-year holding period, we provide current information at the time of sale. Persons who have beneficially owned restricted shares of our common stock for at least six months but who are our affiliates at the time of, or at any time during the three months preceding a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the total number of securities of the same class then outstanding; or closing or bid price requirements;
- the average weekly trading volume of such securities during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale. Such sales by affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Restrictions on the reliance of Rule 144 by shell companies or former shell companies.

We are a former shell company. Historically, the SEC staff has taken the position that Rule 144 is not available for the resale of securities initially issued by companies that are, or previously were, blank check companies. The SEC has codified and expanded this position in amendments to Rule 144 which became effective in February 2008 by prohibiting the use of Rule 144 for resale of securities issued by any shell companies (other than business-combination related shell companies) or any issuer that has been at any time previously a shell company. The SEC has provided an important exception to this prohibition, however, if the following conditions are met:

- The issuer of the securities that was formerly a shell company has ceased to be a shell company;
- The issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;

- The issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Current Reports on Form 8-K; and

- At least one year has elapsed from the time that the issuer has filed current comprehensive disclosure with the SEC reflecting its status as an entity that is not a shell company.

As a result, it is possible that pursuant to Rule 144, stockholders may not be able to sell our shares without registration if one of the aforementioned conditions are not satisfied.

Because we became a public company by means of a "reverse merger," we may not be able to attract the attention of major brokerage firms.

Additional risks may exist since we became public through a "reverse takeover." Securities analysts of major brokerage firms may not provide coverage of our securities since there is little incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on our behalf in the future.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of the OTCQB venture stage marketplace and other applicable securities rules and regulations. Compliance with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Further, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act, enacted in 2010, that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits smaller "emerging growth companies" to implement many of these requirements over a longer period. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Additionally, we may be subject to increased corporate governance requirements in connection with the listing of our common stock on a national securities exchange, such as the NASDAQ Capital Market, which may lead to additional compliance costs and impact the manner in which we operate our business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, current and potential investors could lose confidence in our financial reporting, which could harm our business and have an adverse effect on our stock price.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to annually furnish a report by our management on our internal control over financial reporting. Such report must contain, among other matters, an assessment by our principal executive officer and our principal financial officer on the effectiveness of our internal control over financial reporting, including a statement as to whether or not our internal control over financial reporting is effective as of the end of our fiscal year. This assessment must include disclosure of any material weakness in our internal control over financial reporting identified by management. In addition, under current SEC rules, we may be required to obtain an attestation from our independent registered public accounting firm as to our internal control over financial reporting for our annual report on Form 10-K covering our next fiscal year. Performing the system and process documentation and evaluation needed to comply with Section 404 is both costly and challenging. During the course of our testing we may identify deficiencies which we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002 for compliance with the requirements of Section 404. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

Our common stock is considered "penny stock".

The SEC has adopted regulations, which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The market price of our common stock is currently less than $5.00 per share and therefore may be a "penny stock." Brokers and dealers effecting transactions in "penny stock" must disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell the common stock and may affect your ability to sell shares.

The market for penny stocks has experienced numerous frauds and abuses, which could adversely impact investors in our stock.

Our common stock trades on the OTCQB venture stage marketplace for early stage and developing U.S. and international companies. OTCQB securities and other "bulletin board" securities are frequent targets of fraud or market manipulation, both because of their generally low prices and because OTCQB and other bulletin board" reporting requirements are less stringent than those of national securities exchanges, including the NASDAQ Capital Market.

Patterns of fraud and abuse include:

- Control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer;
- Manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- "Boiler room" practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- Wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- the rate of adoption and/or continued use of our current tests and our planned future tests by healthcare practitioners;
- variations in the level of expenses related to our development and commercialization programs;
- addition or reduction of resources for product commercialization;
- addition or termination of clinical validation studies and clinical utility studies;
- any intellectual property infringement lawsuit in which we may become involved;
- third party payer determinations affecting our tests; and
- regulatory developments affecting our tests.

We expect operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Because we do not expect to pay cash dividends to our common stockholders for the foreseeable future, you must rely on appreciation of our common stock price for any return on your investment. Even if we change that policy, we may be restricted from paying dividends on our common stock.

We do not intend to pay cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial performance, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

Cumulative dividends on the Series B Preferred Stock accrue at the rate of 8% of the Stated Value per annum, payable quarterly on March 31, June 30, September 30, and December 31 of each year, from and after the date of the initial issuance. Dividends are payable in kind in additional shares of Series B Preferred Stock valued at the Stated Value or in cash at the sole option of the Company. At February 28, 2017 and February 29, 2016, the dividend payable to the holders of the Series B Preferred Stock amounted to approximately $16,000 and approximately $48,000, respectively. During the year ended February 28, 2017 and February 29, 2016, the Company issued 34.5085 and 42.8202 shares of Series B Preferred Stock, respectively, for payment of dividends amounting to approximately $190,000 and approximately $236,000, respectively.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Our ability to utilize our federal net operating loss, carryforwards and federal tax credits may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if an "ownership change," as defined by Section 382 of the Code, occurs. If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership (including in connection with this or future offerings, as well as other changes that may be outside of our control), may trigger an "ownership change" and, consequently, limitations under Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. As of February 28, 2017, we had federal net operating loss tax credit carryforwards of approximately $18.7 million, which could be limited if we have experienced or do experience any "ownership changes." We have not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple "ownership changes" since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because early-stage life sciences and diagnostic companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

On August 28, 2014, we entered into a lease agreement (the "Boston Lease") for our diagnostic laboratory and office space located at 27, Drydock Ave, 2nd Floor, Boston, MA 02210 (the "Boston Property"). We paid a $40,000 security deposit in connection with entering into the Boston Lease. Effective April 6, 2016, we entered into an amendment to the Boston Lease (the "Boston Lease Amendment"), whereby we extended the term by one year from September 1, 2016 to August 31, 2017. The basic rent payable under the Boston Lease Amendment is $17,164 per month plus additional monthly payments including tax payments and operational and service costs. We anticipate entering into an additional amendment or new long-term lease agreement on commercially reasonable terms for the Boston Property.

Effective March 1, 2015, we entered into a lease agreement for short-term office space in New York, NY. We paid a $2,100 security deposit in connection with entering into the lease. Effective December 1, 2015 we amended our lease agreement for the short-term office space in New York, NY. The term of the lease is month-to-month and may be terminated with twenty-one (21) days' notice. The basic rent payment is $2,400 per month and we paid an additional $1,500 security deposit in connection with the amended lease.

Item 3. LEGAL PROCEEDINGS

We are not engaged in any material litigation, arbitration or claim, and no material litigation, arbitration or claim is known by our management to be pending or threatened by or against us that would have a material adverse effect on our results from operations or financial condition.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Price Information for our Common Stock

Our common stock is quoted on the OTCQB venture stage marketplace under the symbol "MTST." The following table sets forth the high and low bid information for our common stock for the two most recent fiscal years. The OTCQB quotations reflect inter-dealer prices, are without retail markup, markdowns or commissions, and may not represent actual transactions.

	Common Stock	
	High	Low
March 1, 2015 through May 31, 2015	$ 12.00	$ 3.90
June 1, 2015 through August 31, 2015	$ 6.00	$ 3.00
September 1, 2015 through November 30, 2015	$ 10.00	$ 3.30
December 1, 2015 through February 29, 2016	$ 6.35	$ 1.80
March 1, 2016 through May 31, 2016	$ 3.50	$ 1.55
June 1, 2016 through August 31, 2016	$ 2.19	$ 1.00
September 1, 2016 through November 30, 2016	$ 3.45	$ 1.40
December 1, 2016 through February 28, 2017	$ 1.97	$ 1.26

On May 26, 2017, the last reported price for our common stock on the OTCQB was $1.15.

Number of Record Holders of Our Common Stock

As of May 26, 2017, we had 4,807,942 shares of our common stock outstanding and 174 holders of record of our common stock. The number of record holders was determined from our records and the records of our transfer agent.

Dividend Policy

We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our Common Stock for the foreseeable future.

Future cash dividends, if any, will be at the discretion of our board of directors and will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors as our board of directors may deem relevant. We can pay dividends only out of our profits or other distributable reserves and dividends or distribution will only be paid or made if we are able to pay our debts as they fall due in the ordinary course of business.

Cumulative dividends on the shares of Series B Preferred Stock shall accrue at the rate of 8% of the Stated Value per annum, payable quarterly, on March 31, June 30, September 30, and December 31 of each year, commencing on March 31, 2015. Dividends are payable in additional shares of Series B Preferred Stock valued at the Stated Value or in cash at our sole option.

Securities Authorized for Issuance Under Equity Compensation Plans

On February 27, 2012, in connection with the Share Exchange, we assumed the 2012 Incentive Plan from MBM and reserved 74,453 shares of our common stock for the benefit of our employees, nonemployee directors and consultants. On May 21, 2012, we increased the number of authorized and unissued shares of common stock reserved for issuance pursuant to the 2012 Incentive Plan to 207,786.

On June 22, 2015, our shareholders approved amending our 2012 Incentive Plan to increase the number of authorized shares of common stock reserved for issuance under the 2012 Incentive Plan to a number not to exceed fifteen percent (15%) of the issued and outstanding shares of common stock on an as converted primary basis (the "As Converted Primary Shares") on a rolling basis. For calculation purposes, the As Converted Primary Shares shall include all shares of common stock and all shares of common stock issuable upon the conversion of outstanding preferred stock and other convertible securities, but shall not include any shares of common stock issuable upon the exercise of options, warrants and other convertible securities issued pursuant to the 2012 Incentive Plan. The number of authorized shares of common stock reserved for issuance under the 2012 Incentive Plan shall automatically be increased concurrently with the Company's issuance of fully paid and non- assessable shares of As Converted Primary Shares. Shares shall be deemed to have been issued under the 2012 Incentive Plan solely to the extent actually issued and delivered pursuant to an award. As such, the number of shares authorized for issuance under the 2012 Incentive Plan increased from 207,786 to 347,129.

As of February 28, 2017, there were an aggregate of 908,708 shares authorized for issuance under the 2012 Incentive Plan and 578,194 shares available for issuance under the 2012 Incentive Plan.

The objective of the 2012 Incentive Plan is to maximize the effectiveness and efficiency of the Company's operations by attracting key talent, aligning and incentivizing employees to corporate goals and reducing the risk of voluntary employee turn-over. We may issue securities pursuant to the 2012 Incentive Plan or outside the 2012 Incentive Plan.

Equity Compensation Plan Information as of February 28, 2017

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (b)
Equity compensation plans approved by security holders *	299,807	$ 11.48	578,194
Total	299,807	$ 11.48	578,194

(a) Does not include 30,707 restricted shares of common stock issued under the 2012 Incentive Plan, of which 20,505 have vested and 10,202 are subject to milestone vesting.

* Additionally, as of February 28, 2017, outside of the 2012 Incentive Plan, we have issued an aggregate of 666,667 stock options with a weighted-average strike price of $3.12 per share and an aggregate of 59,989 restricted shares of common stock, of which 58,655 shares have vested and 1,334 are subject to milestone vesting.

Recent Sales of Unregistered Securities

None.

Item 6. SELECTED FINANCIAL DATA

Not applicable.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and the related notes to the consolidated financial statements included elsewhere in this Form 10-K. Our audited consolidated financial statements have been prepared in accordance with U.S. GAAP. In addition, our audited consolidated financial statements and the financial data included in this Form 10-K reflect our reorganization and have been prepared as if our current corporate structure had been in place throughout the relevant periods. The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading "Risk Factors" and elsewhere in this Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements.

Overview

MetaStat is a biotechnology company focused on discovering and developing personalized therapeutic (Rx) and diagnostic (Dx) treatment solutions for cancer patients. Our "driver-based" diagnostic biomarkers, based on the Mena protein isoforms, also serve as novel therapeutic targets for anti-metastatic drugs. Unlike surrogate cancer markers, which are indirect measures of cancer and its progression, driver-based biomarkers are the critical components of intracellular cancer pathways responsible for driving the aggressive activity of cancer cells. Our core expertise includes an understanding of the mechanisms and pathways that drive aggressive cancer, tumor cell invasion and metastasis. MetaStat is developing therapeutic product candidates, based on a novel approach that makes intracellular Mena protein isoforms drugable targets, and corresponding companion diagnostics.

Going Concern

Since our inception, we have generated significant net losses. As of February 28, 2017, we had an accumulated deficit of approximately $26.3 million. We incurred net losses of approximately $2.9 million and approximately $4.7 million for the year ended February 28, 2017 and February 29, 2016, respectively. We expect our net losses to continue for at least the next several years. We anticipate that a substantial portion of our capital resources and efforts will be focused on research and development, both to develop additional tests for breast cancer and to develop products for other cancers, to scale up our commercial organization, and other general corporate purposes. Our financial results will be limited by a number of factors, including establishment of coverage policies by third-party insurers and government payers, and our ability in the short term to collect from payers often requiring a case-by-case manual appeals process. Until we receive routine reimbursement and are able to record revenues as tests are processed and reports delivered, we are likely to continue reporting net losses.

We currently anticipate that our cash and cash equivalents will not be sufficient to fund our operations for the next twelve months, without raising additional capital. Our continuation as a going concern is dependent upon continued financial support from our shareholders, our ability to obtain necessary equity and/or debt financing to continue operations, and the attainment of profitable operations. These factors raise substantial doubt regarding our ability to continue as a going concern. Although we are actively working to obtain additional funding, we cannot make any assurances that additional financings will be available to us and, if available, completed on a timely basis, on acceptable terms or at all. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, it would negatively impact our business and operations and could also lead to the reduction or suspension of our operations and ultimately force us to cease our operations.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2 to our consolidated financial statements included in this Form 10-K for the year ended February 28, 2017. We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our financial statements.

Stock-based Compensation

We account for share-based payment awards issued to employees and members of our Board by measuring the fair value of the award on the date of grant and recognizing this fair value as stock-based compensation using a straight-line basis over the requisite service period, generally the vesting period. For awards issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is the earliest. Accordingly, non-employee awards are remeasured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation over the requisite service period, generally the vesting period.

Debt and Equity Instruments

We analyze debt and equity instruments for various features that would generally require either bifurcation and derivative accounting, or recognition of a debt discount or premium under authoritative guidance.

Detachable warrants issued in conjunction with debt are measured at their relative fair value, if they are determined to be equity instrument, or their fair value, if they are determined to be liability instruments, and recorded as a debt discount.

Conversion features that are in the money at the commitment date constitute a beneficial conversion feature that is measured at its intrinsic value and recognized as debt discount or deemed dividend. Debt discount is amortized as interest expense over the maturity period of the debt using the effective interest method.

Any contingent beneficial conversion feature would be recognized when and if the contingent event occurs based on its intrinsic value at the commitment date.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales or otherwise. In the future, we expect that we will seek to generate revenue primarily from product sales, but we may also seek to generate non-product revenue from sources including, but not limited to research funding, development and milestone payments, and royalties on future product sales in connection with any out-license or other strategic relationships we may establish.

General and Administrative Expenses

Our general and administrative expenses primarily consist of personnel and related costs, including stock-based compensation, legal fees relating to both intellectual property and corporate matters, accounting and audit related costs, insurance, corporate communications and investor relations expenses, information technology and internet related costs, office and facility rents and related expenses, and fees for consulting and other professional services.

We anticipate that our general and administrative expenses will increase in the future to support continued research, development and commercialization activities, including potential partnership and/or collaboration agreements, intellectual property and corporate legal expenses, and public company operating costs, including offering and related expenses in connection with a potential uplisting to a national stock exchange, SEC and exchange compliance, insurance and investor relations costs. These increases will likely include increased costs related to facilities and information technology expansion, the hiring of additional personnel and increased fees to outside consultants, lawyers and accountants, among other expenses.

Research and Development Expenses

Historically, the majority of research and development expenses were focused on our prognostic diagnostic tests for breast cancer, including the MetaSite *Breast*™ and MenaCalc™ tests. During the year ended February 28, 2017, we initiated research and development activities focused on our Mena^{INV} and related driver-based biomarkers, which support our integrated Rx/Dx product development strategy focused on anti-metastatic therapeutics and companion diagnostics. Research and development activities are central to our business model and we expect future research and development expenses to be focused on our Mena^{INV} and related biomarkers in support of our integrated Rx/Dx product development strategy.

We charge all research and development expenses to operations as they are incurred. Any nonrefundable advance payments for goods or services to be received in the future for use in research and development activities will be deferred and capitalized. Such capitalized amounts will be expensed as the related goods are delivered or the services are performed.

We do not record or maintain information regarding costs incurred in research and development on a program or project specific basis. Our research and development staff, outside consultants and contract research organizations are deployed across several programs and/or indications. Additionally, many of our costs are not attributable to individual programs and/or indications. Therefore, we believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

Our therapeutic and companion diagnostic product development programs are in early development stages. Since product candidates in later stages of development generally have higher development costs than those in earlier stages of development, we expect research and development costs relating to therapeutic and companion diagnostic programs to increase significantly for the foreseeable future as those programs progress. We are unable to determine the duration and completion costs of our research and development programs or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of any product candidate.

Results of Operations

Comparison of the Years Ended February 28, 2017 and February 29, 2016

Revenues. There were no revenues for the years ended February 28, 2017 and February 29, 2016, respectively.

General and Administrative Expenses. General and administrative expenses totaled approximately $2.3 million for the year ended February 28, 2017 as compared to approximately $3.4 million for the year ended February 29, 2016. This represents a decrease of approximately $1.1 million or approximately 32% for the year ended February 28, 2017, as compared to the year ended February 29, 2016. Stock-based compensation and depreciation was approximately $495,000 and approximately $15,000, respectively for the year ended February 28, 2017, as compared to approximately $711,000 and approximately $15,000, respectively for the year ended February 29, 2016. Excluding non-cash stock-based compensation related to stock options and depreciation expenses, general and administrative expenses decreased by approximately $0.9 million or approximately 32% to approximately $1.8 million for the year ended February 28, 2017 from approximately $2.7 million for the year ended February 29, 2016.

Reduced general and administrative spending was primarily due to decreases in consulting expense of approximately $252,000, corporate communications and investor relations costs of approximately $225,000, aborted offering costs of approximately $171,000, accounting and auditing expenses of approximately $110,000, travel and related expenses of approximately $53,000, dues and subscription fees of approximately $52,000, and corporate legal expenses of approximately $41,000. These reduced general and administrative expenses were partially offset by increases related to intellectual property legal expenses of approximately $41,000, directors and officers (D&O) insurance of approximately $38,000, rent of approximately $29,000, and information technology and internet related expenses of approximately $20,000.

Research and Development Expenses. Research and development totaled approximately $1.0 million for the year ended February 28, 2017, as compared to approximately $1.4 million for the year ended February 29, 2016. This represents a decrease of approximately $0.4 million or approximately 26% for the year ended February 28, 2017, as compared to the year ended February 29, 2016. Stock-based compensation and depreciation was approximately $85,000 and approximately $81,000, respectively for the year ended February 28, 2017, as compared to approximately $112,000 and approximately $81,000, respectively for the year ended February 29, 2016. Excluding non-cash stock-based compensation related to stock options and depreciation expenses, research and development expenses decreased by approximately $0.3 million or approximately 28% to approximately $0.8 million for the year ended February 28, 2017 from approximately $1.1 million for the year ended February 29, 2016.

Reduced research and development spending was primarily due to decreases in personnel and related costs of approximately $179,000, diagnostic related expenses of approximately $111,000, and consulting expense of approximately $26,000.

Other Expenses (Income). Other income was approximately $406,000 for the year ended February 28, 2017, as compared to other income of approximately $125,000 for the year ended February 29, 2016. This represents a change of approximately $281,000. Other income for the year ended February 28, 2017 mostly comprised of approximately $2.4 million gain from the change in fair value of the warrant liability, and approximately $614,000 gain on the change in fair value of the embedded put feature related to the notes payable, offset by approximately $1.4 million loss on extinguishment related to the exchanges of notes payable, approximately $1.1 million of interest expense on the notes payable, and approximately $112,000 loss on sale of ASET note receivable. Other income for the year ended February 29, 2016 mostly comprised of approximately $150,000 gain on the ASET transaction and approximately $350,000 gain from the change in fair value of the warrant liability, offset by approximately $317,000 of interest expense on the notes payable, and approximately $39,000 loss related to the settlement with two affiliated shareholders.

Net Loss. As a result of the factors described above, our net loss decreased by approximately $1.8 million to approximately $2.9 million for the year ended February 28, 2017 as compared to approximately $4.7 million for the year ended February 29, 2016.

Liquidity and Capital Resources

Since our inception, we have incurred significant losses and, as of February 28, 2017, we had an accumulated deficit of approximately $26.3 million. We have not yet achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. We expect that our research and development, general and administrative and commercialization expenses will continue to grow and, as a result, we will need to generate significant product revenues to achieve profitability. We may never achieve profitability.

Sources of Liquidity

Since our inception, substantially all of our operations have been financed through the sale of our common stock, preferred stock, and promissory notes. Through February 28, 2017, we had received net proceeds of approximately $9.23 million through the sale of common stock to investors, approximately $0.26 million through the sale of Series A Preferred Stock to investors, approximately $3.39 million through the sale of Series B Preferred Stock to investors, approximately $3.46 million from the sale of convertible promissory notes and approximately $1.82 million from the sale of non-convertible promissory notes. As of February 28, 2017, we had cash and cash equivalents of approximately $783,000 and debt of approximately $1.0 million. Through February 28, 2017, we have issued and outstanding warrants to purchase 2,698,694 shares of our common stock at a weighted average exercise price of $5.12 per share, which could result in proceeds to us of approximately $13.8 million if all outstanding warrants were exercised for cash.

Cash Flows

At February 28, 2017, we had approximately $783,000 in cash and cash equivalents, compared to approximately $364,000 on February 29, 2016.

Net cash used in operating activities was approximately $2.3 million for the year ended February 28, 2017, as compared to approximately $3.1 for the year ended February 29, 2016. The decrease in cash used of approximately $0.8 million was primarily due to a reduction operating expenses and the receipt of an upfront payment for research and development reimbursement. We expect amounts used in operating activities to increase for the next fiscal year ending February 28, 2018 and beyond as we grow our corporate operations.

Net cash used in investing activities was approximately $1,000 for the year ended February 28, 2017, compared to approximately $49,000 of cash used for the year ended February 29, 2016. This decrease of approximately $48,000 was attributed to decreases in laboratory equipment purchases and a reduction of proceeds from note receivable. We expect amounts used in investing activities to increase for the next fiscal year ending February 28, 2018 and beyond as we grow our corporate operations, expand research and development activities and add capacity in our laboratory including related to information technology, which is expected to result in an increase of our capital expenditures.

Net cash provided by financing activities during the year ended February 28, 2017 was approximately $2.7 million, compared to approximately $3.3 million for the year ended February 29, 2016. Financing activities consisted primarily of proceeds from the sale of common stock and warrants for the year ended February 28, 2017, and primarily from the issuance of notes and warrants, and Series B Preferred Stock and warrants, for the year ended February 29, 2016.

Capital Raising Requirements

Pursuant to the outstanding License Agreement, and the Second License Agreement, we are required to meet certain capital raising or financing requirements beginning on the first anniversary of the effective date of the License Agreement, or August 26, 2011. These capital raising requirements are inclusive for all the license agreements. We must meet the following conditions:

1. Raise $750,000 in debt, equity or other financing or revenues by the first anniversary of the effective date of the License Agreement, which requirement has been satisfied by us.

2. Raise $2,000,000 in debt, equity or other financing or revenues by the third anniversary of the effective date, which requirement has been satisfied by us.

3. Raise $5,000,000 in debt, equity or other financing or revenues by the fifth anniversary of the effective date, which requirement has been satisfied by us.

Contractual Obligations

As of February 28, 2017, we had the following contractual commitments:

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
	(In thousands)				
License Agreement [1]	$ 600	$ 100	$ 300	$ 200	$ (1)
Second License Agreement [2]	$ 425	$ 5	$ 220	$ 200	$ (2)
Alternative Splicing Diagnostic License Agreements [3]	$ 288	$ 38	$ 150	$ 100	$ (4)
Antibody License Agreement [4]	$ 115	$ 15	$ 60	$ 40	$ (5)
Lease Agreement [5]	$ 103	$ 103	$ -	$ -	$ -

(1) Amount of additional payments depends on several factors, including the duration of the License Agreement, which depends on expiration of the last patent to be issued pursuant to the License Agreement. That duration is uncertain because the last patent has not yet been issued.

(2) Amount of additional payments depends on several factors, including the duration of the Second License Agreement, which depends on expiration of the last patent to be issued pursuant to the Second License Agreement. That duration is uncertain because the last patent has not yet been issued.

(3) Amount of additional payments depends on several factors, including the duration of the Alternative Splicing Diagnostic License Agreement, which depends on expiration of the last patent to be issued pursuant to the Alternative Splicing Diagnostic License Agreement. That duration is uncertain because the last patent has not yet been issued. No annual license maintenance fee payments are due on the Alternative Splicing Therapeutic License Agreement as long as the Alternative Splicing Diagnostic License Agreement is in effect.

(4) Amount of additional payments depends on several factors, including the duration of the Antibody License Agreement, which depends on expiration of the last patent to be issued pursuant to the Antibody License Agreement. That duration is uncertain because the last patent has not yet been issued.

(5) Only includes basic rent payments through August 31, 2017. Additional monthly payments under the lease agreement shall include tax payments and operational costs.

License Agreements

Pursuant to the License Agreement, we are required to make annual license maintenance fee payments beginning August 26, 2011. We have satisfied all license maintenance payments due through February 28, 2017. We are required to make payments of $100,000 in 2017 and every year the license is in effect thereafter. These annual license maintenance fee payments will be credited to running royalties due on net sales earned in the same calendar year, if any. We are in compliance with the License Agreement.

Pursuant to the Second License Agreement, we are required to make annual license maintenance fee payments beginning on January 3, 2013. Effective February 1, 2017, we amended the Second License Agreement to reduce the maintenance payment for 2016 from $30,000 to $5,000, 2017 from $50,000 to $5,000, 2018 from $75,000 to $5,000, 2019 from $100,000 to $60,000, and 2020 from $100,000 to $60,000. We are required to make payments of $100,000 in 2021 and every year the license is in effect thereafter. These annual license maintenance fee payments will be credited to running royalties due on net sales earned in the same calendar year, if any. The license maintenance payment of $5,000 for 2017 is currently outstanding, pending invoice. As such, we are in compliance with the Second License Agreement.

Pursuant to the Alternative Splicing Diagnostic License Agreement and the Alternative Splicing Therapeutic License Agreement, we are required to make annual license maintenance fee payments for each license beginning on January 1, 2015. We have satisfied all license maintenance payments due through February 28, 2017. We are required to make additional payments of $37,500 in 2018, and $50,000 in 2019 and every year each license is in effect thereafter. We are in compliance with the Alternative Splicing License Agreements.

Pursuant to the Antibody License Agreement, we are required to make license maintenance fee payments beginning on January 1, 2015. We have satisfied all license maintenance payments due through February 28, 2017. We are required to make additional payments of $15,000 in 2018 and $20,000 in 2019 and every year the license is in effect thereafter. These annual license maintenance fee payments will be credited to running royalties due on net sales earned in the same calendar year, if any. We are in compliance with the Antibody License Agreement.

Lease Agreements

On August 28, 2014, we entered into a lease agreement (the "Boston Lease") for our diagnostic laboratory and office space located at 27, Drydock Ave, 2 nd Floor, Boston, MA 02210 (the "Boston Property"). We paid a $40,000 security deposit in connection with entering into the Boston Lease. Effective April 6, 2016, we entered into an amendment to the Boston Lease (the "Boston Lease Amendment"), whereby we extended the term by one year from September 1, 2016 to August 31, 2017. The basic rent payable under the Boston Lease Amendment is $17,164 per month plus additional monthly payments including tax payments and operational and service costs. We anticipate entering into an additional amendment or new long-term lease agreement on reasonable commercial terms for the Boston Property.

Effective March 1, 2015 we entered into a lease agreement for short-term office space in New York, NY. We paid a $2,100 security deposit in connection with entering into the lease. Effective December 1, 2015 we amended our lease agreement for the short-term office space in New York, NY. The term of the lease is month-to-month and may be terminated with twenty-one (21) days' notice. The basic rent payment is $2,400 per month and we paid an additional $1,500 security deposit in connection with the amended lease.

Equipment

We intend to enter into arrangements for the acquisition of additional laboratory equipment, computer hardware and software, including data storage, leasehold improvements and office equipment in fiscal year 2018 as we continue to expand our research and development activities. We cannot at this time provide assurances that we will be able to enter into agreements with vendors on terms commercially favorable to us or that we will be able to enter into such arrangements without securing additional financing.

Operating Capital and Capital Expenditure Requirements

We currently anticipate that our cash and cash equivalents will not be sufficient to fund our operations through for the next twelve months, without raising additional capital. We expect to continue to incur substantial operating losses in the future and to make capital expenditures to keep pace with the expansion of our research and development programs and to scale up our commercial operations, which we expect to fund in part with the proceeds of the recent financing activities. It may take several years to move any one of a number of product candidates in clinical research through the development and validation phases to commercialization. We expect that the remainder of the net proceeds and our existing cash and cash equivalents will be used to fund working capital and for capital expenditures and other general corporate purposes, such as licensing technology rights, partnering arrangements for the processing of tests outside the United States or reduction of contractual obligations. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. We have no current plans, agreements or commitments with respect to any such acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction.

The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the progress of our product development, regulatory requirements, commercialization efforts, the amount of cash used by operations and progress in reimbursement.

We cannot be certain that any of our future efforts to develop future products will be successful or that we will be able to raise sufficient additional funds to see these programs through to a successful result.

Our future funding requirements will depend on many factors, including the following:

- the rate of progress in establishing reimbursement arrangements with third-party payers;
- the success of billing, and collecting receivables;
- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;
- the rate of progress and cost of research and development activities associated with expansion of products for breast cancer; and
- the rate of progress and cost of research and development activities associated with products in the research phase focused on cancer, other than breast cancer.

Until we can generate a sufficient amount of revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations. The issuance of equity securities may result in dilution to stockholders. We cannot make any assurances that additional financings will be completed on a timely basis, on acceptable terms or at all. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, it would negatively impact our business and operations, which could cause the price of our common stock to decline. It could also lead to the reduction or suspension of our operations and ultimately force the Company to cease operations.

Income Taxes

Since inception, we have incurred operating losses and, accordingly, have not recorded a provision for income taxes for any of the periods presented. As of February 28, 2017, we had cumulative net operating loss carryforwards for federal income tax purposes of approximately $18.7 million. If not utilized, the federal net operating loss and tax credit carryforwards will expire beginning in the year 2029. Utilization of net operating loss and credit carryforwards may be subject to a substantial annual limitation due to restrictions contained in the Internal Revenue Code that are applicable if we experience an “ownership change.” The annual limitation may result in the expiration of our net operating loss and tax credit carryforwards before they can be used.

Recent Accounting Pronouncements

We have implemented all new relevant accounting pronouncements that are in effect through the date of these financial statements. These pronouncements did not have any material impact on the financial statements unless otherwise disclosed. We are currently assessing the impact of the new accounting pronouncements disclosed in footnote 2 of our consolidated financial statements and do not know whether they might have a material impact on our financial position or results of operations.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY FINANCIAL DATA

Consolidated Financial Statements

The financial statements required by this item begin on page F-1 hereof.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 ("Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed under the Exchange Act is accumulated and communicated to management, including principal executive and financial officers, as appropriate, to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Management carried out an evaluation, under the supervision of the Chief Executive Officer and Vice President, Finance, of the effectiveness of disclosure controls and procedures as of February 28, 2017. Based upon that evaluation, management, including the Chief Executive Officer and Vice President, Finance, concluded that the design and operation of disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in the Securities Exchange Act of 1934, as amended. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of internal control over financial reporting as of February 28, 2017. In making this assessment, management used the criteria set forth by *Internal Control—Integrated Framework* (2013 Framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment using those criteria, management concluded that internal control over financial reporting was effective as of February 28, 2017.

As a smaller reporting company, we are not required to obtain an attestation report from our registered public accounting firm regarding internal controls over financial reporting.

Changes in Internal Controls over Financial Reporting.

We have had no changes in internal control over financial reporting during the quarter ended February 28, 2017 that have materially affected, or are reasonably likely to materially affect, internal control over financial reporting have been described above.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Name	Age	Position
Douglas A. Hamilton	51	President, Chief Executive Officer and Director (1)
Daniel H. Schneiderman	39	Vice President of Finance (2)
Jerome B. Zeldis, M.D., Ph.D.	67	Chairman of the Board of Directors (3)
Paul Billings, M.D., Ph.D.	64	Director (4)

(1) Appointed as president and chief executive officer effective as of June 17, 2015, and as a member of our board of directors effective as of May 4, 2017.
(2) Appointed as vice president of finance, effective December 21, 2012.
(3) Appointed as a member and vice chairman of our board of directors effective as of April 25, 2016, and chairman of our board of directors effective as of May 4, 2017.
(4) Appointed as a member of our board of directors effective as of May 24, 2017.

Douglas A. Hamilton. Mr. Hamilton was appointed our president and chief executive officer effective as of June 17, 2015, and appointed to our board of directors effective as of May 4, 2017. Mr. Hamilton has consulted for us as acting chief financial officer since August 2014. Prior to joining the Company, Mr. Hamilton served as partner at New Biology Ventures, LLC, a life-sciences focused venture capital incubator founded by Mr. Hamilton since 2007. From January 2012 through January 2014, Mr. Hamilton was chief financial officer of S.E.A. Medical Systems, Inc. From 1999 to 2006, Mr. Hamilton served as chief financial officer and chief operating officer for Javelin Pharmaceuticals, Inc. (acquired by Hospira, Inc.), in which he led the company to commercialization and through the private to public transition, including a successful national markets up-listing. Prior to Javelin, Mr. Hamilton was the chief financial officer and director of business development for PolaRx Biopharmaceuticals, Inc. (acquired by Cell Therapeutics, Inc., now owned by Teva Pharmaceuticals). Mr. Hamilton also served for several years in portfolio and project management at Pfizer, Inc. and Amgen, Inc., sales and marketing at Pharmacia Biotech (now GE Healthcare Life Sciences), and research at Connaught Laboratories (now Sanofi-Pasteur). Mr. Hamilton earned his Bachelor of Science degree from the Department of Medical Genetics at the University of Toronto and his MBA from the Ivey Business School at Western University.

Daniel H. Schneiderman. Mr. Schneiderman was appointed vice president of finance effective December 21, 2012 and has served as the Company's vice president, controller and corporate secretary since February 27, 2012. Mr. Schneiderman has over fifteen years of investment banking and corporate finance experience, focusing on private and public small capitalization companies mainly in the healthcare, life sciences and technology sectors. Prior to joining the Company, he was vice president of investment banking for Burnham Hill Partners LLC, where he worked since 2008. From 2004 through 2008, Mr. Schneiderman was vice president of investment banking at Burnham Hill Partners, a division of Pali Capital, Inc. While at Burnham Hill Partners, Mr. Schneiderman helped raise in excess of $500 million in capital through private placements, PIPEs and registered offerings as well as more complex transactions including restructurings and recapitalizations. Previously, Mr. Schneiderman worked at H.C. Wainwright & Co., Inc. in 2004 as an investment banking analyst. Mr. Schneiderman holds a Bachelor's Degree in Economics from Tulane University. Mr. Schneiderman serves as a board member for *Un*leashed, a not-for-profit organization in New York dedicated to dog rescue and animal rights.

Jerome B. Zeldis, M.D., Ph.D. Dr. Zeldis was appointed to our board of directors and vice chairman of the board effective as of April 25, 2016, and as Chairman of the Board effective as of May 5, 2017. Dr. Zeldis is currently the Chief Medical Officer and President of Clinical Research at Sorrento Therapeutics, Inc., positions he has held since August 2016. Previously, Dr. Zeldis was Chief Medical Officer of Celgene Corporation and CEO of Celgene Global Health, until June 2016. Prior to that he was Celgene's Senior Vice President of Clinical Research and Medical Affairs and had been at Celgene since February 1997. He attended Brown University for an A.B., M.S., followed by Yale University for an M.Phil., M.D., Ph.D. in Molecular Biophysics and Biochemistry (immunochemistry). Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and Gastroenterology at the Massachusetts General Hospital and Harvard Medical School. He was Assistant Professor of Medicine at the Harvard Medical School, Associate Professor of Medicine at University of California, Davis, Clinical Associate Professor of Medicine at Cornell Medical School and Professor of Clinical Medicine at the Robert Wood Johnson Medical School in New Brunswick, New Jersey. Prior to working at Celgene, Dr. Zeldis worked at Sandoz Research Institute and Janssen Research Institute in both clinical research and medical development. He has been a board member of a few start-up biotechnology companies and is currently Chairman of the board of Alliqua Biomedical and Trek Therapeutics in addition to board positions at PTC Therapeutics and Soligenix. He has published 122 peer reviewed articles and is the named inventor on 43 U.S. patents. Dr. Zeldis' extensive knowledge of the biotechnology industry, his extensive role in drug development and clinical studies as well as his directorships in other life science companies qualify him to serve as our director and Chairman of the Board

Paul Billings, M.D., Ph.D. Dr. Billings was appointed to our board of directors effective as of May 24, 2017. Dr. Billings is a board certified internist and clinical geneticist. Dr. Billings is currently a partner at the Bethesda Group Fund L.P., a position he has held since January 2016. From January 2015 to January 2016, Dr. Billings served as Executive-in-Residence at the California Innovation Center of Johnson and Johnson, Inc. He has also served as the Medical Director of the IMPACT program at Thermo Fisher Scientific, Inc. (TFS) from 2013 to 2015. From 2010 to 2014, he served as the first and only Chief Medical Officer at Life Technologies Corporation (which was acquired by TFS), and the Genetic Sciences Division of TFS. Dr. Billings currently serves on the board of directors of Trovagene, Inc. since October 2013, and Rennova Health, Inc. (formerly CollabRx, Inc.) since November 2015. Dr. Billings has previously served as a director of Ancestry.com Inc. from February 2012 to May 2013. He serves as an advisor or director for many companies, including Fabric Genomics, Inc. (formerly Omicia, Inc.), BioScale Inc., Applied Immunology, Inc., Aueon, Inc. and PAX Neuroscience Inc. He held senior management positions at Cord Blood Registry, Inc, GeneSage, Inc., Laboratory Corporation of America Holdings (LabCorp), and CELLective DX Corporation. Dr. Billings' clinical experience includes senior administrative positions at El Camino Hospital and the Veteran's Administration and he served as a physician at many medical centers. He has held numerous academic appointments at prestigious universities including Harvard University, Stanford University, U.C. Berkeley, and U.C. San Francisco. He is a prolific author with nearly 200 publications and books on genomic medicine. Dr. Billings holds an M.D. from Harvard Medical School and a Ph.D. in immunology, also from Harvard University. Dr. Billings is a nationally recognized expert on genomic and precision medicine, and his extensive medical and managerial experience in the field of personalized medicine qualifies him to serve as our director.

Other Key Consultants and Employees

Michael J. Donovan, Ph.D., M.D. Dr. Donovan joined the company as a consultant (acting chief medical officer) as of August 1, 2015. Dr. Donovan is board-certified in anatomic and clinical pathology and pediatric pathology with extensive experience in designing and implementing clinical studies. He has spearheaded the utilization of multiplex tissue and fluid-based assays and coupled mathematic applications to produce clinically relevant diagnostic/predictive/prognostic outcome models for a variety of tumor types and disease states. Dr. Donovan also serves as a Professor of Experimental Pathology and Director of the Biorepository and Pathology core at the Icahn School of Medicine at Mt. Sinai, New York City, New York. In addition to an academic career at Harvard Medical School and Boston Children's Hospital, Dr. Donovan has over 20 years' experience in the biotechnology industry, serving in various senior management roles at Millennium Pharmaceuticals and Incyte Pharmaceuticals. He most recently served as chief medical officer of Exosome Diagnostics, Inc. and chief scientific officer for Aureon Biosciences Corporation. Dr. Donovan graduated from Rutgers University with a BS in zoology, a MS in endocrinology and a PhD in cell and developmental biology. He received his MD from the University of Medicine and Dentistry of New Jersey.

Rick Pierce. Mr. Pierce commenced working with the company as a consultant, as vice president of investor relations as of March 1, 2015. Mr. Pierce is the founder of FEP Capital Advisors, LLC, which provides investor relations and corporate development services to biotech, specialty pharmaceuticals and medical device companies. He has been involved in the up-listing of two OTCBB listed companies to the NASDAQ and NYSE stock exchanges. Mr. Pierce has 31 years of experience in specialty pharma, biotech, medical device and diagnostics operations and finance. He has a comprehensive understanding and broad exposure to most aspects of medical device and drug development from preclinical development, chemistry and manufacturing controls, through commercial product launch. Prior to entering industry in 1998, Mr. Pierce spent several years on Wall Street at firms including Merrill Lynch and Lehman Brothers, where he placed over a billion dollars in equity and debt securities. He has extensive capital markets and investment banking experience including, IPOs, secondary offerings, PIPEs, M&A, sales and trading. He has been involved in U.S./cross border pharmaceutical and biotech business development since 1994 and involved in closing a number of strategic transactions. At his last three companies Javelin Pharmaceuticals, Inc., SemBioSys Genetics and GlycoGenesys, Inc., Mr. Pierce helped raise more than $335 million and successfully close a number of transformative business development deals, including the buyout of Javelin Pharmaceuticals by Hospira (now Pfizer).

Scientific and Clinical Advisory Board

Effective as of October 24, 2012, the board of directors formally established a Scientific Advisory Board whose primary responsibilities include advising our management and the board on the long-term direction of our scientific and research goals and a Clinical Advisory Board whose primary responsibilities include advising our management and the Board on the most efficient translation of our scientific and research discoveries to clinical practice. We are in the process of reconstituting our Scientific and Clinical Advisory Board based on our Rx/Dx strategy and expect to enter into new Scientific and Clinical Advisory Board consulting contracts for the year ending February 28, 2018. We currently have consulting contracts with Bruce Zetter, Ph.D. and Frank Gertler, Ph.D. for scientific advisory services.

Bruce R. Zetter, Ph.D. Dr. Bruce Zetter serves as chief scientific officer and vice president of research at Boston Children's Hospital and the Charles Nowiszewski Professor of Cancer Biology at Harvard Medical School. Dr. Zetter serves as a consultant and scientific advisor to major biotechnology and pharmaceutical companies. He is highly regarded nationally and internationally as a leader in the research of tumor angiogenesis, progression, cancer diagnosis, and cancer metastasis. He served as head of scientific advisors at ProNAi Therapeutics, Inc. since November 2012. He served as a medical & scientific advisor of Mersana Therapeutics Inc. He co-founded Predictive Biosciences Inc. in 2006. Dr. Zetter served as an expert witness for the United States Senate Cancer Coalition hearings in Washington, DC. He serves as chairman of Scientific Advisory Board of the Scientific Advisory Board of SynDevRx, Inc., and Cerulean Pharma Inc. He served as chairman of Scientific Advisory Board of Tempo Pharmaceuticals Inc. and Predictive Biosciences, Inc. He serves as member of Scientific Advisory Board at Blend Therapeutics, Inc. He serves as member of Scientific & Medical Advisory Board at ProNAi Therapeutics, Inc. Dr. Zetter serves as a member of the board of directors and member of Advisory Board of Attenuon, LLC. Dr. Zetter serves on the Advisory Boards of Angstrom Pharmaceuticals and GMP Companies. He also serves on several grant review boards for public agencies such as the American Heart Association and American Cancer Society, and serves on the editorial board of 11 peer-reviewed journals. Dr. Zetter served as member of Scientific Advisory Board of Tempo Pharmaceuticals Inc., Synta Pharmaceuticals Corp., and BioTrove, Inc. His research interests focus on tumor metastasis and on identifying diagnostic and prognostic markers that can guide treatment decisions. He has chaired the grant review board on breast and prostate cancer for the National Institutes of Health. Dr. Zetter is a pioneer in understanding how cell movement affects tumor metastasis and is recognized for his key discovery of the inhibitory effects of alpha interferon to endothelial cell locomotion. His work led to the use of interferon alpha to treat hemangiomas. Dr. Zetter serves as a professor in the Department of Surgery at Harvard Medical School since 1978. Dr. Zetter has won numerous national and international awards for his work in the field of cancer research including a Faculty Research Award from the American Cancer Society and the prestigious MERIT award from the US National Cancer Institute. He has also received three teaching awards from the students at Harvard Medical School for excellence as a teacher and as a course director. He has authored more than 100 articles and has more than 20 patents to his credit. Dr. Zetter received a B.A. degree in Anthropology from Brandeis University. Dr. Zetter earned his Ph.D. from University of Rhode Island and he completed postdoctoral fellowships at Massachusetts Institute of Technology (MIT) and the Salk Institute in San Diego.

Frank B. Gertler, Ph.D. Dr. Frank Gertler received his B.S. degree from the University of Wisconsin-Madison in 1985. During his post-graduate thesis work at the University of Wisconsin-Madison, Dr. Gertler discovered the Enabled (Ena) gene in a search for functional downstream targets of signaling by the Drosophila homolog of the c-Abl proto-oncogene. He proceeded to demonstrate that Abl and Ena function were key components of the machinery required to establish normal connections during development of the nervous system. After receiving his Ph.D. in Oncology and Genetics in 1992, Dr. Gertler trained as a Postdoctoral Fellow in the laboratory of Philippe Soriano at the Fred Hutchinson Center for Cancer Research from 1993 through 1997. During this time, he cloned Mena, the mammalian homolog of Drosophila Ena, and discovered a family of related molecules, the “Ena/VASP” proteins. In 1997, Dr. Gertler joined the Biology Department at the Massachusetts Institute of Technology (MIT). His laboratory continued to work on Mena and the related Ena/VASP proteins and described pivotal roles for these proteins in controlling cell movement, shape and adhesion during fetal development. In 2005, Dr. Gertler moved to the MIT Center for Cancer Research and began to work on the role of Mena in metastatic progression and launched other efforts geared at understanding how the control of cell motility is dysregulated during metastatic diseases. Currently, Dr. Gertler is a Full Professor in the Koch Institute for Integrative Cancer Research at MIT and a member of the MIT Biology Department.

Family Relationships

There are no family relationships between any of our directors or executive officers.

Code of Ethics

We adopted a Code of Ethics that applies to all directors, officers and employees. Our Code of Ethics is available on our website at *www.metastat.com*. A copy of our code of ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 27 Drydock Ave., 2nd Floor, Boston, Massachusetts 02210.

Corporate Governance

Board Leadership Structure

Our board of directors (the "Board") has a chairman, currently Dr. Zeldis, who has authority, among other things, to call and preside over board meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the chairman has substantial ability to shape the work of the board of directors.

The positions of chief executive officer and chairman of our Board are held by different persons. The chairman of our Board, Dr. Zeldis, chairs director and any stockholder meetings and participates in preparing their agendas. Mr. Hamilton serves as a focal point for communication between management and the Board between board meetings, although there is no restriction on communication between directors and management. Mr. Hamilton serves as our chief executive officer as well as a member of our Board. We believe that these arrangements afford the other members of our Board sufficient resources to supervise management effectively, without being overly engaged in day-to-day operations.

Dr. Zeldis also serves as lead independent director for our Board and Dr. Billings serves as an independent director.

We believe that there is a weakness in our current leadership structure as a result of the current and ongoing restructuring of our Board. The Company intends to appoint independent directors to the Board and to chair each committee of our Board as soon as reasonably possible. The Board considers all of its members equally responsible and accountable for oversight and guidance of its activities.

Board Committees

Effective as of October 24, 2012, the Board established an Audit Committee, a Nominating and Corporate Governance Committee and a Compensation Committee.

Currently, Dr. Zeldis, Dr. Billings, and Mr. Hamilton will serve on each of the Audit Committee, Nominating and Corporate Governance Committee and Compensation Committee, until such time that the Company shall appoint independent directors to fulfil the requirements of such committees.

Board Practices

Our business and affairs are managed under the direction of our Board. The primary responsibilities of our Board are to provide oversight, strategic guidance, counseling and direction to our management.

Policy Regarding Board Attendance

Our directors are expected to attend meetings of the Board as frequently as necessary to properly discharge their responsibilities and to spend the time needed to prepare for each such meeting. Our directors are expected to attend annual meetings of stockholders, but we do not have a formal policy requiring them to do so.

Shareholder Communications

We have a process for shareholders who wish to communicate with our board of directors. Shareholders who wish to communicate with the board may write to it at our address given above. These communications will be reviewed by one or more of our employees designated by the board, who will determine whether they should be presented to the board. The purpose of this screening is to allow the board to avoid having to consider irrelevant or inappropriate communications.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires our executive officers, directors and persons who beneficially own more than 10% of a registered class of our equity securities to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. These executive officers, directors, and greater than 10% beneficial owners are required by SEC regulation to furnish us with copies of all Section 16(a) forms filed by such reporting persons.

Based solely on our review of such forms furnished to us and written representations from certain reporting persons, we believe that during the fiscal year ended February 28, 2017, all filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners were filed in a timely manner, except that Dr. Bronsther, Mr. Berman, Mr. Driscoll and Mr. Hamilton failed to timely file Form 4s with respect to their participation in the private placement of our common stock on October 30, 2016, in connection with their exchange of Series B Preferred. Additionally, Mr. Schneiderman failed to timely file a Form 4 in February 2016 in connection with an option issuance, and Mr. Hamilton failed to timely file a Form 4 in November 2016 in connection with purchases of our common stock.

Nominees to the Board of Directors

The Board will consider director candidates recommended by security holders. Potential nominees to the Board are required to have such experience in business or financial matters as would make such nominee an asset to the Board and may, under certain circumstances, be required to be “independent”, as such term is defined under Rule 5605 of the listing standards of NASDAQ and applicable SEC regulations. Security holders wishing to submit the name of a person as a potential nominee to the Board must send the name, address, and a brief (no more than 500 words) biographical description of such potential nominee to the Board at the following address: Richard Berman, Chairman of the Board of Directors, MetaStat, Inc., 27 Drydock Ave., 2nd Floor, Boston, MA 02210. Potential director nominees will be evaluated by personal interview, such interview to be conducted by one or more members of the Board, and/or any other method the Board deems appropriate, which may, but need not, include a questionnaire. The Board may solicit or receive information concerning potential nominees from any source it deems appropriate. The Board need not engage in an evaluation process unless (i) there is a vacancy on the Board, (ii) a director is not standing for re-election, or (iii) the Board does not intend to recommend the nomination of a sitting director for re-election. A potential director nominee recommended by a security holder will not be evaluated differently from any other potential nominee. Although it has not done so in the past, the Board may retain search firms to assist in identifying suitable director candidates.

The Board does not have a formal policy on Board candidate qualifications. The Board may consider those factors it deems appropriate in evaluating director nominees made either by the Board or stockholders, including judgment, skill, strength of character, experience with businesses and organizations comparable in size or scope to the Company, experience and skill relative to other Board members, and specialized knowledge or experience. Depending upon the current needs of the Board, certain factors may be weighed more or less heavily. In considering candidates for the Board, the directors evaluate the entirety of each candidate’s credentials and do not have any specific minimum qualifications that must be met. “Diversity,” as such, is not a criterion that the Board considers. The directors will consider candidates from any reasonable source, including current Board members, stockholders, professional search firms or other persons. The directors will not evaluate candidates differently based on who has made the recommendation.

Limitation of Liability and Indemnification of Officers and Directors

We are a Nevada corporation and generally governed by the Nevada Private Corporations Code, Title 78 of the Nevada Revised Statutes, or NRS. Our officers and directors are indemnified as provided by NRS and our bylaws.

Section 78.138 of the NRS provides that, unless the corporation’s articles of incorporation provide otherwise, a director or officer will not be individually liable unless it is proven that (i) the director’s or officer’s acts or omissions constituted a breach of his or her fiduciary duties, and (ii) such breach involved intentional misconduct, fraud, or a knowing violation of the law. Our articles of incorporation provide the personal liability of our directors is eliminated to the fullest extent permitted under the NRS.

Section 78.7502 of the NRS permits a company to indemnify its directors and officers against expenses, judgments, fines, and amounts paid in settlement actually and reasonably incurred in connection with a threatened, pending, or completed action, suit, or proceeding, if the officer or director (i) is not liable pursuant to NRS 78.138, or (ii) acted in good faith and in a manner the officer or director reasonably believed to be in or not opposed to the best interests of the corporation and, if a criminal action or proceeding, had no reasonable cause to believe the conduct of the officer or director was unlawful. Section 78.7502 of the NRS requires a corporation to indemnify a director or officer that has been successful on the merits or otherwise in defense of any action or suit. Section 78.7502 of the NRS precludes indemnification by the corporation if the officer or director has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court determines that in view of all the circumstances, the person is fairly and reasonably entitled to indemnity for such expenses and requires a corporation to indemnify its officers and directors if they have been successful on the merits or otherwise in defense of any claim, issue, or matter resulting from their service as a director or officer.

Section 78.751 of the NRS permits a Nevada company to indemnify its officers and directors against expenses incurred by them in defending a civil or criminal action, suit, or proceeding as they are incurred and in advance of final disposition thereof, upon determination by the stockholders, the disinterested board members, or by independent legal counsel. If so provided in the corporation's articles of incorporation, bylaws, or other agreement, Section 78.751 of the NRS requires a corporation to advance expenses as incurred upon receipt of an undertaking by or on behalf of the officer or director to repay the amount if it is ultimately determined by a court of competent jurisdiction that such officer or director is not entitled to be indemnified by the company. Section 78.751 of the NRS further permits the company to grant its directors and officers additional rights of indemnification under its articles of incorporation, bylaws, or other agreement.

Section 78.752 of the NRS provides that a Nevada company may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee, or agent of the company, or is or was serving at the request of the company as a director, officer, employee, or agent of another company, partnership, joint venture, trust, or other enterprise, for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee, or agent, or arising out of his status as such, whether or not the company has the authority to indemnify him against such liability and expenses.

Our bylaws implement the indemnification provisions permitted by Chapter 78 of the NRS by providing that we shall indemnify our directors and officers to the fullest extent permitted by the NRS against expense, liability, and loss reasonably incurred or suffered by them in connection with their service as an officer or director. Our bylaws provide shall advance costs and expenses incurred with respect to any proceeding to which a person is made a party as a result of being a director or officer in advance of final disposition of such proceeding upon receipt of an undertaking by or on behalf of the director or officer to repay such amount if it is ultimately determined that such person is not entitled to indemnification. We may purchase and maintain liability insurance, or make other arrangements for such obligations or otherwise, to the extent permitted by the NRS.

At the present time, there is no pending litigation or proceeding involving a director, officer, employee, or other agent of ours in which indemnification would be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

Item 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the compensation paid or accrued by us to our chief executive officer and vice president of finance and other executive officers. For each of our last two completed fiscal years, no other officer's compensation exceeded $100,000 in each year.

Name and Principal Position	Fiscal Year Ended February 28/29	Salary ($)	Bonus ($)	Stock Awards	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Douglas A. Hamilton, President, CEO and Director **(2)**	2017	260,000	-	-	452,534	-	712,534
Douglas A. Hamilton, President, CEO and Director **(2)**	2016	287,213	-	-	221,100	-	508,313
Daniel H. Schneiderman, VP, Finance	2017	165,000	-	-	169,701	-	334,701
Daniel H. Schneiderman, VP, Finance	2016	165,000	5,000	-	53,650	-	223,650
Oscar L. Bronsther, Former CEO and CMO **(3)**	2017	-	-	-	-	138,185	138,185
Oscar L. Bronsther, Former CEO and CMO **(3)**	2016	174,207	-	-	85,867	2,000	262,074
Mark Gustavson, Former VP, Diagnostics **(4)**	2017	5,192	207	-	-	-	5,399
Mark Gustavson, Former VP, Diagnostics **(4)**	2016	150,000	6,000	-	53,650	-	209,650

(1) Reflects the aggregate grant date fair value computed in accordance with FASB ASC Topic 718.

(2) Mr. Hamilton was appointed President and Chief Executive Officer effective June 17, 2015 and Director effective as of May 4, 2017. From August 1, 2014 through June 16, 2015, Mr. Hamilton served as a consultant to the Company through New Biology Ventures, LLC. Salary for the year ended February 29, 2016 includes $103,046 of consulting fees paid to New Biology Ventures, LLC, $119,167 of salary, $65,000 of accrued and unpaid salary, and excludes $15,200 of accrued stock-based compensation to New Biology Ventures, of which, Mr. Hamilton agreed to cancel without replacement and will not be issued any shares in connection with such stock-based compensation. Salary for the year ended February 28, 2017 includes $97,500 of paid salary and $162,500 of accrued and unpaid salary.

(3) Dr. Bronsther resigned as Chief Executive Officer and Chief Medical Officer effective June 17, 2015 and entered into a consulting agreement with the Company effective as of June 17, 2015. Salary for the year ended February 29, 2016 includes $64,039 of paid consulting fees and $57,780 of accrued and unpaid consulting fees.

(4) Mr. Gustavson resigned as Vice President, Diagnostics effective March 11, 2016.

Employment Agreements with Executive Officers

Employment Agreement with Douglas A. Hamilton

Effective as of June 17, 2015, we entered into an employment agreement with Douglas A. Hamilton to serve as our president and chief executive officer for a term of two years. The employment agreement with Mr. Hamilton provides for a base salary of $260,000 and an annual milestone bonus, at the sole discretion of the board of directors and the compensation committee, equal to 150% of Mr. Hamilton's compensation thereunder, based on his attainment of certain financial, clinical development, and/or business milestones to be established annually by the Company's board of directors or compensation committee. The employment agreement is terminable by either party at any time. In the event of termination by the Company without cause or by Mr. Hamilton for good reason not in connection with a change of control, as those terms are defined in the agreement, he is entitled to six months' severance. In the event of termination by the Company without cause or by Mr. Hamilton for good reason in connection with a change of control, as those terms are defined in the agreement, he is entitled to twelve months' severance.

Mr. Hamilton was also granted ten-year options to be governed by the terms of the 2012 Incentive Plan to purchase 60,000 shares of common stock at an exercise price equal to the greater of $8.25 per share and the closing price of the common stock on the date of issuance, being the fair market value on such date, which 10,000 options vest immediately, and 50,000 vest upon achieving various milestones as set forth in the employment agreement. Those milestones include (i) up-listing of the common stock to a national securities exchange, (ii) certification of the CLIA laboratory, (iii) achieving a market capitalization of $100 million, (iv) first commercial product sales, and (v) achieving a sales threshold of $25 million over 12 consecutive months. The employment agreement contains standard confidential and proprietary information, and one-year non-competition and non-solicitation provisions.

We expect to enter into a new employment agreement with Mr. Hamilton on substantially similar terms to his current employment agreement prior to the expiration of the term under his existing employment agreement.

Employment Agreement with Daniel H. Schneiderman

Effective as of May 27, 2013, we entered into an employment agreement with Daniel H. Schneiderman, to serve as our vice president of finance and secretary. The employment agreement with Mr. Schneiderman provides for a base salary of $125,000, and an annual milestone bonus upon the attainment of certain financial, clinical development and/or business milestones to be established annually by our board of directors or compensation committee. Effective October 1, 2014, the compensation committee and board of directors authorized an increase to Mr. Schneiderman's annual base salary to $165,000. The employment agreement is terminable by either party at any time. In the event of termination by us without cause or by Mr. Schneiderman for good reason not in connection with a change of control, as those terms are defined in the agreement, he is entitled to six months' severance. In the event of termination by us without cause or by Mr. Schneiderman for good reason in connection with a change of control, as those terms are defined in the agreement, he is entitled to twelve months' severance.

Consulting Agreements with Key Consultants

Consulting Agreement with Michael J. Donovan, Ph.D., M.D.

Effective as of August 1, 2015, the Company and Dr. Donovan entered into a consulting agreement whereby Dr. Donovan will serve as the Company's acting Chief Medical Officer. Dr. Donovan was paid a $12,500 retainer upon signing and will be paid at a rate of $400 per hour up to a maximum of $2,500 per day. The term of the agreement is one year and may be terminated by either party with thirty days' notice.

Consulting Agreement with Rick Pierce

Effective March 1, 2015, the Company and Mr. Pierce, through an affiliated limited liability company, entered into a consulting agreement whereby Mr. Pierce will perform internal investor relations activities for a minimum of ten days per month. Mr. Pierce will be paid a fee of $6,500 per month of service. The term of the agreement was twelve months and is automatically extended for 12 month periods unless terminated by either party in writing. Additionally, either party may terminate the consulting agreement with 30 days' written notice. In connection with the consulting agreement, Mr. Pierce was issued an aggregate of 6,667 stock options, which vest based on achieving certain market based and milestone based conditions.

Director Compensation

The following table sets forth certain information concerning compensation paid or accrued to our non-executive directors during the year ended February 28, 2017.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation ($)	Total ($)
Jerome B. Zeldis (2)	$ -	-	185,500	-	-	-	$ 185,500
Richard C. Berman (3)	$ -	-	144,525	-	-	-	$ 144,525

(1) Reflects the aggregate grant date fair value computed in accordance with FASB ASC Topic 718.

(2) Dr. Zeldis was issued options to purchase 100,000 shares of common stock at $2.19 per share on May 26, 2016. 50,000 options vest in three equal installments on each of May 26, 2017, May 26, 2018, and May 26, 2019, and 50,000 options vest upon achieving a certain milestone.

(3) Mr. Berman was issued options to purchase 100,000 shares of common stock at $2.00 per share on July 7, 2016. 33,334 options vested immediately and the remaining 66,666 options are subject to time-based vesting. At issuance the grant date fair value of these options was $144,525. Effective November 30, 2016, Mr. Berman voluntarily cancelled the 100,000 options. Mr. Berman resigned as a director in May 2017.

Employee Benefits Plans

Pension Benefits

We do not sponsor any qualified or non-qualified pension benefit plans.

Nonqualified Deferred Compensation

We do not maintain any non-qualified defined contribution or deferred compensation plans.

Severance Arrangements

The employment agreements with each of Douglas A. Hamilton and Daniel H. Schneiderman provide that in the event of termination by us without cause or by the executives for good reason not in connection with a change of control, as those terms are defined in the agreement, such executives are entitled to six months' severance. In the event of termination by us without cause or by the executives for good reason in connection with a change of control, as those terms are defined in the agreement, such executives are entitled to twelve months' severance.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of securities underlying outstanding 2012 Incentive Plan awards for each named executive officer as of February 28, 2017.

	Option Awards					Stock Awards			
	Equity Incentive Plan Awards:					Equity Incentive Plan Awards:			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares of stock that have not vested (#)	Market value of shares of stock that have not vested ($) (1)	Number of unearned shares that have not vested (#)	Market or payout value of unearned shares that have not vested ($) (1)
Douglas A. Hamilton	20,000	-	40,000	$ 8.25	6/17/2025	-	$ -	-	-
Daniel H. Schneiderman	20,000	-	-	$ 3.55	2/3/2026	-	$ -	-	-
	3,334	-	-	$ 48.75	4/5/2023	-	$ -	-	-
	3,667	-	-	$ 10.20	1/6/2022		$	-	-
	-	-	-	$		1,334	$ 2,401		

(1) Market value based on closing price of common stock at February 28, 2017.

The following table summarizes the number of securities underlying awards that fall outside of the 2012 Incentive Plan for each named executive officer as of February 28, 2017.

	Option Awards					Stock Awards			
	Equity Incentive Plan Awards:					Equity Incentive Plan Awards:			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Number of securities underlying unexercised unearned options (#)	Option expiration price ($)	Option expiration date	Number of shares of stock that have not vested (#)	Market value of shares of stock that have not vested ($) (1)	Number of unearned shares that have not vested (#)	Market or payout value of unearned shares that have not vested ($) (1)
Douglas A. Hamilton	88,886	231,114	-	$ 2.00	7/7/2026	-	-	-	-
Daniel H. Schneiderman	33,336	86,664	-	$ 2.00	7/7/2026	-	-	-	-
	11,112	8,888	-	$ 16.50	10/14/2024	-	-	-	-

(1) Market value based on closing price of common stock at February 28, 2017.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding beneficial ownership of our common stock as of May 26, 2017 by (i) each person (or group of affiliated persons) who is known by us to own more than five percent of the outstanding shares of our common stock, (ii) each director and executive officer, and (iii) all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. Unless otherwise noted, the address of each stockholder listed below is 27 Drydock Ave. 2nd Floor, Boston, MA 02210.

We had 4,807,942 shares of our common stock outstanding as of May 26, 2017.

Names and Addresses of Beneficial Owners	Amount and Nature of Beneficial Ownership (1)	Percent of Class (2)
Douglas A. Hamilton, President, Chief Executive Officer, and Director (3)	399,753	7.7%
Daniel H. Schneiderman, Vice President of Finance and Secretary (4)	192,169	3.9%
Jerome B. Zeldis, M.D., Ph.D., Chairman of the Board of Directors (5)	120,000	2.4%
Paul Billings, M.D., Ph.D., Director	-	-
All Directors and Officers as a Group (4 Persons)	711,922	13.0%

* Less than 1%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of our common stock subject to securities anticipated to be exercisable or convertible at or within 60 days of the date hereof, are deemed outstanding for computing the percentage of the person holding such option or warrant but are not deemed outstanding for computing the percentage of any other person. The indication herein that shares are anticipated to be beneficially owned is not an admission on the part of the listed stockholder that he, she or it is or will be a direct or indirect beneficial owner of those shares.

(2) Based on 4,807,942 shares of our common stock outstanding as of May 26, 2017.

(3) Consists of (i) 19,753 shares of common stock, (ii) 108,886 shares of common stock underlying vested options. Also, includes 271,114 shares of common stock underlying unvested options subject to certain time-based and milestone vesting. Excludes 6,241 shares of Common Stock underlying warrants with 4.9% and 9.9% ownership blockers.

(4) Consists of (i) 23,834 shares of common stock, (ii) 1,334 restricted shares of common stock issued pursuant to the 2012 Incentive Plan that vest and become transferable upon the listing of the common stock on a national securities exchange, (iii) 71,449 shares of common stock underlying vested options. Also includes 95,552 shares of common stock underlying unvested options subject to certain time-based and milestone vesting (as of February 28, 2017).

(5) Consists of (i) 20,000 shares of common stock. Also includes 100,000 shares of common stock underlying unvested options, of which, 50,000 options are subject to annual time-based vesting and 50,000 options are subject to performance milestone vesting.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

None.

Director Independence

Jerome B. Zeldis, M.D., Ph.D. and Paul Billings, M.D., Ph.D. have been determined to be independent as defined by NASDAQ Listing Rule 5605(a)(2) of The NASDAQ Stock Market, LLC and Section 10A(m)(3) of the Exchange Act. No transactions, relationships or arrangements were considered by the board of directors in determining that these directors were independent. Under NASDAQ Listing Rule 5605(a)(2), an "independent director" is a "person other than an officer or employee of the company or any other individual having a relationship which, in the opinion of the company's board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director."

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Public Accounting Fees

The following charts sets forth public accounting fees in connection with services rendered by EisnerAmper LLP during the two years ended February 28, 2017.

	Fiscal Year Ended February 28, 2017	Fiscal Year Ended February 29, 2016
Audit Fees	$ 128,227	$ 155,987
Audit-Related Fees	$ -	$ -
Fees	$ 8,850	$ 8,000
All Other Fees	$ -	$ -
Total	$ 137,077	$ 163,987

Audit fees were for professional services rendered by EisnerAmper LLP for the audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Forms 10-Q for the two years ended February 28, 2017. Audit fees also includes professional services rendered with the filing of our registration statements.

Pre-Approval of Services

Our audit committee pre-approved all of the foregoing services.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit No.	Description
2.1	Share Exchange Agreement dated February 27, 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 25, 2012).
3.1	Articles of Incorporation of MetaStat, Inc., as amended (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 21, 2012).
3.2	Certificate of Designation of Rights and Preferences of the Series A Preferred Stock dated June 30, 2014 (Incorporated by reference to our Current Report on Form 8-K filed on July 2, 2014).
3.3	Amended and Restated Certificate of Designation of the Preferences, Rights and Limitations of the Series B Preferred Stock filed on December 31, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on April 2, 2015).
3.4	By-laws (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 21, 2012).
4.1	Form of Investor Warrant dated February 27, 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 21, 2012).
4.2	Form of Warrant issued to certain affiliates dated February 27, 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 21, 2012).
4.3	Form of Investor Warrant dated May 1, 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 7, 2012).
4.4	Form of May 2014 Convertible Promissory Note (Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on June 13, 2014).
4.5	Form of Warrant issued to Holders of May 2014 Convertible Promissory Notes (Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on June 13, 2014).
4.6	Form of Investor Warrant dated June 30, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on July 2, 2014).
4.7	Form of Series A Warrant dated December 31, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 7, 2015).
4.8	Form of Series B Warrant dated December 31, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 7, 2015).
4.9	Form of Amended and Restated Series A Warrant dated March 27, 2015 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on April 2, 2015).
4.10	Form of August 2015 Promissory Note (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 5, 2015).
4.11	Form of August 2015 Warrant (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 5, 2015).
10.1	Form of Securities Purchase Agreement dated February 27, 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 25, 2012).

10.2	Form of Registration Rights Agreement dated February 27, 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 21, 2012).
10.3 †	License Agreement with AECOM, MIT, Cornell and IFO-Regina dated August 26, 2010 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 13, 2012).
10.4	Second Amended and Restated 2012 Omnibus Securities and Incentive Plan (Incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed with the Commission on May 29, 2015).
10.5	Form of Consultant Non-Qualified Stock Option Agreement (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 21, 2012).
10.6	Form of Employee Non-Qualified Stock Option Agreement (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 21, 2012).
10.7	Form of Securities Purchase Agreement dated May 1, 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 7, 2012).
10.8	Form of Registration Rights Agreement dated May 1, 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 7, 2012).
10.9	Sponsored Research Agreement with AECOM and Cornell University, dated April 2011 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 25, 2012).
10.10 †	"Second" License Agreement with AECOM effective March 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 13, 2012).
10.11 †	"Third" License Agreement with AECOM effective March 2012 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 13, 2012).
10.12	Consulting Agreement of Oscar L. Bronsther dated June 17, 2015 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on June 18, 2015).
10.13	Separation and Release Agreement of Oscar L. Bronsther dated June 17, 2015 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on June 18, 2015).
10.14	Employment Agreement of Daniel Schneiderman dated May 24, 2013 (Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on June 13, 2014).
10.15	Form of May 2014 Convertible Note and Warrant Purchase Agreement (Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on June 13, 2014).
10.16 †	Diagnostic License Agreement with the Massachusetts Institute of Technology and its David H. Koch Institute for Integrative Cancer Research at MIT and its Department of Biology, AECOM, and Montefiore Medical Center as of December 7, 2013 (Incorporated by reference to our Current Report on Form 8-K, as amended, initially filed with the Commission on December 12, 2013).
10.17 †	Therapeutic License Agreement with the Massachusetts Institute of Technology and its David H. Koch Institute for Integrative Cancer Research at MIT and its Department of Biology, AECOM, and Montefiore Medical Center as of December 7, 2013 (Incorporated by reference to our Current Report on Form 8-K, as amended, initially filed with the Commission on December 12, 2013).
10.18	Form of Securities Purchase Agreement dated June 30, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on July 2, 2014).

10.19	Form of Registration Rights Agreement dated June 30, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on July 2, 2014).
10.20	Antibody License Agreement with MIT dated June 2, 2014 (Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on July 15, 2014).
10.21	Memorandum of Understanding dated July 14, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on July 17, 2014).
10.22	Amendment No. 1 to Memorandum of Understanding dated October 12, 2014 (Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on October 15, 2014).
10.23	Employment Agreement with Douglas Hamilton dated June 17, 2015 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on June 18, 2015).
10.24	Form of Securities Purchase Agreement dated October 10, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 14, 2014).
10.25	Form of Registration Rights Agreement dated October 10, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 14, 2014).
10.26	Form of Securities Purchase Agreement dated October 24, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 30, 2014).
10.27	Form of Registration Rights Agreement dated December 31, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 7, 2014).
10.28	Form of Registration Rights Agreement dated December 31, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 7, 2014).
10.29	Form of Amended and Restated Securities Purchase Agreement dated March 27, 2015 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on April 2, 2015).
10.30	Form of Amended and Restated Registration Rights Agreement dated March 27, 2015 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on April 2, 2015).
10.31†	License, Development and Commercialization Agreement by and between MetaStat, Inc., MetaStat BioMedical, Inc., and ASET Therapeutics LLC, dated November 25, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 13, 2015).
10.32	Form of Note Purchase Agreement dated June 30, 2014 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 5, 2015).
10.33	Form of OID Note Purchase Agreement (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on February 19, 2016).
10.34	Form of Subscription Agreement dated May 26, 2016 2016 (Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on May 31, 2016) 2016 (Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on May 31, 2016).
10.35	Form of Registration Rights Agreement dated May 26, 2016 (Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on May 31, 2016).
10.36	Form of Subscription Agreement in connection with the 2016 Unit Private Placement (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 17, 2016).

10.37	Form of Registration Rights Agreement in connection with the 2016 Unit Private Placement (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 17, 2016).
10.38††	Pilot Materials Transfer Agreement between MetaStat, Inc. and Celgene Corporation dated August 22, 2016 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 6, 2016).
10.39††	First Amendment to Pilot Materials Transfer Agreement between MetaStat, Inc. and Celgene Corporation dated September 29, 2016 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 6, 2016).
10.40	Form of Convertible Note dated January 17, 2017 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 23, 2017).
10.41	Form of Warrant dated January 17, 2017 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 23, 2017).
10.42	Form of Exchange Agreement dated January 17, 2017 (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 23, 2017).
21.1	Subsidiaries of the Registrant (Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on May 28, 2013).
31*	Certification of Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document.
101.SCH**	XBRL Taxonomy Extension Schema.
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF**	XBRL Taxonomy Extension Definition Linkbase.
101.LAB**	XBRL Taxonomy Extension Label Linkbase.
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase.

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† Confidential treatment has been granted with respect to portions of this exhibit.

†† Confidential treatment has been requested with respect to portions of this exhibit.

* Filed herewith.

** Pursuant to Rule 406T of Regulation S-T, the XBRL (Extensible Business Reporting Language) information included in Exhibit 101 hereto is deemed furnished and not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

METASTAT, INC.

May 30, 2017

By: /s/ Douglas A. Hamilton
Douglas A. Hamilton, President, Chief Executive Officer, and Director
(Principal Executive Officer and Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	Capacity	Date
/s/ Douglas A. Hamilton Douglas A. Hamilton	Director	May 30, 2017
/s/ Jerome B. Zeldis Jerome B. Zeldis, M.D., Ph.D.	Chairman of the Board of Directors	May 30, 2017

METASTAT, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED FEBRUARY 28, 2017 AND FEBRUARY 29, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
MetaStat, Inc.

We have audited the accompanying consolidated balance sheets of MetaStat, Inc. and its subsidiary (the "Company") as of February 28, 2017 and February 29, 2016, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for each of the years in the two-year period ended February 28, 2017. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of MetaStat, Inc. and its subsidiary as of February 28, 2017 and February 29, 2016, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended February 28, 2017, in accordance with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, as of February 28, 2017, the Company has a total stockholders' deficit and an accumulated deficit. The Company has not generated revenues or positive cash flows from operations and has a negative working capital. The aforementioned conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/ EisnerAmper LLP

New York, New York
May 30, 2017

METASTAT, INC.
Consolidated Balance Sheets
as of February 28, 2017 and February 29, 2016

	February 28, 2017	February 29, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 782,707	$ 363,783
Note receivable	-	125,000
Prepaid expenses	20,856	33,121
Total Current Assets	**803,563**	**521,904**
Equipment (net of accumulated depreciation of $265,234 and $169,396, respectively)	414,635	497,052
Refundable deposits	43,600	43,600
TOTAL ASSETS	**$ 1,261,798**	**$ 1,062,556**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
LIABILITIES		
Current Liabilities:		
Accounts payable	$ 572,195	$ 746,144
Accrued expense	179,680	214,311
Deferred research & development reimbursement	177,517	-
Notes payable (net of debt discount of $743,282)	-	1,533,120
Convertible note payable (net of debt discount of $10,914)	989,086	-
Accrued interest payable	15,890	56,000
Accrued dividends on Series B Preferred Stock	15,638	48,317
Total Current Liabilities	**1,950,006**	**2,597,892**
Warrant liability	2,106,972	234,461
Total Liabilities	**4,056,978**	**2,832,353**
STOCKHOLDERS' DEFICIT		
Series A convertible preferred stock ($0.0001 par value; 1,000,000 shares authorized; 874,257 and 874,257 issued and outstanding, respectively)	87	87
Series A-2 convertible preferred stock ($0.0001 par value; 1,000,000 shares authorized; 70,541 and 0 issued and outstanding, respectively)	7	
Series B convertible preferred stock ($0.0001 par value; 1,000 shares authorized; 213 and 659 shares issued and outstanding, respectively)	-	-
Common Stock, ($0.0001 par value; 150,000,000 shares authorized; 4,707,942 and 1,851,201 shares issued and outstanding, respectively)	471	185
Additional paid-in-capital	23,523,140	21,607,259
Accumulated deficit	(26,318,885)	(23,377,328)
Total stockholders' deficit	**(2,795,180)**	**(1,769,797)**
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	**$ 1,261,798**	**$ 1,062,556**

The accompanying notes are an integral part of the consolidated financial statements

METASTAT, INC.
Consolidated Statements of Operations
For the Years ended February 28, 2017 and February 29, 2016

	Year ended February 28, 2017	Year ended February 29, 2016
Revenue	$ -	$ -
Total Revenue	-	-
Operating Expenses		
General & administrative	2,338,818	3,418,235
Research & development	1,009,134	1,360,739
Total Operating Expenses	3,347,952	4,778,974
Other Expenses (income)		
Interest expense	1,062,389	317,238
Other income, net	(965)	(141,549)
Change in fair value of warrant liability	(2,405,985)	(349,596)
Change in fair value of put option embedded in notes payable	(614,484)	10,015
Loss on sale of notes receivable	112,500	-
Loss on extinguishment of debt	1,375,829	-
Loss on settlement of accounts payable	64,323	-
Settlement expense	-	39,097
Total Other Expenses (Income)	(406,395)	(124,795)
Net Loss	**$ (2,941,557)**	**$ (4,654,179)**
Loss attributable to common shareholders and loss per common share:		
Net loss	**(2,941,557)**	**(4,654,179)**
Deemed dividend on Series B Preferred Stock issuance	(708,303)	(1,067,491)
Accrued dividend on Series B Preferred Stock	(227,163)	(267,058)
Deemed dividend on Series B Preferred Stock holders exchange of warrants	(2,340,552)	-
Loss attributable to common shareholders	**$ (6,217,575)**	**$ (5,988,728)**
Net loss per share, basic and diluted	$ (2.10)	$ (3.30)
Weighted average of shares outstanding, basic and diluted	2,965,910	1,816,060

The accompanying notes are an integral part of the consolidated financial statements

METASTAT, INC.
Consolidated Statements of Changes in Stockholders' Deficit
For the years ended February 28, 2017 and February 29, 2016

	Series A Preferred Stock		Series A -2 Preferred Stock		Series B Preferred Stock		Common Stock		Paid-in	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at February 28, 2015	**874,257**	**$ 87**	**-**	**$ -#**	**229**	**$ -**	**1,831,483**	**$ 183**	**$18,965,529**	**$(18,723,149)**	**$242,650**
Common stock issued for services	-	-	-	-	-	-	30,446	3	237,059	-	237,062
Share-based compensation	-	-	-	-	-	-			585,739	-	585,739
Series B preferred units issued for cash, conversion of accounts payable and conversion of short-term notes	-	-	-	-	387	-	-	-	1,945,244	-	1,945,244
Beneficial conversion feature of Series A Preferred Stock	-	-	-	-	-	-	-	-	1,067,491	-	1,067,491
Deemed dividend to Series B Preferred Stock	-	-	-	-	-	-	-	-	(1,067,491)	-	(1,067,491)
Accrued dividends on Series B Preferred Stock	-	-	-	-	-	-	-	-	(267,058)	-	(267,058)
Series B PIK Dividend	-	-	-	-	43	-	-	-	235,508	-	235,508
Placement agent warrants issued with note payable	-	-	-	-	-	-	-	-	16,800	-	16,800
Common stock and warrants cancellation settlement	-	-	-	-	-	-	(10,728)	(1)	(111,562)	-	(111,563)
Net loss	-	-	-	-	-	-	-	-	-	(4,654,179)	(4,654,179)
Balance at February 29, 2016	**874,257**	**$ 87**	**-**	**$ -**	**659**	**$ -**	**1,851,201**	**$ 185**	**$21,607,259**	**$(23,377,328)**	**$(1,769,797)**
Issuance of common stock, preferred stock and warrants for cash, net of offering costs	-	-	48,300	5	-	-	1,065,750	107	962,550	-	962,662
Issuance of common stock and warrants to convert accounts payable	-	-	-	-	-	-	32,500	3	212,275	-	212,278
Issuance of common stock											

and warrants to convert notes payable	-	-	16,000	2	-	-	440,500	44	1,566,755	-	1,566,801
Beneficial conversion feature of Series B Preferred Stock	-	-	-	-	-	-	-	-	708,303	-	708,303
Deemed dividend to Series B Preferred Stock holders	-	-	-	-	-	-	-	-	(708,303)	-	(708,303)
Accrued dividends on Series B Preferred Stock	-	-	-	-	-	-	-	-	(227,163)	-	(227,163)
Series B PIK Dividend	-	-	-	-	35	-	-	-	191,941	-	191,941
Issuance of common stock, preferred stock and warrants in exchange for cancellation of Series B preferred stock and Series A Warrants	-	-	6,241	-	(481)	-	1,292,991	129	747,486	-	747,615
Deemed dividend to Series B Preferred Stock holders for exchange of warrants	-	-	-	-	-	-	-	-	(2,340,552)	-	(2,340,552)
Issuance of warrants in connection with OID Notes amendment	-	-	-	-	-	-	-	-	44,095	-	44,095
Issuance of warrants in connection with convertible note	-	-	-	-	-	-	-	-	117,632	-	117,632
Share-based compensation	-	-	-	-	-	-	25,000	3	640,862	-	640,865
Net loss	-	-	-	-	-	-	-	-	-	(2,941,557)	(2,941,557)
Balance at February 28, 2017	**874,257**	**$ 87**	**70,541**	**$ 7**	**213**	**$ -**	**4,707,942**	**$ 471**	**$23,523,140**	**$(26,318,885)**	**$(2,795,180)**

The accompanying notes are an integral part of the consolidated financial statements

METASTAT, INC.
Consolidated Statements of Cash Flows
For the years ended February 28, 2017 and February 29, 2016

	Year ended	
	February 28, 2017	**February 29, 2016**
Cash Flows from Operating Activities:		
Net loss	$ (2,941,557)	$ (4,654,179)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	95,838	96,188
Share-based compensation	640,865	822,801
Accretion of debt discount included in interest expense	958,053	253,313
Loss on sale of note receivable and sale of assets	112,500	10,196
Loss on settlement of accounts payable	64,323	-
Loss on settlement of capital lease	-	8,820
Gain related to reimbursement of prior period research and development expense (Note 4)	-	(150,000)
Loss on extinguishment of debt	1,375,829	-
Change in fair value of warrant liability	(2,405,985)	(349,596)
Change in fair value of put option embedded in notes payable	(614,484)	10,015
Net changes in assets and liabilities:		
Prepaid expenses	170,664	112,877
Refundable deposit	-	(3,600)
Accounts payable and accrued expenses	(50,095)	648,980
Deferred research and development reimbursement	177,517	-
Interest payable	101,889	53,649
Net Cash used in Operating Activities	**(2,314,643)**	**(3,140,536)**
Cash Flows from Investing Activities:		
Proceeds from note receivable		100,000
Proceeds received from settlement of capital lease		2,897
Proceeds from sale of note receivable	12,500	-
Purchase of equipment	(13,421)	(151,830)
Net Cash used in Investing Activities	**(921)**	**(48,933)**
Cash Flows from Financing Activities:		
Proceeds from issuance of debt, net	122,790	1,611,408
Proceeds from issuance of common stock and warrants, net	2,746,688	-
Proceeds from issuance of Series B preferred stock and warrant, net	-	1,945,244
Re-purchase of common stock and warrants	-	(111,563)
Payment of notes	(8,000)	-
Payment of capital lease obligation	-	(42,407)
Payment of short-term debt	(126,990)	(107,250)
Net Cash provided by Financing Activities	**2,734,488**	**3,295,432**
Net increase in cash and cash equivalents	418,924	105,963
Cash and cash equivalents:		
Cash at the beginning of the year	363,783	257,820
Cash at the end of the year	**$ 782,707**	**$ 363,783**
Supplemental Disclosure of Non-cash Financing Activities:		
Warrant liability associated with note payable	$ 15,225	$ 311,057
Placement agent warrants issued with note payable	$ -	$ 16,800
Issuance of common stock and warrants as payment of accounts payable	$ 212,278	$ -
Issuance of common stock and warrants to convert debt and accrued interest	$ 2,326,321	$ -
Financing of insurance premium through notes payable	$ 158,400	$ 107,250
Note receivable received from the sale of assets	$ -	$ 75,000
Warrants issued to placement agents	$ 278,223	$ 175,241
Series B Preferred PIK dividend	$ 191,941	$ 235,508
Series B Preferred Stock accrued dividends	$ 227,163	$ 267,058
Capital lease settled against deposit	$ -	$ 227,235
Deemed dividend related to Series B Preferred Stock BCF adjustment for conversion price adjustment	$ 708,303	$ -
Issuance of common stock , preferred stock and warrants in exchange for cancellation of Series B preferred stock and Series A Warrants	$ 67,900	$ -
Deemed dividend to Series B preferred stock holders upon exercising Most Favorable Nation option	$ 2,340,552	$ -
Exchange OID notes and note payable to convertible debt	$ 986,269	$ -
Issuance of warrants in connection with OID Notes amendment	$ 44,095	$ -

The accompanying notes are an integral part of the consolidated financial statements

METASTAT, INC.
Notes to Consolidated Financial Statements
February 28, 2017 and February 29, 2016

NOTE 1 – ORGANIZATION, BASIS OF PRESENTATION AND GOING CONCERN

MetaStat, Inc. ("we," "us," "our," the "Company," or "MetaStat") is a pre-commercial molecular diagnostic company focused on the development and commercialization of novel diagnostics to provide physicians and patients actionable information regarding the risk of systemic metastasis and adjuvant chemotherapy treatment decisions. We believe cancer treatment strategies can be personalized and outcomes improved through new diagnostic tools that identify the aggressiveness and metastatic potential of primary tumors. The Company was incorporated on March 28, 2007 under the laws of the State of Nevada.

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, MetaStat Biomedical, Inc., a Delaware corporation and all significant intercompany balances have been eliminated by consolidation.

Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced net losses and negative cash flows from operations since its inception and currently has a stockholders' deficit of approximately $2.8 million. The Company has sustained cumulative losses of approximately $26.3 million as of February 28, 2017 and has not generated revenues or positive cash flows from operations. The continuation of the Company as a going concern is dependent upon continued financial support from its shareholders, the ability of the Company to obtain necessary equity and/or debt financing to continue operations, and the attainment of profitable operations. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. Although it is actively working on obtaining additional funding, the Company cannot make any assurances that additional financings will be available to it and, if available, completed on a timely basis, on acceptable terms or at all. If the Company is unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, it would negatively impact its business and operations and could also lead to the reduction or suspension of the Company's operations and ultimately force the Company to cease operations. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying consolidated financial statements have been prepared in accordance with the FASB "FASB Accounting Standard Codification™" or "ASC," which is the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles ("GAAP") in the United States.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities reported and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period, including contingencies. Accordingly, actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from date of purchase to be cash equivalents. All cash balances were highly liquid at February 28, 2017 and February 29, 2016.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company primarily maintains its cash balances with financial institutions in federally insured accounts. The Company may from time to time have cash in banks in excess of FDIC insurance limits. The Company has not experienced any losses to date resulting from this practice. The Company mitigates its risk by maintaining the majority of its cash and equivalents with high quality financial institutions.

Equipment

Equipment is stated at cost. The cost of equipment is depreciated over the estimated useful lives of the related assets. Depreciation is computed using the straight-line method for financial reporting purposes and accelerated methods for income tax purposes. Expenditures for major renewals or betterments that extend the useful lives of equipment are capitalized. Expenditures for maintenance and repairs are charged to expense as incurred.

Long-lived Assets

Long-lived assets are evaluated for impairment whenever events or conditions indicate that the carrying value of an asset may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the asset or group of assets. There was no impairment of long-lived assets as of February 28, 2017 and February 29, 2016.

Debt Issuance Costs

Effective March 1, 2016 debt issuance costs are recorded as a direct reduction of the carrying amount of the related debt. Debt issuance costs are amortized over the maturity period of the related debt instrument using the effective interest method.

Debt Instruments

We analyze debt instruments for various features that would generally require either bifurcation and derivative accounting, or recognition of a debt discount or premium under authoritative guidance.

Detachable warrants issued in conjunction with debt are measured at their relative fair value, if they are determined to be equity instrument, or their fair value, if they are determined to be liability instruments, and recorded as a debt discount. Conversion features that are in the money at the commitment date constitute a beneficial conversion feature that is measured at its intrinsic value and recognized as debt discount. Debt discount is amortized as interest expense over the maturity period of the debt using the effective interest method. Contingent beneficial conversion features are recognized when the contingency has been resolved.

Fair Value Measurements

The Company groups its assets and liabilities measured at fair value in three levels based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (an exit price).

Financial instruments with readily available active quoted prices or for which fair value can be measured from actively quoted prices generally will have a higher degree of market price observability and a lesser degree of judgment used in measuring fair value.

The three levels of the fair value hierarchy are as follows:

Level 1 – Valuation is based on quoted prices in active markets for identical assets or liabilities. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2 – Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, some discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, an instrument's level within the fair value hierarchy is based on the lowest level of input that is significant to the overall fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the financial instrument.

The Company recognizes transfers between levels as if the transfers occurred on the last day of the reporting period.

Revenues

We currently do not have any revenues. We expect to primarily derive our revenues from sale of our products, which are currently under development.

Net Loss Per Share

Basic net loss per common share is computed based on the weighted average number of common shares outstanding during the period. Restricted shares issued with vesting conditions that have not been met at the end of the period are excluded from the computation of the weighted average shares. As of February 28, 2017 and February 29, 2016, 11,536 and 11,536, respectively, restricted shares of common stock were excluded from the computation of the weighted average shares.

Diluted net loss per common share is calculated giving effect to all dilutive potential common shares that were outstanding during the period. Diluted potential common shares generally consist of incremental shares issuable upon exercise of stock options and warrants and conversion of outstanding options and warrants and shares issuable from convertible securities, as well as nonvested restricted shares.

In computing diluted loss per share for the years ended February 28, 2017 and February 29, 2016, no effect has been given to the common shares issuable at the end of the period upon the conversion or exercise of the following securities as their inclusion would have been anti-dilutive:

	February 28, 2017	**February 29, 2016**
Stock options	966,474	426,976
Warrants	2,698,694	913,514
Preferred stock	1,350,109	497,527
Convertible debt	507,946	-
Total	**5,523,223**	**1,838,017**

Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to net operating loss carry forwards and temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. These assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which the temporary differences are expected to reverse. A valuation allowance is recorded if it is not more likely than not that some portion or all of the deferred tax assets will be realized in future periods.

Research and Development Costs

Research and development costs are charged to operations when incurred and are included in operating expenses. Research and development costs consist principally of (i) compensation and related expenses for our employees and consultants that perform our research activities, (ii) the fees paid to maintain our licenses, (iii) the payments to third parties for clinical testing and additional product development including contract research organizations, (iv) facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, and (v) laboratory and other supplies, consumables and other materials used in research and development. Research and development costs were approximately $1.0 million and approximately $1.36 million for the years ended February 28, 2017 and February 29, 2016, respectively. During the year ended February 28, 2017, the Company recorded approximately $309,000 of research and development expense reimbursement related to a research agreement (See Note 11).

In the future, the Company may be required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments will be deferred and expensed when the activity has been performed or when the goods have been received.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses.

Stock-Based Compensation

We account for share-based payments award issued to employees and members of our Board of Directors (the "Board") by measuring the fair value of the award on the date of grant and recognizing this fair value as stock-based compensation using a straight-line basis over the requisite service period, generally the vesting period. For award issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is the earliest. Accordingly, non-employee award is remeasured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation over the requisite service period, generally the vesting period.

For award with performance conditions that affect their vesting, such as the occurrence of certain transactions or the achievement of certain operating or financial milestones, recognition of fair value of the award occurs when vesting becomes probable. For awards with market conditions that affect their vesting, the fair value of the award is recognized as stock-based compensation over the requisite service period, generally the vesting period.

Recently Issued Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements-Going Concern" ("ASU 2014-15"), which establishes management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern in connection with preparing financial statements for each annual and interim reporting period. ASU 2014-15 also provides guidance to determine whether to disclose information about relevant conditions and events when there is substantial doubt about an entity's ability to continue as a going concern. This update is effective for annual reporting periods ending after December 15, 2016. The adoption of this guidance in 2016 had no effect on the consolidated financial statements.

In February 2016, FASB issued ASU No. 2016-02, *Leases (Topic 842)* which supersedes FASB ASC Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. We are currently evaluating the impact of this guidance on our consolidated financial statements.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). ASU 2016-09 simplifies certain aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. ASU 2016-09 is effective for reporting periods beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact ASU 2016-09 will have on our consolidated financial statements.

NOTE 3 – CAPITAL STOCK

The Company has authorized 160,000,000 shares of capital stock, par value $0.0001 per share, of which 150,000,000 are shares of common stock and 10,000,000 are shares of “blank-check” preferred stock.

Our Board is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights, which could adversely affect the voting power or other rights of the holders of common stock. The preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us.

Common Stock

The holders of our common stock are entitled to one vote per share. In addition, the holders of our common stock will be entitled to receive ratably such dividends, if any, as may be declared by our Board out of legally available funds; however, the current policy of our Board is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our common stock will be entitled to share ratably in all assets that are legally available for distribution.

Series A Convertible Preferred Stock

Pursuant to the Certificate of Designation of Rights and Preferences of the Series A Preferred Stock (the “Series A Certificate of Designation”), the terms of the Series A Preferred Stock are as follows:

Ranking

The Series A Preferred Stock will rank (i) senior to our common stock, ii) *pari passu* with our Series A-2 Preferred Stock (as defined below) and (iii) junior to our Series B Preferred Stock (as defined below) with respect to distributions of assets upon the liquidation, dissolution or winding up of the Company.

Dividends

The Series A Preferred Stock is not entitled to any dividends.

Liquidation Rights

In the event of any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of the Series A Preferred Stock shall be entitled to receive out of the assets of the Company, whether such assets are capital or surplus, for each share of Series A Preferred Stock an amount equal to the fair market value as determined in good faith by the Board.

Voluntary Conversion; Anti-Dilution Adjustments

Each fifteen (15) shares of Series A Preferred Stock shall be convertible into one share of common stock (the "Series A Conversion Ratio"). The Series A Conversion Ratio is subject to customary adjustments for issuances of shares of common stock as a dividend or distribution on shares of the common stock, or mergers or reorganizations.

Voting Rights

The Series A Preferred Stock has no voting rights. The common stock into which the Series A Preferred Stock is convertible shall, upon issuance, have all of the same voting rights as other issued and outstanding common stock, and none of the rights of the Series A Preferred Stock.

Series A-2 Convertible Preferred Stock

Pursuant to the Certificate of Designation of Rights and Preferences of the Series A-2 Convertible Preferred Stock (the "Series A-2 Preferred Stock" or "Series A-2 Preferred"), the terms of the Series A-2 Preferred Stock are as follows:

Ranking

The Series A-2 Preferred will rank (i) senior to our common stock, (ii) *pari passu* with our Series A Preferred Stock, and (iii) junior to our Series B Preferred Stock (as defined below) with respect to distributions of assets upon the liquidation, dissolution or winding up of the Company.

Dividends

The Series A-2 Preferred is not entitled to any dividends.

Liquidation Rights

In the event of any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of the Series A-2 Preferred shall be entitled to receive out of the assets of the Company, whether such assets are capital or surplus, for each share of Series A-2 Preferred an amount of cash, securities or other property to which such holder would be entitled to receive with respect to each such share of Preferred Stock if such shares had been converted to common stock immediately prior to such liquidation, dissolution or winding-up of the Company.

Voluntary Conversion; Anti-Dilution Adjustments

Each share of Series A-2 Preferred shall, at any time, and from time to time, at the option of the holder, be convertible into ten (10) shares of common stock (the "Series A-2 Conversion Ratio"). The Series A-2 Conversion Ratio is subject to customary adjustments for issuances of shares of common stock as a dividend or distribution on shares of common stock, or mergers or reorganizations.

Conversion Restrictions

The holders of the Series A-2 Preferred may not convert their shares of Series A-2 Preferred into shares of common stock if the resulting conversion would cause such holder and its affiliates to beneficially own (as determined in accordance with Section 13(d) of the Exchange Act, and the rules thereunder) in excess of 4.99% or 9.99% of the common stock outstanding, when aggregated with all other shares of common stock owned by such holder and its affiliates at such time; provided, however, that such holder may elect to waive these conversion restrictions.

Voting Rights

The Series A-2 Preferred has no voting rights. The common stock into which the Series A-2 Preferred is convertible shall, upon issuance, have all of the same voting rights as other issued and outstanding common stock, and none of the rights of the Series A-2 Preferred.

Series B Convertible Preferred Stock

Pursuant to the Certificate of Designation of Rights and Preferences of the Series B Preferred Stock (the "Series B Certificate of Designation"), the terms of the Series B Preferred Stock are as follows:

Ranking

The Series B Preferred Stock will rank senior to our Series A Preferred Stock, Series A-2 Preferred Stock and common stock with respect to distributions of assets upon the liquidation, dissolution or winding up of the Company.

Stated Value

Each shares of Series B Preferred Stock will have a stated value of $5,500, subject to adjustment for stock splits, combinations and similar events (the "Stated Value").

Dividends

Cumulative dividends on the Series B Preferred Stock accrue at the rate of 8% of the Stated Value per annum, payable quarterly on March 31, June 30, September 30, and December 31 of each year, from and after the date of the initial issuance. Dividends are payable in kind in additional shares of Series B Preferred Stock valued at the Stated Value or in cash at the sole option of the Company. At February 28, 2017 and February 29, 2016, the dividend payable to the holders of the Series B Preferred Stock amounted to approximately $16,000 and approximately $48,000, respectively. During the year ended February 28, 2017 and February 29, 2016, the Company issued 34.5085 and 42.8202 shares of Series B Preferred Stock, respectively, for payment of dividends amounting to approximately $190,000 and approximately $236,000, respectively.

Liquidation Rights

If the Company voluntarily or involuntarily liquidates, dissolves or winds up its affairs, each holder of the Series B Preferred Stock will be entitled to receive out of the Company's assets available for distribution to stockholders, after satisfaction of liabilities to creditors, if any, but before any distribution of assets is made on the Series A Preferred Stock or common stock or any of the Company's shares of stock ranking junior as to such a distribution to the Series B Preferred Stock, a liquidating distribution in the amount of the Stated Value of all such holder's Series B Preferred Stock plus all accrued and unpaid dividends thereon. At February 28, 2017 and February 29, 2016, the value of the liquidation preference of the Series B Preferred stocks aggregated to approximately $1.19 million and approximately $3.67 million, respectively.

Conversion; Anti-Dilution Adjustments

Each share of Series B Preferred Stock will be convertible at the holder's option into common stock in an amount equal to the Stated Value plus accrued and unpaid dividends thereon through the conversion date divided by the then applicable conversion price. The initial conversion price was $8.25 per share (the "Series B Conversion Price") and is subject to customary adjustments for issuances of shares of common stock as a dividend or distribution on shares of common stock, or mergers or reorganizations, as well as "full ratchet" anti-dilution adjustments for future issuances of other Company securities (subject to certain standard carve-outs) at prices less than the applicable Series B Conversion Price.

The issuance of shares of common stock pursuant to the 2016 Unit Private Placement (as defined in Note 4) triggered the full ratchet anti-dilution price protection provision of the Series B Preferred Stock. Accordingly, the Series B Conversion Price was adjusted from $8.25 to $2.00 per share. See Note 4 for the accounting treatment of the conversion price adjustment.

The Series B Preferred Stock is subject to automatic conversion (the "Mandatory Conversion") at such time when the Company's common stock has been listed on a national stock exchange such as the NASDAQ, New York Stock Exchange or NYSE MKT; provided, that, on the Mandatory Conversion date, a registration statement providing for the resale of the shares of common stock underlying the Series B Preferred Stock is effective. In the event of a Mandatory Conversion, each share of Series B Preferred Stock will convert into the number of shares of common stock equal to the Stated Value plus accrued and unpaid dividends divided by the applicable Series B Conversion Price.

Voting Rights

On March 27, 2015, the holders of the Series B Preferred Stock entered into an Amended and Restated Series B Preferred Purchase Agreement, whereby the Company filed an Amended and Restated Series B Preferred Certificate of Designation. The Amended and Restated Series B Preferred Certificate of Designation provides that the holders of the Series B Preferred Stock shall be entitled to the number of votes equal to the number of shares of common stock into which such Series B Preferred Stock could be converted for purposes of determining the shares entitled to vote at any regular, annual or special meeting of stockholders of the Company, and shall have voting rights and powers equal to the voting rights and powers of the common stock (voting together with the common stock as a single class).

Most Favored Nation

For a period of up to 30 months after March 31, 2015, if the Company issues any New Securities (as defined below) in a private placement or public offering (a "Subsequent Financing"), the holders of Series B Preferred Stock may exchange all of the Series B Preferred Stock at their Stated Value plus all Series A Warrants (as defined below) issued to the Series B Preferred Stock investors in the Series B Private Placement for the securities issued in the Subsequent Financing on the same terms of such Subsequent Financing. This right expires upon the earlier of (i) September 30, 2017 and (ii) the consummation of a bona fide underwritten public offering in which the Company receives aggregate gross proceeds of at least $5.0 million. "New Securities" means shares of the common stock, any other securities, options, warrants or other rights where upon exercise or conversion the purchaser or recipient receives shares of the common stock, or other securities with similar rights to the common stock, subject to certain standard carve-outs.

See Note 4 for the accounting treatment of the Series B Preferred Stock.

NOTE 4 – EQUITY ISSUANCES

Common stock financing – the 2016 Unit Private Placement

During the year ended February 28, 2017, the Company entered into a subscription agreement pursuant to a private placement (the "2016 Unit Private Placement") with a number of accredited investors pursuant to which the Company issued units for an offering price of $10,000 per unit, with each unit consisting of (i) 5,000 shares of its common stock, and (ii) five-year warrants (the "Unit Warrants") to purchase 2,500 shares of common stock at an exercise price of $3.00 per share.

During the year ended February 28, 2017, the Company issued an aggregate of 49.5 units consisting of an aggregate of 247,500 shares of common stock and 123,750 Unit Warrants for an aggregate purchase price of $495,000. After deducting placement agent fees and other offering expenses, including legal expenses, net proceeds amounted to approximately $390,000. Additionally, the Company issued an aggregate of 24,750 placement agent warrants in substantially the same form as the Unit Warrants.

Registration Rights Agreement

Pursuant to a registration rights agreement entered into by the parties, the Company agreed to file a registration statement with the SEC providing for the resale of the shares of common stock and the shares of common stock underlying the Unit Warrants issued pursuant to the 2016 Unit Private Placement on or before the date which is forty-five (45) days after the date of the final closing of the 2016 Unit Private Placement. The Company will use its commercially reasonable efforts to cause the registration statement to become effective within one hundred fifty (150) days from the filing date. The Company has received a waiver from a majority of the 2016 Unit Private Placement investors extending the filing date of the registration statement to no later than December 15, 2016. The Company filed the Registration Statement on Form S-1 with the SEC on December 14, 2016.

Most Favored Nation Exchange – the MFN Exchange

On July 12, 2016, the Company and one Series B Preferred Stock shareholder (the "Exchange Purchaser") entered into an exchange agreement effective July 1, 2016 (the "Exchange Agreement") whereby the Exchange Purchaser elected to exercise their Most Favored Nation exchange right into the securities offered pursuant to the 2016 Unit Private Placement (the "MFN Exchange"). Accordingly, the Exchange Purchaser tendered all of their 19.4837 shares of Series B Preferred Stock and approximately $2,000 of accrued and unpaid dividends for an aggregate exchange amount of approximately $109,000, plus 9,000 Series A Warrants with an exercise price of $10.50 per share originally issued in connection with the Series B Private Placement for an aggregate of 54,652 shares of common stock and Unit Warrants to purchase 27,326 shares of common stock at an exercise price of $3.00 per share. Additionally, the parties entered into a joinder agreement, and the Exchange Purchaser was granted all rights and benefits under the 2016 Unit Private Placement financing agreements.

The Company analyzed and determined that the MFN Exchange is a contingent beneficial conversion feature that should be recognized upon the occurrence of the contingent event based on its intrinsic value at the commitment date. Since the Company had fully recognized all allocated proceeds of the Series B Preferred Stock in previously recognized beneficial conversion features, no beneficial conversion was recognized upon the exchange of the Series B Preferred Stock in the MFN Exchange.

For the year ended February 28, 2017, the Company has recorded a non-cash deemed dividend to Additional Paid-in Capital of approximately $29,000, in connection with the MFN Exchange equal to the excess fair value of the shares of common stock and Unit Warrants received over the carrying value of the exchanged shares of Series B Preferred and Series A Warrants

Common stock financing – Additional 2016 Unit Private Placement

During the year ended February 28, 2017, the Company entered into a subscription agreement (the "Additional 2016 Unit Subscription Agreement") pursuant to a private placement (the "Additional 2016 Unit Private Placement") whereby the Company may issue units for an offering price of $10,000 per unit, with each unit consisting of (i) 5,000 shares of its common stock at an effective price of $2.00 per share (the "Effective Price"), and (ii) five-year warrants (the "Additional Unit Warrants") to purchase 2,500 shares of common stock at an exercise price of $3.00 per share. Pursuant to the Additional 2016 Unit Subscription Agreement, for the benefit of certain investors that would be deemed to have beneficial ownership in excess of 4.99% or 9.99%, the Company may issue shares of Series A-2 Preferred Stock in lieu of issuing shares of common stock to such investors.

Pursuant to the Additional 2016 Unit Subscription Agreement, for a period of one hundred eighty (180) days following the final closing of the Additional 2016 Unit Private Placement, the investors shall have “full-ratchet” anti-dilution price protection (the “Price Protection”) based on certain issuances by the Company of common stock or securities convertible into shares of common stock at an effective price per share less than the Effective Price (a "Down-round Issuance"), whereby the Company would be required to issue the investors additional shares of common stock and Additional Unit Warrants. On April 30, 2017, the Price Protection provision lapsed without the Company issuing any additional shares of common stock and additional Unit Warrants.

During the year ended February 28, 2017, the Company issued an aggregate of 260.25 units consisting of an aggregate of 818,250 shares of common stock, 48,300 shares of Series A-2 Preferred Stock convertible into 483,000 shares of common stock, and Additional Unit Warrants to purchase 650,625 shares of common stock, for an aggregate purchase price of approximately $2.6 million. After deducting placement agent fees and other offering expenses, including legal expenses, net proceeds amounted to approximately $2.4 million.

Additionally, in connection with the Additional 2016 Unit Private Placement, the Company issued placement agent warrants to purchase an aggregate of 108,958 shares of common stock in substantially the same form as the Additional Unit Warrants but without the Price Protection provision.

Exchange of Payables – the Company Payable Exchange

During the year ended February 28, 2017, the Company entered into the Additional 2016 Unit Subscription Agreement with certain accredited vendors of the Company in connection with the exchange (the “Company Payable Exchange”) of an aggregate of $65,000 of accounts payable into the Additional 2016 Unit Private Placement. Pursuant to the Company Payable Exchange, the Company issued an aggregate of 6.5 units consisting of an aggregate of 32,500 shares of common stock, and Additional Unit Warrants to purchase 16,250 shares of common stock in consideration for the cancellation of $65,000 of accounts payable in the aggregate. As a result of the Company Payable Exchange, the Company recognized a loss of approximately $62,000.

Exchange of Promissory Note – the Promissory Note Exchange

During the year ended February 28, 2017, the Company entered into the Additional 2016 Unit Subscription Agreement with the holder (the “Noteholder”) of the Promissory Note (as defined in Note 7) in connection with the exchange (the “Promissory Note Exchange”) of $600,000 principal amount of Promissory Notes plus $48,000 of accrued and unpaid interest into the Additional 2016 Unit Private Placement. In connection with the Promissory Note Exchange, the Company issued 64.8 units consisting of 230,000 shares of common stock, 9,400 shares of Series A-2 Preferred, convertible into 94,000 shares of common stock, and Additional Unit Warrants to purchase 162,000 shares of common stock in exchange for the cancellation of $600,000 principal amount plus $48,000 of accrued and unpaid interest of the Promissory Note (See Note 7).

Exchange of OID Notes – the OID Note Exchange

During the year ended February 28, 2017, the Company entered into the Additional 2016 Unit Subscription Agreement with certain holders of OID Notes (the “OID Noteholders”) in connection with the exchange (the “OID Note Exchange”) of an aggregate of $553,000 principal amount of OID Notes (the “OID Exchange Amount”) into the Additional 2016 Unit Private Placement. In connection with the OID Note Exchange, the Company issued an aggregate of 55.3 units consisting of 210,500 shares of common stock, 6,600 shares of Series A-2 Preferred, convertible into 66,000 shares of common stock and Additional Unit Warrants to purchase 138,250 shares of common stock in exchange for the cancellation of $553,000 of OID Notes (See Note 7).

Most Favored Nation Exchange – the Additional MFN Exchange

During the year ended February 28, 2017, the Company and certain Series B Preferred Stockholders (the "Additional Exchange Purchasers") entered into exchange agreements (the "Exchange Agreements") whereby the Additional Exchange Purchasers elected to exercise their Most Favored Nation exchange rights into the securities offered pursuant to the Additional 2016 Unit Private Placement (the "Additional MFN Exchange"). Accordingly, the Additional Exchange Purchasers tendered all of their 460.6480 shares of Series B Preferred Stock and approximately $68,000 of accrued and unpaid dividends for an aggregate exchange amount of approximately $2.6 million, plus 208,027 Series A Warrants with an exercise price of $10.50 per share originally issued in connection with the Series B Private Placement (as defined below) for an aggregate of 1,238,339 shares of common stock, 6,240.8 shares of Series A-2 Preferred Stock convertible into 62,408 shares of common stock, and Additional Unit Warrants to purchase 650,381 shares of common stock. Additionally, the parties entered into a joinder agreement, and the Exchange Purchasers were granted all rights and benefits under the Additional 2016 Unit Private Placement financing agreements.

The Company analyzed and determined that the Additional MFN Exchange is a contingent beneficial conversion feature that should be recognized upon the occurrence of the contingent event based on its intrinsic value at the commitment date. Since the Company had fully recognized all allocated proceeds of the Series B Preferred Stock in previously recognized beneficial conversion features, no beneficial conversion was recognized upon the exchange of the Series B Preferred Stock in the Additional MFN Exchange.

For the year ended February 28, 2017, the Company recorded a non-cash deemed dividend to Additional Paid-in Capital of approximately $2.3 million in connection with the Additional MFN Exchange equal to the excess fair value of the shares of common stock, shares of Series A-2 Preferred Stock and Additional Unit Warrants issued over the carrying value of the cancelled shares of Series B Preferred Stock and exchanged Series A Warrants.

Accounting for the Price Protection Provision

The Company analyzed the Price Protection provision for embedded derivatives that require bifurcation. The Company evaluated the Price Protection provision for both the issuance of additional shares of common stock and additional warrants in connection with a down-round issuance in accordance with ASC 480 and ASC 815. In connection with the potential issuance of additional shares of common stock, the Company concluded that since the embedded down-round feature is within the equity host contract, the embedded Price Protection provision would be considered clearly and closely related to the equity host under ASC 815-15-25-1(a) and that the Price Protection provision should not be bifurcated. In connection with the potential issuance of additional warrants, the Company concluded that the freestanding Additional Unit Warrants are not indexed to the Company's common stock within the scope of ASC 815-40 and therefore was initially bifurcated and measured at fair value and recorded as a derivative liability in the Consolidated Balance Sheet. The derivative liability will be measured at fair value on an ongoing basis, with changes in fair value recognized in the statement of operations until the Price Protection provision lapses.

Registration Rights Agreement

Pursuant to a registration rights agreement entered into by the parties, the Company agreed to file a registration statement with the SEC providing for the resale of the shares of common stock and the shares of common stock underlying the Additional Unit Warrants issued pursuant to the Additional 2016 Unit Private Placement on or before the date which is forty-five (45) days after the date of the final closing of the Additional 2016 Unit Private Placement, which occurred on October 30, 2016. The Company will use its commercially reasonable efforts to cause the registration statement to become effective within one hundred fifty (150) days from the filing date. The Company filed the Registration Statement on Form S-1 with the SEC on December 14, 2016.

Issuances of common stock for services

During the year ended February 29, 2016, the Company issued an aggregate of 28,001 shares of common stock to consultants for services that vested immediately and 6,667 shares of common stock to a consultant for services that vested over 6 months. The weighted average fair value of these shares of common stock amounted to $4.96.

During the year ended February 29, 2016, the Company terminated a contract with a consultant whereby the consultant returned an aggregate of 4,222 shares of common stock previously issued to the consultant and the Company reduced stock-based expense in the amount of approximately $22,000.

During the year ended February 28, 2017, the Company issued an aggregate of 25,000 shares of common stock to a consultant for services that vested over a two-month term and to settle $32,000 of accounts payable. The fair value of the shares amounted to approximately $46,000 on the grant date.

During the year ended February 28, 2017 and February 29, 2016, the Company recognized approximately $14,000 and approximately $221,000, respectively, of share-based compensation related to common stock issued for services, all of which was recognized into general and administrative expense.

Settlement

During the year ended February 29, 2016, the Company entered into a settlement agreement to settle a dispute with two affiliated security holders in which the Company paid $150,000, in exchange for the cancellation of all Company securities held by such parties, which included an aggregate of 10,728 shares of common stock, 1,667 common stock purchase warrants with an exercise price of $31.50 and 5,001 common stock purchase warrants with an exercise price of $22.50. Additionally, the Company reimbursed $3,000 of legal expenses to the two affiliated security holders. The Company recorded the fair value of the instruments as a reduction of equity as equity instruments were cancelled and recognized a settlement expense of approximately $39,000 for the excess of the amount paid over the fair value of the cancelled equity instruments.

Series B preferred stock financing – the Series B Private Placement

The Company entered into an amended and restated securities purchase agreement (the "A&R Series B Purchase Agreement") on March 27, 2015 and March 31, 2015 with a number of new and existing accredited investors (collectively, the "Series B Investors") pursuant to which it sold approximately $2,131,000 of Series B Preferred Stock convertible into common stock at $8.25 per share in a private placement (the "Series B Private Placement"). In addition, pursuant to the A&R Series B Purchase Agreement, the Company issued series A warrants (the "Series A Warrants") to purchase up to 193,708 shares of common stock at an initial exercise price per share of $10.50 to the Series B Investors. The Series A Warrants expire on March 31, 2020.

Pursuant to the closings of the Series B Private Placement on March 2015, the Company issued an aggregate of 387.4088 shares of Series B Preferred Stock convertible into 258,281 shares of common stock and Series A Warrants to purchase 193,708 shares of common stock for an aggregate purchase price of $2,130,750, of which $18,000 represents the exchange of stock-based compensation to a consultant that was to be settled in the form of shares of common stock but was actually settled with Series B Preferred Stock and Series A Warrants. As a result of the exchange, the Company recorded approximately $13,000 of stock-based compensation.

In connection with the March 2015 closings of the Series B Private Placement, the placement agents were paid a total cash fee of approximately $147,000 including expense allowances and reimbursements, and were issued an aggregate of 20,668 Series A Warrants. On the grant dates, the fair value of the placement agent warrants amounted to approximately $158,000 and was recorded as a stock issuance cost. Net proceeds amounted to approximately $1,945,000 after deducting offering expenses to be paid in cash, including the placement agent fees and legal fees and other expense.

Accounting for the Series B Preferred Stock

The Company determined the Series B Preferred Stock should be classified as equity as it is not mandatorily redeemable, and there are no unconditional obligations in that (1) the Company must or may settle in a variable number of its equity shares and (2) the monetary value is predominantly (a) fixed, (b) varying with something other than the fair value of the Company's equity shares or (c) varying inversely in relation to the Company's equity shares.

Because the Series B Preferred Stock contain certain embedded features that could affect the ultimate settlement of the Series B Preferred Stock, the Company analyzed the instrument for embedded derivatives that require bifurcation. The Company's analysis began with determining whether the Series B Preferred Stock is more akin to equity or debt. The Company evaluated the following criteria/features in this determination: redemption, voting rights, collateral requirements, covenant provisions, creditor and liquidation rights, dividends, conversion rights and exchange rights. The Company determined that the preponderance of evidence suggests the Series B Preferred Stock was more akin to equity than to debt when evaluating the economic characteristics and risks of the entire Series B Preferred Stock, including the embedded features. The Company then evaluated the embedded features to determine whether their economic characteristics and risks were clearly and closely related to the economic characteristics and risks of the Series B Preferred Stock. Since the Series B Preferred Stock was determined to be more akin to equity than debt, and the underlying that causes the value of the embedded features to fluctuate would be the value of the Company's common stock, the embedded features were considered clearly and closely related to the Series B Preferred Stock. As a result, the embedded features would not need to be bifurcated from the Series B Preferred Stock.

Any beneficial conversion features related to the exercise of the Most Favored Nation exchange right or the application of the Mandatory Conversion provision will be recognized upon the occurrence of the contingent events based on its intrinsic value at the commitment date.

Accounting for the Series B Warrants

The Series B Warrants issued in the Series B Private Placement contain an adjustment clause affecting the exercise price of the Series B Warrants, which may be reduced if the Company issues shares of common stock or convertible securities at a price below the then-current exercise price of the Series B Warrants. As a result, we determined that the Series B Warrants were not indexed to the Company's common stock and therefore should be recorded as a derivative liability, based on their fair value at the time of issuance. The fair value of Series B Warrants will be re-measured at each reporting period, and any resultant changes in fair value will be recorded in the Company's Consolidated Statement of Operations.

Accounting for the Series A Warrants

The Company concluded the freestanding Series A Warrants did not contain any provision that would require liability classification and therefore should be classified in stockholder's equity, based on their relative fair value.

Allocation of Proceeds of the 2015 Series B Private Placement

For the year ended February 29, 2016, the proceeds of approximately $2,131,000 from the closings of the Series B Private Placement on March 27, 2015 and March 31, 2015 were allocated to the Series B Preferred Stock and Series A Warrant instruments based on their relative fair values.

The Series B Preferred Stock was valued on an as-if-converted basis based on the underlying common stock. The Series A Warrants were valued using the Black-Scholes model with the following weighted-average input at the time of issuance: expected term of 5.0 years based on their contractual life, volatility of 125% based on the Company's historical volatility and risk free rate of 1.4% based on the rate of the 5-years U.S. treasury bill.

After allocation of the proceeds, the effective conversion price of the Series B Preferred Stock was determined to be beneficial and, as a result, the Company recorded a non-cash deemed dividend of approximately $1,067,000 equal to the intrinsic value of the beneficial conversion feature.

Deemed Dividend due to Conversion Price Adjustment.

During the year ended February 28, 2017, as a result of the adjustment of the Series B Conversion Price from $8.25 to $2.00 per share due to the 2016 Unit Private Placement, the Company recorded a non-cash deemed dividend, amounting to approximately $708,000. The expense was measured at the intrinsic value of the beneficial conversion feature for each issuance of Series B Preferred Stock in the Series B Private Placement and was limited to the amount of Series B Preferred Stock allocated proceeds less previously recognized beneficial conversion features.

The Series B Registration Rights Agreement

In connection with the closing of the Series B Private Placement, the Company entered into a registration rights agreement (the "Series B Registration Rights Agreement") with all the Series B Investors, in which the Company agreed to file a registration statement (the "Registration Statement") with the Securities and Exchange Commission ("SEC") to register for resale the shares of common stock underlying the Series B Preferred Stock, the Series A Warrants and the Series B Warrants within 30 calendar days of the final closing date of March 31, 2015 (the "Filing Date"), and to have the registration statement declared effective within 120 calendar days of the Filing Date.

If the Registration Statement has not been filed with the SEC on or before the Filing Date, the Company shall, on the business day immediately following the Filing Date, and each 15th day thereafter, make a payment to the Series B Investors as partial liquidated damages for such delay (together, the "Late Registration Payments") equal to 2.0% of the purchase price paid for the Series B Preferred Stock then owned by the Series B Investors for the initial 15 day period and 1.0% of the purchase price for each subsequent 15 day period until the Registration Statement is filed with the SEC. Late Registration Payments will be prorated on a daily basis during each 15 day period and will be paid to the Series B Investors by wire transfer or check within five business days after the end of each 15 day period following the Filing Date.

The Company filed the Registration Statement on Form S-1 with the SEC on April 10, 2015 and the Registration Statement was declared effective on July 29, 2015. As a result, no penalty was incurred.

Deferred Offering Costs

During the year ended February 29, 2016, the Company incurred approximately $171,000 of incremental costs in connection with a proposed public offering of the Company's common stock that was aborted due to market conditions. These costs were charged to expense.

NOTE 5 – STOCK OPTIONS

Our 2012 Incentive Plan, which is administrated by the compensation committee of the Board, reserves shares of common stock available for issuance that we may grant to employees, non-employee directors and consultants, equity incentives in the form of, among other, stock options, restricted stock, and stock appreciation rights. On June 22, 2015, our stockholders approved amending our 2012 Incentive Plan to increase the number of authorized shares of common stock reserved for issuance under the 2012 Incentive Plan to a number not to exceed fifteen percent (15%) of the issued and outstanding shares of common stock on an as converted primary basis (the "As Converted Primary Shares") on a rolling basis. For calculation purposes, the As Converted Primary Shares shall include all shares of common stock and all shares of common stock issuable upon the conversion of outstanding preferred stock and other convertible securities, but shall not include any shares of common stock issuable upon the exercise of options, warrants and other convertible securities issued pursuant to the 2012 Incentive Plan. The number of authorized shares of common stock reserved for issuance under the 2012 Incentive Plan shall automatically be increased concurrently with the Company's issuance of fully paid and non- assessable shares of As Converted Primary Shares. Shares shall be deemed to have been issued under the 2012 Incentive Plan solely to the extent actually issued and delivered pursuant to an award under the 2012 Incentive Plan. As of February 28, 2017, there are an aggregate of 908,708 total shares available under the 2012 Incentive Plan, of which 330,514 are issued and outstanding and 578,194 shares are available for potential issuances. The Company may issue shares outside of the 2012 Incentive Plan.

During the year ended February 29, 2016, the Company issued options to purchase 6,667 shares of common stock at $11.25 per share to a consultant. The options vest upon achieving certain performance-based milestones and expire on March 1, 2025. The Company will measure the fair value of these options with vesting contingent on achieving certain performance-based milestones and recognize the compensation expense when vesting becomes probable. The fair value will be measured using a Black-Scholes model. During the year ended February 29, 2016, 3,334 of these options, with an aggregate fair value of approximately $15,000, vested based on achieving certain milestones.

During the year ended February 29, 2016, the Company issued options to purchase 80,000 shares of common stock at $8.25 per share to non-executive members of its Board of Directors. The options vest in three equal installments on each of May 18, 2016, May 18, 2017, and May 18, 2018 and expire on May 18, 2025. These options had a total fair value of approximately $388,000 as calculated using the Black-Scholes model.

During the year ended February 29, 2016, the Company issued options to purchase an aggregate of 5,001 shares of common stock at $8.25 per share to employees. The options vest over time through September 2017.

During the year ended February 29, 2016, the Company issued options to purchase 60,000 shares of common stock at $8.25 per share to our Chief Executive Officer. Certain of these options vest upon achieving certain performance-based or market-based milestones and expire on June 17, 2025. The fair value of these options on the grant date was $221,100 as calculated using the Black-Scholes model. The Company will recognize the compensation expense when vesting becomes probable. During the year ended February 29, 2016, 10,000 of these options vested immediately and 10,000 of these options vested upon achieving a performance based milestone.

During the year ended February 29, 2016, the Company issued options to purchase 26,667 shares of common stock at $8.25 per share to our former Chief Executive Officer and Chief Medical Officer. These options vested immediately. These options had a total fair value of approximately $44,000 as calculated using the Black-Scholes model. The Company also modified the expiration date of certain vested options previously granted to our former Chief Executive Officer and Chief Medical Officer, which resulted in an additional compensation expense of approximately $22,000 being recorded during the year ended February 29, 2016.

During the year ended February 29, 2016, the Company issued options to purchase 10,000 shares of common stock at $8.25 per share to a consultant. The options vest upon achieving certain performance-based milestones and expire on June 17, 2025. The Company will measure the fair value of these options with vesting contingent on achieving certain performance-based milestones and recognize the compensation expense when vesting becomes probable. The fair value will be measured using a Black-Scholes model.

During the year ended February 29, 2016, the Company issued options to purchase an aggregate of 45,500 shares of common stock at $3.55 per share to members of its management team and employees. These options expire on February 2, 2026. The fair value of these options on the grant date was approximately $122,000 as calculated using the Black-Scholes model. During the year ended February 29, 2016, 11,375 of these options vested immediately and 34,125 of these options will vest based on achieving certain milestones, which the Company deems probable to occur in December 2016.

During the year ended February 29, 2016, the Company issued options to purchase 10,000 shares of common stock at $3.55 per share to a consultant. These options expire on February 2, 2026. The fair value of these options on the measurement dates was approximately $20,000 as calculated using the Black-Scholes model. During the year ended February 29, 2016, 2,500 of these options vested immediately and 7,500 of these options will vest based on achieving certain milestones, which the Company deems probable to occur in December 2016.

During the year ended February 29, 2016, 534 options previously issued to a member of the Company's Scientific and Clinical Advisory Board were mutually cancelled by the parties. The member will continue to serve on the Company's Scientific and Clinical Advisory Board without any equity compensation.

For the year ended February 29, 2016, the Company recognized approximately $555,000 of compensation expense related to stock options, of which approximately $442,000 was recognized in general and administrative expenses and approximately $113,000 was recognized in research and development expenses.

During the year ended February 28, 2017, the Company issued options to purchase 50,000 shares of common stock at $2.19 per share to a non-executive member of its Board. These 50,000 options vest in three equal installments on each of May 26, 2017, May 26, 2018, and May 26, 2019 and expire on May 26, 2026. These options had a total fair value of approximately $87,000 as calculated using the Black-Scholes model.

During the year ended February 28, 2017, the Company issued options to purchase 50,000 shares of common stock at $2.19 per share to a non-executive member of its Board for performing other services. These 50,000 options vest upon achieving a certain milestone and expire on May 26, 2026. These options will be measured and recognized when vesting becomes probable.

During the year ended February 28, 2017, the Company issued options to purchase an aggregate of 440,000 shares of common stock at an exercise price of $2.00 per share to members of its management team. These options expire on July 7, 2026. These options had a grant date fair value of approximately $622,000 as calculated using the Black-Scholes model. 73,333 of these options vested immediately and 146,667 of these options vest in equal monthly installments over a twenty-four-month period. 220,000 options are subject to certain milestone-based vesting. The Company has not recognized any stock based compensation for the options with performance-vesting conditions, and expects to recognize the compensation expense when vesting become probable, which has not yet occurred.

During the year ended February 28, 2017, the Company issued options to purchase an aggregate of 100,000 shares of common stock at an exercise price of $2.00 per share to a non-executive member of its Board. These options expire on July 7, 2026. These options had a total fair value of approximately $143,000 as calculated using the Black-Scholes model. 33,333 of these options vested immediately and 66,667 of these options vest in equal monthly installments over a twenty-four-month period.

During the year ended February 28, 2017, the Company issued options to purchase an aggregate of 240,000 shares of common stock at an exercise price of $2.00 per share to consultants. These options expire on July 7, 2026. 33,333 of these options, with an aggregate fair value of approximately $57,000, vest on the first anniversary date and then 66,667 of these options vest in equal monthly installments over a twenty-four-month period. 140,000 of these options are subject to certain milestone-based vesting and the Company will measure the fair value of these options with vesting contingent on achieving certain performance-based milestones and recognize the compensation expense when vesting becomes probable.

During the year ended February 28, 2017, the Company and a member of its Board voluntarily cancelled options to purchase an aggregate of 100,000 shares of common stock at an exercise price of $2.00 per share without replacement. The Company recognized approximately $69,000 of compensation expense related to the cancellation of these options.

During the year ended February 28, 2017, the Company issued options to purchase an aggregate of 21,000 shares of common stock at an exercise price of $3.00 per share to employees. These options expire between on November 21, 2026 and December 1, 2026. These options had a grant date fair value of approximately $29,000 as calculated using the Black-Scholes model. 7,000 of these options vest one year following issuance and then 14,000 of these options vest in equal monthly installments over the following twenty-four-month period.

During the year ended February 28, 2017, the Company issued options to purchase 100,000 shares of common stock at $3.00 per share to a consultant. These options expire on January 13, 2027 and vest upon achieving certain performance-based milestones. The Company will measure the fair value of these options with vesting contingent on achieving certain performance-based milestones and recognize the compensation expense when vesting becomes probable. The fair value will be measured using a Black-Scholes model.

For the year ended February 28, 2017, the Company recognized approximately $580,000 of compensation expense related to stock options, of which approximately $495,000 was recognized in general and administrative expenses and approximately $85,000 in research and development expenses.

The inputs to the Black-Scholes model used to value the stock options granted during the year ended February 28, 2017 and February 29, 2016 are as follows:

	February 28, 2017	**February 29, 2016**
Expected volatility	98.9% - 133.4%	114.8%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	0.97% - 1.90%	1.64%
Weighted-average expected Term	6.31 years	5.60 years

The following table summarizes common stock options issued and outstanding:

	Options	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life (years)
Outstanding at February 28, 2015	**187,575**	**$ 23.70**	**$ 20,670**	**8.29**
Granted	243,835	$ 7.26	$ -	-
Expired/ Exercised/ Forfeited	(4,201)	$ (9.93)	$ -	-
Outstanding at February 29, 2016	**426,976**	**$ 14.45**	**$ -**	**7.98**
Granted	1,001,000	$ 2.14	$ -	-
Expired/ Exercised/ Forfeited	(461,502)	$ 6.05	$ -	-
Outstanding and expected to vest at February 28, 2017	**966,474**	**$ 5.71**	**$**	**8.87**
Exercisable at February 28, 2017	**315,476**	**$ 10.84**	**$ -**	**8.08**

The following table breaks down exercisable and unexercisable common stock options by exercise price as of February 28, 2017:

Exercisable			Unexercisable		
Number of Options	Exercise Price	Weighted Average Remaining Life (years)	Number of Options	Exercise Price	Weighted Average Remaining Life (years)
142,222	$ 2.00	9.36	337,778	$ 2.00	9.36
-	$ 2.19	-	100,000	$ 2.19	9.24
-	$ 3.00	-	121,000	$ 3.55	9.86
30,000	$ 3.55	8.94	-	$ 8.10	-
1,068	$ 8.10	7.92	-	$ 8.25	-
40,001	$ 8.25	8.26	79,999	$ 10.20	8.26
41,434	$ 10.20	4.86	-	$ 10.50	-
3,334	$ 11.25	8.22	3,333	$ 11.25	8.22
11,112	$ 16.50	7.63	8,888	$ 16.50	7.63
8,068	$ 22.50	7.92	-	$ 22.50	-
38,237	$ 48.75	6.10	-	$ 48.75	-
315,476	**$ 10.84**	**8.08**	**650,998**	**$ 3.23**	**9.27**

As of February 28, 2017, we had approximately $212,000 of unrecognized compensation related to employee and consultant stock options that are expected to vest over a weighted average period of 0.90 years and, approximately $500,000 of unrecognized compensation related to employee stock options whose recognition is dependent on certain milestones to be achieved. Additionally, there were approximately $213,000 stock options with a performance vesting condition that were granted to consultants which will be measured and recognized when vesting becomes probable.

NOTE 6 – WARRANTS

For the year ended February 29, 2016, the Company issued to a consultant for services a five-year warrant to purchase 9,134 shares of common stock at an exercise price of $8.25 per share. This warrant vested immediately. The fair value of this warrant was determined to be approximately $27,000, as calculated using the Black-Scholes model. Average assumptions used in the Black-Scholes model included: (1) a discount rate of 1.54%; (2) an expected term of 5.0 years; (3) an expected volatility of 128%; and (4) zero expected dividends. For the year ended February 29, 2016, the Company recognized approximately $27,000 of stock-based compensation for this warrant.

For the year ended February 29, 2016, the Company issued an aggregate of 1,251 warrants to a consultant for services. These warrants were issued on May 31, 2015 and expire on May 31, 2020. A total of 556 of such warrants are exercisable at $15.00 per share and 695 of such warrants are exercisable at $18.75 per share. These warrants vested immediately. The fair value of these warrants was determined to be approximately $5,000, as calculated using the Black-Scholes model. Average assumptions used in the Black-Scholes model included: (1) a discount rate of 1.49%; (2) an expected term of 5.0 years; (3) an expected volatility of 124%; and (4) zero expected dividends. For the year ended February 29, 2016, the Company recognized approximately $5,000 of stock-based compensation for these warrants.

For the year ended February 29, 2016, the Company issued an aggregate of 214,376 Series A Warrants in connection with the issuances of Series B Preferred Stock in March 2015, referenced in Note 6, including 20,668 warrants issued to the placement agent. These Series A Warrants were issued on March 27, 2015 and March 31, 2015, are exercisable at $10.50 per share and expire on March 31, 2020. The Series A Warrants vested immediately. The Series A Warrants do not contain any provision that would require liability treatment, therefore they were classified as equity in the Consolidated Balance Sheet. The fair value of the placement agent warrants was determined to be approximately $158,000, as calculated using the Black-Scholes model, and recorded as stock issuance cost. Weighted-average assumptions used in the Black-Scholes model included: (1) a discount rate of 1.41%; (2) an expected term of 5.0 years; (3) an expected volatility of 125%; and (4) zero expected dividends.

For the year ended February 29, 2016, the Company issued a warrant to purchase an aggregate of 43,636 shares of common stock in connection with the issuance of the Promissory Note pursuant to the Note Purchase Agreement on July 31, 2015, referenced in Note 7. This warrant is exercisable at $8.25 per share and expires on July 30, 2020. The warrant vested immediately. The warrant contains a clause affecting its exercise price that caused it to be classified as a derivative warrant liability (see Note 7 and Note 8). Such clause will lapse upon listing of the Company's common stock on a National Trading Market. The warrant was recorded as a debt discount based on its fair value.

For the year ended February 29, 2016, in connection with the issuance of the Promissory Note pursuant to the Note Purchase Agreement on July 31, 2015, the Company issued placement agent warrants to purchase an aggregate of 5,600 shares of common stock. These placement agent warrants were issued on July 31, 2015, are exercisable at $10.50 per share and expire on July 31, 2020. These placement agent warrants vested immediately. The fair value of these warrants was determined to be approximately $17,000, as calculated using the Black-Scholes model. Weighted-average assumptions used in the Black-Scholes model included: (1) a discount rate of 1.54%; (2) an expected term of 5.0 years; (3) an expected volatility of 128%; and (4) zero expected dividends. Approximately $17,000 was recorded as part of the debt discount against the stated value of the Promissory Note (see Note 7).

For the year ended February 29, 2016, the Company issued a warrant to purchase an aggregate of 43,636 shares of common stock in connection with the Note Amendment on February 12, 2016, referenced in Note 9. This warrant is exercisable at $8.25 per share and expire on July 30, 2020. The warrant vested immediately. This warrant contained an anti-dilution price protection provision, which required the warrant to be recorded as derivative warrant liability (see Note 7 and Note 8). Such clause will lapse upon completion of a Qualified Offering, as defined in the warrant agreement. The warrant was recorded as a debt discount based on its fair value.

For the year ended February 29, 2016, the Company issued warrants to purchase an aggregate of 36,367 shares of common stock in connection with the issuance of the OID Notes pursuant to the OID Note Purchase Agreement dated February 12, 2016, referenced in Note 9. These warrants are exercisable at $8.25 per share and expire on between February 12 and 22, 2021. These warrants vested immediately. Such clause will lapse upon completion of a Qualified Offering, as defined in the warrant agreement. These warrants were recorded as a debt discount based on their fair value.

During the year ended February 29, 2016, a total of 1,668 common stock purchase warrants with an exercise price of $31.50 per share and 5,001 common stock purchase warrants with an exercise price of $22.50 per share were repurchased and cancelled as part of a settlement of a dispute with two affiliated security holders (see Note 4).

For the year ended February 28, 2017, the Company issued warrants to purchase an aggregate of 9,092 shares of common stock in connection with the issuance of the OID Notes pursuant to the March 2016 OID Note Purchase Agreements dated between March 3 and 15, 2016, referenced in Note 7. These warrants vested immediately, were initially exercisable at $8.25 per share and expire between March 3 and 15, 2021. These warrants contained an anti-dilution price protection provision, which required the warrants to be recorded as derivative warrant liability. In connection with the issuances of common stock pursuant to the 2016 Unit Private Placement, the exercise price of these warrants was adjusted to $2.00 per share. Such clause will lapse upon completion of a Qualified Offering, as defined in the warrant agreement. These warrants were recorded as a debt discount based on their fair value.

For the year ended February 28, 2017, the Company issued Unit Warrants to purchase an aggregate of 175,826 shares of common stock to investors in connection with the 2016 Unit Private Placement and MFN Exchange referenced in Note 4. These Unit Warrants vested immediately, are exercisable at $3.00 per share and expire between May 26, 2021 and June 7, 2021. These Unit Warrants do not contain any provision that would require liability treatment, therefore they were classified as equity in the Consolidated Balance Sheet. Additionally, in connection with the MFN Exchange, the Company cancelled Series A Warrants to purchase an aggregate of 9,000 shares of common stock that were exercisable at $10.50 per share and originally issued in connection with the Series B Private Placement.

For the year ended February 28, 2017, the Company issued warrants to purchase an aggregate of 45,459 shares of common stock in connection with the OID Note Amendments referenced in Note 7. These warrants vested immediately, are exercisable at $2.00 per share and expire between August 11, 2021 and August 18, 2021. The fair value of these warrants was determined to be approximately $44,000, as calculated using the Black-Scholes model and were recorded as a debt discount based on their fair value.

For the year ended February 28, 2017, the Company issued Additional Unit Warrants to purchase an aggregate of 650,625 shares of common stock in connection with the Additional 2016 Unit Private Placement referenced in Note 4. These Additional Unit Warrants vested immediately, are exercisable at $3.00 per share and expire between August 30, 2021 and October 20, 2021. As discussed in Note 4, due to the Price Protection Provision, these Additional Unit Warrants are being classified as a derivative liability and measured at fair value.

For the year ended February 28, 2017, the Company issued Additional Unit Warrants to purchase an aggregate of 966,881 shares of common stock in connection with the Company Payable Exchange, Promissory Note Exchange, OID Note Exchange, and Additional MFN Exchange referenced in Note 4. These Additional Unit Warrants vested immediately, are exercisable at $3.00 per share and expire between October 20, 2021 and October 29, 2021. As discussed in Note 4, due to the Price Protection Provision, these Additional Unit Warrants are being classified as a derivative liability and measured at fair value. Additionally, in connection with the Additional MFN Exchange, the Company cancelled Series A Warrants to purchase an aggregate of 208,027 shares of common stock that were exercisable at $10.50 per share and originally issued in connection with the Series B Private Placement.

For the year ended February 28, 2017, in connection with the Additional 2016 Unit Private Placement, the Company issued placement agent warrants to purchase an aggregate of 108,958 shares of common stock. These placement agent warrants were issued between August 30, 2016 and October 28, 2016, vested immediately, are exercisable at $3.00 per share and expire between August 29, 2021 and October 27, 2021. The fair value of these warrants was determined to be approximately $259,000, as calculated using the Black-Scholes model. Weighted-average assumptions used in the Black-Scholes model included: (1) a discount rate of 1.25%; (2) an expected term of 5.0 years; (3) an expected volatility of 133% and (4) zero expected dividends.

For the year ended February 28, 2017, in connection with the Debt Exchange referenced in Note 7, the Company issued warrants to purchase an aggregate of 100,000 shares of common stock. These warrants were issued on January 17, 2017, vested immediately, are exercisable at $3.00 per share and expire January 16, 2022. The fair value of these warrants was determined to be approximately $118,000, as calculated using the Black-Scholes model. Average assumptions used in the Black-Scholes model included: (1) a discount rate of 1.84%; (2) an expected term of 5.0 years; (3) an expected volatility of 132%; and (4) zero expected dividends. For the year ended February 28, 2017, the Company recorded approximately $118,000 to Additional Paid-in Capital in connection with the debt extinguishment accounting related to the Debt Exchange (See Note 7).

For the year ended February 28, 2017, the Company issued warrants to purchase an aggregate of 37,500 shares of common stock to a consultant for financial advisory services. These warrants were issued between on December 31, 2016 February 28, 2017, vested immediately, are exercisable at $3.00 per share, and expire between December 30, 2021 and February 27, 2022. The fair value of these warrants was determined to be approximately $47,000, as calculated using the Black-Scholes model. Average assumptions used in the Black-Scholes model included: (1) a discount rate of 1.91%; (2) an expected term of 5.0 years; (3) an expected volatility of 131%; and (4) zero expected dividends. For the year ended February 28, 2017, the Company recognized approximately $47,000 of stock-based compensation for these warrants.

For the year ended February 28, 2017, the Company issued warrants to purchase an aggregate of 75,618 shares of common stock in connection with a settlement of an outstanding cash obligation payable to Dr. Oscar Bronsther, the Company's former chief executive officer and board member, per a consulting agreement, dated June 17, 2015, between the parties. These warrants were issued on February 15, 2017, vested immediately, are exercisable at $3.00 per share, and expire on February 14, 2022. The fair value of these warrants was determined to be approximately $95,000, as calculated using the Black-Scholes model. Average assumptions used in the Black-Scholes model included: (1) a discount rate of 2.01%; (2) an expected term of 5.0 years; (3) an expected volatility of 131%; and (4) zero expected dividends. For the year ended February 28, 2017, the Company recorded approximately $95,000 to Additional Paid-in Capital in connection with this settlement.

The following table summarizes common stock purchase warrants issued and outstanding:

	Warrants	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life (years)
Outstanding at February 29, 2015	**580,604**	**$ 17.81**	**$ 72,250**	**3.33**
Granted	354,000	$ 9.68	$ -	-
Expired/ Exercised/ Cancelled	(21,090)	$ 22.19	$ -	-
Outstanding at February 29, 2016	**913,514**	**$ 14.56**	**$ -**	**3.14**
Granted	2,169,959	$ 2.97	$ -	-
Expired/ Exercised/ Cancelled	(384,779)	$ 12.94	$ -	-
Outstanding and expected to vest at February 28, 2017	**2,698,694**	**$ 5.11**	**$**	**4.21**

Warrants exercisable at February 28, 2017 are:

Exercise Prices	Number of shares	Weighted average remaining life (years)	Exercisable number of shares
$ 2.00	164,888	2.57	164,888
$ 2.20	43,636	3.96	43,636
$ 3.00	2,115,408	0.12	2,115,408
$ 8.25	9,134	3.49	9,134
$ 10.50	126,978	3.10	126,978
$ 15.00	556	3.25	556
$ 18.75	695	3.25	695
$ 22.50	209,754	1.38	209,754
$ 31.50	25,912	1.30	25,912
$ 37.50	1,733	0.87	1,733
	2,698,694	**4.21**	**2,698,694**

NOTE 7 – NOTES PAYABLE

Promissory Note and Promissory Note Amendments

During the year ended February 29, 2016, the Company entered into a note purchase agreement effective July 31, 2015 (the "Note Purchase Agreement") with one its existing institutional investors (the "Note Holder"). Pursuant to the Note Purchase Agreement, the Company issued and sold a non-convertible promissory note in the principal amount of $1.2 million (the "Promissory Note") and a warrant (the "Note Warrant") to purchase 43,636 shares of the Company's common stock in a private placement (the "Note Private Placement").

The Promissory Note matured on July 30, 2016, accrued interest at a rate of eight percent (8%) per annum and may be prepaid by the Company at any time prior to the maturity date without penalty or premium. The Note Holder has the right at its option to exchange (the "Note Voluntary Exchange") the outstanding principal balance of the Promissory Note plus the Conversion Interest Amount (as defined below) into such number of securities to be issued in the Public Offering (as defined below). Upon effectuating such Note Voluntary Exchange, the Note Holder shall be deemed to be a purchaser in the Public Offering. "Public Offering" means a registered offering of equity or equity-linked securities resulting in gross proceeds of at least $5.0 million to the Company; and "Conversion Interest Amount" means interest payable in an amount equal to all accrued but unpaid interest assuming the Promissory Note had been held from the issuance date to the maturity date. In the event the Company completes a Public Offering and the Note Holder elected not to effectuate the Note Voluntary Exchange, then the Company shall promptly repay the outstanding principal amount of the Promissory Note plus all accrued and unpaid interest following completion of the Public Offering.

The Note Warrant contains an adjustment clause affecting its exercise price, which may be reduced if the Company issues shares of common stock or convertible securities at a price below the then-current exercise price of the Note Warrant. As a result, we determined that the Note Warrant was not indexed to the Company's common stock and therefore should be recorded as a derivative liability. The detachable Note Warrant issued in connection with the Promissory Note was recorded as a debt discount based on its fair value (see Note 8 for fair value measurement). The adjustment clause lapses upon listing of the Company's common stock on a national stock exchange such as the NASDAQ, New York Stock Exchange or NYSE MKT.

The Company evaluated the Note Voluntary Exchange provision, which provides for settlement of the Promissory Note at an 8% premium to the Promissory Note's stated principal amount, in accordance with ASC 815-15-25. The Voluntary Exchange provision is a contingent put that is not clearly and closely related to the debt host instrument and therefore was initially bifurcated and measured at fair value and recorded as a derivative liability in the Consolidated Balance Sheet. The derivative liability was measured at fair value on an ongoing basis, with changes in fair value recognized in the statement of operations. The proceeds of the Note Private Placement were first allocated to the fair value of the Note Warrant in the amount of approximately $151,000 and to the fair value of the Note Voluntary Exchange provision in the amount of approximately $228,000, with the difference of approximately $822,000 representing the initial carrying value of the Promissory Note. Further, approximately $105,000 of debt issuance cost was recorded as additional debt discount at issuance.

On February 12, 2016, the Company entered into an amendment (the "Note Amendment") with the Note Holder, whereby the Company and the Note Holder agreed to extend the maturity date of the Promissory Note from July 31, 2016 to December 31, 2016 and increase the interest rate commencing August 1, 2016 to 12% per annum. The Company also obtained the Note Holder's consent to the consummation of the OID Note Private Placement (as defined below), as required under the Promissory Note.

Additionally, pursuant to the Note Amendment, the Note Voluntary Exchange was modified to effect a voluntary exchange of $600,000 principal amount ("Initial Exchange Principal Amount") of the Promissory Note plus the Initial Conversion Interest Amount into a Qualified Offering (as defined below) or Public Offering. "Initial Conversion Interest Amount" shall mean interest payable in an amount equal to all accrued but unpaid interest assuming the Initial Exchange Principal Amount has been held from the issuance date to the original maturity date of July 31, 2016 (for the avoidance of doubt, such amount that is calculated using the following formula: (a) 8% multiplied by the Initial Exchange Principal Amount ($600,000), multiplied by (b) the actual number of days elapsed in a year of three hundred and sixty-five (365) days, which amount shall equal $48,000 in the aggregate). "Qualified Offering" means one or a series of offerings of equity or equity-linked securities resulting in aggregate gross proceeds of at least $2,000,000 to the Company.

Further, under the modified Note Voluntary Exchange, the Note Holder shall have the right to effect a voluntary exchange with respect to the remaining $600,000 principal amount (the "Remaining Principal Amount") plus the Remaining Conversion Interest Amount into a Qualified Offering or Public Offering. "Remaining Conversion Interest Amount" shall mean interest payable in an amount equal to the sum of (A) all accrued but unpaid interest on such portion of the Remaining Principal Amount subject to such Voluntary Exchange assuming such portion of the Remaining Principal Amount had been held from the original maturity date of July 31, 2016 to the amended maturity date of December 31, 2016 (for the avoidance of doubt, such amount that is calculated using the following formula: (a) 12% multiplied by such portion of the Remaining Principal Amount subject to such Voluntary Exchange, multiplied by (b) the actual number of days elapsed in a year of three hundred and sixty-five (365) days, which amount shall equal $30,000 in the aggregate assuming the aggregate Remaining Principal Amount of $600,000 is used in such calculation), plus (B) all accrued but unpaid interest assuming such portion of the Remaining Principal Amount had been held from the issuance date to the original maturity date of July 31, 2016 (for the avoidance of doubt, such amount that is calculated using the following formula: (a) 8% multiplied by such portion of the Remaining Principal Amount, multiplied by (b) the actual number of days elapsed in a year of three hundred and sixty-five (365) days, which amount shall equal $48,000 in the aggregate assuming the aggregate Remaining Principal Amount of $600,000 is used in such calculation).In consideration for entering into the Note Amendment, the Company issued the Note Holder a warrant to purchase 43,636 shares of the Company's common stock (the "Amendment Warrant") in substantially the same form as the Note Warrant issued in the Note Private Placement, provided, however, that with respect to the "full-ratchet" anti-dilution price protection adjustments for future issuances of other Company equity or equity-linked securities (subject to certain standard carve-outs), such price protection adjustment shall be equal to 110% of the consideration price per share of the issued equity or equity-linked securities.

The Company evaluated the Note Amendment transaction in accordance with ASC 470-50-40-12 and determined the Note Amendment did not constitute a substantive modification of the Promissory Note and that the transaction should be accounted for as a debt modification.

The Amendment Warrant contains an adjustment clause affecting its exercise price, which may be reduced if the Company issues shares of common stock or convertible securities at a price below the then-current exercise price of the Amendment Warrant. As a result, the Company determined that the Amendment Warrant was not indexed to the Company's common stock and therefore should be recorded as a derivative liability. The fair value of the detachable Amendment Warrant issued in connection with the Note Amendment was recorded as a debt discount. The adjustment clause lapses upon the Company completing a Qualified Offering.

Accordingly, the Company recorded a debt discount related to the warrant liability of approximately $85,000 and a debt discount related to the Voluntary Exchange of approximately $104,000 during the year ended February 29, 2016.

Effective October 21, 2016, in connection with the Promissory Note Exchange as referenced in Note 4, $600,000 principal amount of the Promissory Note plus $48,000 of accrued and unpaid interest was exchanged into the Additional 2016 Unit Private Placement. Accordingly, the Company recorded a loss on extinguishment of approximately $694,000 during the year ended February 28, 2017.

On January 17, 2017, in connection with the Debt Exchange (as described in the Convertible Note subsection below), $600,000 principal amount of the Promissory Note plus $96,000 of accrued and unpaid interest was exchanged into the Convertible Note.

During the year ended February 29, 2016, the Company recognized approximately $301,000 of interest expense related to the Promissory Note, as amended, including amortization of debt discount of approximately $245,000 and accrued interest expense of $56,000. Additionally, the Company recognized a loss of approximately $8,500 in the year ended February 29, 2016 due to the change in estimated fair value of the Voluntary Exchange provision.

During the year ended February 28, 2017, the Company recognized approximately $461,000 of interest expense related to the Promissory Note, as amended, including amortization of debt discount of approximately $367,000 and accrued interest expense of approximately $94,000. Additionally, the Company recognized a gain of approximately $340,000 in the year ended February 28, 2017 due to the change in estimated fair value of the Voluntary Exchange provision.

OID Notes and OID Note Amendments

During the year ended February 29, 2016, the Company entered into an OID note purchase agreement dated February 12, 2016 (the "OID Note Purchase Agreement") in a private placement (the "OID Note Private Placement") with various accredited investors (the "OID Note Holders"). Pursuant to the OID Note Purchase Agreement, the Company may issue and sell non-convertible OID promissory notes (the "OID Notes") up to an aggregate purchase price of $1,000,000 (the "Purchase Price") and warrants (the "OID Warrants") to purchase 7,273 shares of the Company's common stock for every $100,000 of Purchase Price. The OID Notes shall have an initial principal balance equal to 120% of the Purchase Price (the "OID Principal Amount").

During the year ended February 29, 2016, the Company entered into OID Note Purchase Agreements between February 12 and 22, 2016 (the "February 2016 OID Note Purchase Agreements") with various accredited investors. Pursuant to the February 2016 OID Note Purchase Agreements, the Company received an aggregate Purchase Price of $500,000 and issued OID Notes in the aggregate OID Principal Amount of $600,000 and OID Warrants to purchase an aggregate of 36,367 shares of the Company's common stock.

During the year ended February 28, 2017, the Company entered into OID Note Purchase Agreements between March 4 and 15, 2016 (the "March 2016 OID Note Purchase Agreements") with various accredited investors. Pursuant to the March 2016 OID Note Purchase Agreements, the Company received an aggregate Purchase Price of $125,000 and issued OID Notes with an aggregate OID Principal Amount of $150,000 and OID Warrants to purchase 9,902 shares of the Company's common stock.

The OID Notes mature six (6) months following the issuance date of each OID Note and may be prepaid by the Company at any time prior to the maturity date without penalty or premium. In the event the OID Notes are prepaid in full on or before the date that is ninety (90) days following the issuance date of each OID Note, the prepayment amount shall be equal to 110% of the Purchase Price and in the event the OID Notes are prepaid following such initial ninety (90) day period, the prepayment amount shall be equal to the OID Principal Balance (the "Optional Redemption"). The Company determined the Optional Redemption feature represents a contingent call option. The Company evaluated the Optional Redemption provision in accordance with ASC 815-15-25. The Company determined that the Optional Redemption feature is clearly and closely related to the debt host instrument and is not an embedded derivative requiring bifurcation.

Each OID Note Holder has the right at its option to act as a purchaser in a Qualified Offering and, in lieu of investing new cash subscriptions, mechanically effect a voluntary exchange (the "OID Note Voluntary Exchange") of the OID Principal Amount of the OID Notes into such number of securities to be issued in a Qualified Offering. Upon effectuating such OID Voluntary Exchange, the OID Note Holders shall be deemed to be purchasers in the Qualified Offering. The Company evaluated the OID Note Voluntary Exchange provision, which provides for settlement of the OID Notes at the OID Principal Amount in accordance with ASC 815-15-25. The Company determined the OID Note Voluntary Exchange provision is a contingent put that is not clearly and closely related to the debt host instrument and therefore was initially separately measured at fair value and will be measured at fair value on an ongoing basis, with changes in fair value recognized in the statement of operations.

The OID Warrants contain an adjustment clause affecting their exercise price, which may be reduced if the Company issues shares of common stock or convertible securities at a price below the then-current exercise price of the OID Warrants. As a result, we determined that the OID Warrants were not indexed to the Company's common stock and therefore should be recorded as a derivative liability. The detachable OID Warrants issued in connection with the OID Notes were recorded as a debt discount based on their fair value (see Note 8 for fair value measurement). The adjustment clause lapses upon the Company completing the Qualified Offering.

Pursuant to the February 2016 closings of the OID Note Private Placement, the OID Principal Amount was first allocated to the fair value of the OID Warrants in the amount of approximately $76,000, next to the value of the original issuance discount in the amount of $100,000, then to the fair value of the OID Note Voluntary Exchange provision in the amount of approximately $135,000, and lastly to the debt discount related to offering costs of approximately $14,000 with the difference of approximately $275,000 representing the initial carrying value of the OID Notes.

During the year ended February 29, 2016, the Company recognized approximately $9,000 of interest expense related to the OID Notes, including amortization of debt discount. Additionally, the Company recognized a loss of approximately $2,000 in the year ended February 29, 2016 due to the change in estimated fair value of the OID Note Voluntary Exchange provision

Pursuant to the March 2016 closings of the OID Note Private Placement, the OID Principal Amount was first allocated to the fair value of the OID Warrants in the amount of approximately $15,000, next to the value of the original issuance discount in the amount of $25,000, then to the fair value of the OID Note Voluntary Exchange provision in the amount of approximately $33,000, and lastly to the debt discount related to offering costs of approximately $2,000 with the difference of approximately $75,000 representing the initial carrying value of the OID Notes issued in March 2016.

Between August 12, 2016 and August 19, 2016, the Company entered into certain amendments (the "OID Note Amendments"), to its outstanding non-convertible OID Notes originally issued between February 12, 2016 and March 15, 2016 (the "OID Notes"), with the holders of an aggregate of $750,000 principal amount of OID Notes, whereby the holders of the OID Notes extended the maturity date of the OID Notes an additional three (3) months to between November 12, 2016 and December 15, 2016. In consideration for entering into the Note Amendments, the Company (i) increased the principal amount of the OID Notes by 10% to $825,000 in the aggregate from $750,000 in the aggregate, (ii) issued an aggregate of 45,459 common stock purchase warrants with an exercise price of $2.00 per share and a term of five years, and (iii) modified the voluntary exchange provision of the OID Notes by reducing the "Qualified Offering" threshold amount to $500,000 from $2,000,000. Additionally, the Company will have the sole option to extend the maturity date of the OID Notes an additional three (3) months in consideration for a further 10% increase in the principal amount from $825,000 to $907,500.

The Company evaluated the OID Note Amendments transactions in accordance with ASC 470-50-40-12 and determined the OID Note Amendments did not constitute a substantive modification of the OID Notes and that the transaction should be accounted for as a debt modification.

Effective October 28, 2016, in connection with the OID Note Exchange as referenced in Note 4, $553,000 principal amount of OID Notes was exchanged into the Additional 2016 Unit Private Placement. Accordingly, the Company recorded a loss on extinguishment of approximately $555,000. Additionally, the Company repaid $8,000 of OID Notes.

Effective November 12, 2016, the Company provided notice that it effected its sole option to extend the maturity date (the "Second OID Note Amendment") of its outstanding OID Note in the aggregate of $264,000 principal amount of OID Note, whereby the holder of the OID Note extended the maturity date of the OID Note an additional three (3) months to February 12, 2017. In consideration for entering into the Note Amendment, the Company increased the principal amount of the OID Note by 10% or $26,400 to $290,400 in the aggregate.

The Company evaluated the Second OID Note Amendment in accordance with ASC 470-50-40-12 and determined the OID Note Amendments did not constitute a substantive modification of the OID Notes and that the transaction should be accounted for as a debt modification.

On January 17, 2017, in connection with the Debt Exchange, the OID Note with an OID Principal Amount of $290,400 was exchanged into the Convertible Note. See Convertible Note.

During the year ended February 28, 2017, the Company recognized approximately $583,000 of interest expense related to the OID Notes, as amended, including amortization of debt discount. Additionally, the Company recognized a gain of approximately $275,000 in the year ended February 28, 2017 due to the change in estimated fair value of the Voluntary Exchange provision.

Convertible Note

On January 17, 2017, the Company entered into an exchange agreement, pursuant to which the Company issued to a new convertible promissory note in the principal amount of $1,000,000 (the "Convertible Note") in exchange (the "Debt Exchange") for the cancellation of (i) $600,000 principal amount of the Promissory Note plus $96,000 of accrued and unpaid interest, and (ii) $290,400 principal amount of the OID Note. In consideration for the Debt Exchange, the Company issued a warrant to purchase 100,000 shares of common stock at an exercise price of $3.00 per share and a term of five years.

The Convertible Note matures on September 30, 2017, accrues interest at a rate of ten percent (10%) per annum commencing as of January 1, 2017, and may be prepaid upon 10 days' advanced written notice by the Company at any time prior to the maturity date without penalty or premium (the "Prepayment Option"). The holder has the right to convert the outstanding principal balance of the Convertible Note plus all accrued and unpaid interest thereon into shares of the Company's common stock at a conversion price per share of $2.00 (the "Conversion Option").

The Company evaluated the Debt Exchange transaction in accordance with ASC 470-50-40-12 and determined the Debt Exchange constituted a substantive modification and that the transaction should be accounted for as an extinguishment.

The Company determined the Prepayment Option feature represents a contingent call option. The Company evaluated the Prepayment Option in accordance with ASC 815-15-25. The Company determined that the Prepayment Option feature is clearly and closely related to the debt host instrument and is not an embedded derivative requiring bifurcation. Additionally, the Company determined the Conversion Option represents an embedded call option. The Company evaluated the Conversion Option in accordance with ASC 815-15-25. The Company determined that the Conversion Option feature meets the scope exception from ASC 815 and is not an embedded derivative requiring bifurcation.

The Company evaluated the Convertible Note for a beneficial conversion feature in accordance with ASC 470-20. The Company determined that the effective conversion price was above the closing stock price on the commitment date, and the Convertible Note did not contain a beneficial conversion feature.

The Company recorded the Convertible Note at fair value of approximately $986,000 with an initial debt discount of $14,000. Accordingly, in accordance with ASC 470-50-40-2, the Company recognized a loss on extinguishment of approximately $127,000, which equals the difference between the reacquisition price of debt and the net carrying amount of the extinguished debt.

During the year ended February 28, 2017, the Company recognized approximately $19,000 of interest expense related to the Convertible Note, including amortization of debt discount of approximately $3,000 and accrued interest expense of approximately $16,000

The following table summarizes the notes payable:

	Note Payable	Convertible Note Payable	Note Discount	Put Exchange Feature	Note Payable, Net
February 28, 2015 balance	**$ -**	$ -	$ -	$ -	$ -
Proceeds from issuance of notes	1,800,000	-	(996,595)	466,387	1,269,792
Amortization of debt discount	-	-	253,313	-	253,313
Change in fair value of voluntary exchange feature	-	-	-	10,015	10,015
February 29, 2016 balance	1,800,000	-	(743,282)	476,402	1,533,120
Issuance of notes	150,000	-	(74,931)	32,496	107,565
Repayment of notes	(8,000)	-		-	(8,000)
Additional debt discount upon Notes amendments	101,400	-	(251,081)	105,586	(44,095)
Note conversions	(2,043,400)	1,000,000	100,327	-	(943,073)
Amortization of debt discount	-	-	958,053	-	958,053
Change in fair value of voluntary exchange feature	-	-	-	(614,484)	(614,484)
February 28, 2017 balance	**$ -**	**$1,000,000**	**$ (10,914)**	**$ -**	**$ 989,086**

NOTE 8 – FAIR VALUE MEASUREMENTS

In accordance with ASC 820, Fair Value Measurements, financial instruments were measured at fair value using a three-level hierarchy which maximizes use of observable inputs and minimizes use of unobservable inputs:

- Level 1: Observable inputs such as quoted prices in active markets for identical instruments
- Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the market
- Level 3: Significant unobservable inputs supported by little or no market activity. Financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, for which determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

Derivative Warrant Liability

At February 28, 2017 and February 29, 2016, the warrant liability balances of approximately $2.1 million and approximately $234,000, respectively, were classified as Level 3 instruments.

The following table sets forth the changes in the estimated fair value for our Level 3 classified derivative warrant liability:

	Note Payable Warrants	Series B Warrants	PPM Warrants	Total
Fair value at February 28, 2015	**$ -**	**$ 273,000**	**$ -**	**$ 273,000**
Additions:	311,057	-	-	311,057
Change in fair value:	(122,706)	(226,890)	-	(349,596)
Fair value at February 29, 2016	**188,351**	**46,110**	**-**	**234,461**
Additions:	15,225		4,263,271	4,278,496
Change in fair value:	(46,372)	(10,420)	(2,349,193)	(2,405,985)
Fair value at February 28, 2017	**$ 157,204**	**$ 35,690**	**$ 1,914,078**	**$ 2,106,972**

In connection with the initial closing of the Series B Private Placement on December 31, 2014, the Company issued a warrant to purchase an aggregate of 30,334 shares of common stock (the "Series B Warrant"), originally exercisable at $8.25 per share and expiring on March 31, 2020. The Series B Warrant contains a full-ratchet anti-dilution price protection provision that requires liability treatment and the exercise price of the Series B Warrant was adjusted to $2.00 during the year ended February 28, 2017. The fair value of the Series B Warrant at February 28, 2017 and February 29, 2016 was determined to be approximately $36,000 and $46,000, respectively, as calculated using the Monte Carlo simulation. The Monte Carlo simulation as of February 28, 2017 and February 29, 2016 used the following assumptions: (1) a stock price of $1.50 and $1.80, respectively; (2) a risk-free rate of 1.50% and 1.08%, respectively; (3) an expected volatility of 131% and 134%, respectively; and (4) a fundraising event to occur on May 31, 2017 and May 15, 2016, respectively, that would result in the issuance of additional common stock.

In connection with the issuance of the Promissory Note on July 31, 2015, the Company issued a warrant to purchase an aggregate of 43,636 shares of common stock, originally exercisable at $8.25 per share and expiring on July 31, 2020. This warrant contains a full-ratchet anti-dilution price protection provision that requires liability treatment and the exercise price of this warrant was adjusted to $2.00 during the year ended February 28, 2017. The fair value of the warrant at February 28, 2017 and February 29, 2016 was determined to be approximately $51,000 and $64,000, respectively, as calculated using the Monte Carlo simulation. The Monte Carlo simulation as of February 28, 2017 and February 29, 2016 used the following assumptions: (1) stock price of $1.50 and $1.80, respectively; (2) a risk-free rate of 1.57% and 1.13%, respectively; (3) an expected volatility of 131% and 134%, respectively; and (4) a fundraising event to occur on May 31, 2017 and May 15, 2016, respectively, that would result in the issuance of additional common stock.

In connection with the execution of the Note Amendment on February 12, 2016, the Company issued a warrant to purchase an aggregate of 43,636 shares of common stock, initially exercisable at $8.25 per share and expiring on February 11, 2021. This warrant contains a ratchet anti-dilution price protection provision that requires liability treatment and the exercise price of this warrant was adjusted to $2.20 during the year ended February 28, 2017. The fair value of the warrant at February 28, 2017 and February 29, 2016 was determined to be approximately $51,000 and $68,000, respectively, as calculated using the Monte Carlo simulation. The Monte Carlo simulation as of February 28, 2017 and February 29, 2016 used the following assumptions: (1) stock price of $1.50 and $1.80, respectively; (2) a risk-free rate of 1.68% and 1.20%, respectively; (3) an expected volatility of 131% and 134%, respectively; and (4) a fundraising event to occur on May 31, 2017 and May 15, 2016, respectively, that would result in the issuance of additional common stock.

In connection with the issuance of OID Notes in February 2016, the Company issued warrants to purchase an aggregate of 36,367 shares of common stock. These warrants were issued between February 12 and 22, 2016, were initially exercisable at $8.25 per share and expire between February 11 and 21, 2021. These warrants contain a full-ratchet anti-dilution price protection provision that requires liability treatment and the exercise price of these warrants were adjusted to $2.00 during the year ended February 28, 2017. The fair value of these warrants at February 28, 2017 and February 29, 2016 was determined to be approximately $44,000 and $56,000, respectively, as calculated using the Monte Carlo simulation. The Monte Carlo simulation as of February 28, 2017 and February 29, 2016 used the following weighted-average assumptions: (1) stock price of $1.50 and $1.80, respectively; (2) a risk-free rate of 1.68% and 1.21%, respectively; (3) an expected volatility of 131% and 134%, respectively; and (4) a fundraising event to occur on May 31, 2017 and May 15, 2016, respectively, that would result in the issuance of additional common stock.

In connection with the issuance of OID Notes in March 2016, the Company issued warrants to purchase an aggregate of 9,092 shares of common stock. These warrants were issued between March 4 and 15, 2016, were initially exercisable at $8.25 per share and expire between March 4 and 15, 2021. These warrants contain a full-ratchet anti-dilution price protection provision that requires liability treatment and the exercise price of these warrants were adjusted to $2.00 during the year ended February 28, 2017. The fair value of these warrants at February 28, 2017 and at issuance between March 4 and 15, 2016 was determined to be approximately $11,000 and approximately $15,000, respectively, as calculated using the Monte Carlo simulation. The Monte Carlo simulation as of November 30, 2016, and between March 4 and 15, 2016, used the following weighted-average assumptions: (1) stock price of $1.50 and $1.97, respectively; (2) a risk-free rate of 1.69% and 1.41%, respectively; (3) an expected volatility of 131% and 136%, respectively; and (4) a fundraising event to occur on May 31, 2017 and July 31, 2016, respectively, that would result in the issuance of additional common stock.

In connection with the Additional 2016 Unit Private Placement including the Company Payable Exchange, the OID Note Exchange, the Promissory Note Exchange and the Additional 2016 MFN Exchange, the Company issued warrants to purchase an aggregate of 1,617,506 shares of common stock. These warrants were issued between August 31, 2016 and October 30, 2016, are exercisable at $3.00 per share and expire between August 30, 2021 and October 29, 2021. As referenced in Note 6, the Price Protection provision associated with these warrants requires liability treatment. The fair value of these warrants at February 28, 2017 and issuance between August 31, 2016 and October 30, 2016 was determined to be approximately $1.9 million and $4.3 million, respectively, as calculated using the Monte Carlo simulation. The Monte Carlo simulation as of February 28, 2017 and issuance between August 31, 2016 and October 30, 2016, used the following weighted-average assumptions: (1) stock price of $1.50 and $2.61, respectively; (2) a risk-free rate of 1.66% and 1.81%, respectively; (3) an expected volatility of 131% and 134%, respectively; and (4) a fundraising event to occur on May 31, 2017 and March 31, 2017, respectively, that would result in the issuance of additional common stock.

Put Exchange Feature Liability

At February 29, 2016 and February 28, 2017, the put exchange feature liability balances of approximately $476,000 and $0, respectively, were classified as Level 3 instruments.

The following table sets forth the changes in the estimated fair value for our Level 3 classified put exchange feature liabilities:

	Promissory Note, as amended	OID Notes	Total
Fair value, February 29, 2016:	**$ 339,979**	**$ 136,423**	**$ 476,402**
Additions	-	138,082	138,082
Change in fair value:	(339,979)	(274,505)	(614,484)
Fair value, February 28, 2017:	**$ -**	**$ -**	**$ -**

The Promissory Note originally issued on July 31, 2015, as amended, contains a Note Voluntary Exchange provision that is a contingent put that requires liability treatment (see Note 7). The fair value of this put exchange feature at February 29, 2016 was determined to be approximately $340,000. At February 29, 2016, the fair value was calculated using a probability weighted present value methodology. The significant inputs to the fair value model were 1) the timing of a Qualified Offering expected to occur in May 2016 at February 29, 2016; 2) the combined probability of both a Qualified Offering and a voluntary exchange to occur, which was determined to be 71% at February 29, 2016 and 3) a discount rate of 18%, approximating high yield distressed debt rates. The Promissory Note was extinguished as of February 28, 2017.

The OID Notes originally issued between February 12, 2016 and March 15, 2016, as amended, contain an OID Note Voluntary Exchange provision that is a contingent put that requires liability treatment (see Note 7). The fair value of this put exchange feature at February 29, 2016 was determined to be approximately $136,000. At February 29, 2016, the fair value was calculated using a probability weighted present value methodology. The significant inputs to the fair value model were 1) the timing of a Qualified Offering expected to occur in May 2016; 2) the combined probability of both a Qualified Offering and a voluntary exchange to occur, which was determined to be 81%; and 3) a discount rate of 18%, approximating high yield distressed debt rates. The OID Notes were extinguished as of February 28, 2017.

NOTE 9 – EQUIPMENT

Equipment consists of the following:

	Estimated Useful lives	February 28, 2017	February 29, 2016
Research equipment	7 years	$ 601,720	$ 590,373
Computer and software equipment	5 years	78,149	76,075
		679,869	666,448
Accumulated depreciation and amortization		(265,234)	(169,396)
Equipment, net		**$ 414,635**	**$ 497,052**

Total depreciation and amortization expense was approximately $96,000 for each of the years ended February 28, 2017 and February 29, 2016.

Depreciation of equipment utilized in research and development activities is included in research and development expenses and amounted to approximately $81,000 for each of the years ended February 28, 2017 and February 29, 2016. All other depreciation is included in general and administrative expense and amounted to approximately $15,000 for each of the years ended February 28, 2017 and February 29, 2016.

NOTE 10 – LICENSE AGREEMENTS AND COMMITMENTS

License Agreements

Pursuant to the License Agreement, we are required to make annual license maintenance fee payments beginning August 26, 2011. We have satisfied all license maintenance payments due through February 28, 2017. We are required to make payments of $100,000 in 2017 and every year the license is in effect thereafter. These annual license maintenance fee payments will be credited to running royalties due on net sales earned in the same calendar year, if any. We are in compliance with the License Agreement.

Pursuant to the Second License Agreement, we are required to make annual license maintenance fee payments beginning on January 3, 2013. Effective February 1, 2017, we amended the Second License Agreement to reduce the maintenance payment for 2016 from $30,000 to $5,000, 2017 from $50,000 to $5,000, 2018 from $75,000 to $5,000, 2019 from $100,000 to $60,000, and 2020 from $100,000 to $60,000. We are required to make payments of $100,000 in 2021 and every year the license is in effect thereafter. These annual license maintenance fee payments will be credited to running royalties due on net sales earned in the same calendar year, if any. The license maintenance payment of $5,000 for 2017 is currently outstanding, pending invoice. As such, we are in compliance with the Second License Agreement.

Pursuant to the Alternative Splicing Diagnostic License Agreement and the Alternative Splicing Therapeutic License Agreement, we are required to make annual license maintenance fee payments for each license beginning on January 1, 2015. We have satisfied all license maintenance payments due through February 28, 2017. We are required to make additional payments of $37,500 in 2018, and $50,000 in 2019 and every year each license is in effect thereafter.

Pursuant to the Antibody License Agreement, we are required to make license maintenance fee payments beginning on January 1, 2015. We have satisfied all license maintenance payments due through February 28, 2017. We are required to make additional payments of $15,000 in 2018 and $20,000 in 2019 and every year the license is in effect thereafter. These annual license maintenance fee payments will be credited to running royalties due on net sales earned in the same calendar year, if any. We are in compliance with the Antibody License Agreement.

Lease Agreements

On August 28, 2014, we entered into a lease agreement (the "Boston Lease") for our diagnostic laboratory and office space located at 27, Drydock Ave, 2 nd Floor, Boston, MA 02210 (the "Boston Property"). We paid a $40,000 security deposit in connection with entering into the Boston Lease. Effective April 6, 2016, we entered into an amendment to the Boston Lease (the "Boston Lease Amendment"), whereby we extended the term by one year from September 1, 2016 to August 31, 2017. The basic rent payable under the Boston Lease Amendment is $17,164 per month plus additional monthly payments including tax payments and operational and service costs. We anticipate entering into an additional amendment or new long-term lease agreement on reasonable commercial terms for the Boston Property.

Effective March 1, 2015 we entered into a lease agreement for short-term office space in New York, NY. We paid a $2,100 security deposit in connection with entering into the lease. Effective December 1, 2015 we amended our lease agreement for the short-term office space in New York, NY. The term of the lease is month-to-month and may be terminated with twenty-one (21) days' notice. The basic rent payment is $2,400 per month and we paid an additional $1,500 security deposit in connection with the amended lease.

NOTE 11 – COLLABORATIVE AND OTHER RELATIONSHIPS

In connection with our business strategy, we may enter into research and development and other collaboration agreements. Depending on the arrangement, we may record payments as advances, funding receivables, payable balances or non-product income with our partners, based on the nature of the cost-sharing mechanism and activity within the collaboration.

On September 29, 2016, the Company entered into an amendment (the "Amendment") to a previously executed pilot materials transfer agreement (the "MTA" and together with the Amendment, the "Research Agreement") with Celgene Corporation ("Celgene"), to conduct a mutually agreed upon pilot research project (the "Pilot Project"). The Amendment provides for milestone payments to the Company of up to approximately $973,000. Under the terms of the Research Agreement, Celgene will provide certain proprietary materials to the Company and the Company will evaluate Celgene's proprietary materials in the Company's metastatic cell line and animal nonclinical models. The milestone schedule calls for Celgene to pay the Company approximately $487,000 upon execution of the Amendment, which the Company has received, and the balance in accordance with the completion of three (3) milestones to Celgene's reasonable satisfaction. The term of the Research Agreement is one (1) year, unless extended by the parties. Either party may terminate the Research Agreement with thirty (30) days prior written notice.

The Company recognizes the upfront payment as a deferred research and development reimbursement in the Consolidated Balance Sheet and will amortize the deferred research and development reimbursement as incurred over the term of the Research Agreement. For the year ended February 28, 2017, the Company recorded approximately $309,000 in deferred research and development reimbursement, and, at February 28, 2017, the Company had a deferred research and development reimbursement amount of approximately $178,000.

The Company will recognize deferred research and development reimbursement for each subsequent milestone in the period in which the milestone is achieved. As of February 28, 2017, none of the milestone has been achieved.

NOTE 12 – INCOME TAXES

During the fiscal years ended February 28, 2017, and February 29, 2016, MetaStat incurred net losses and, therefore, has no tax liability.

The difference between income taxes at the statutory federal income tax rate and income taxes reported in the statements of operations are attributable to the following:

	February 28, 2017	February 29, 2016
Income tax benefit at the federal statutory rate	34%	34%
Permanent differences	(19)%	(2)%
Increase in valuation allowance	(15)%	(32%
Provision for income tax	0%	0%

Included in the permanent differences for the year ended February 28, 2017, are the change in fair value of warrant liability and put option embedded in notes payable (33%), offset by the loss on extinguishment of debt (16%).

At February 28, 2017, and February 29, 2016, deferred tax assets (liabilities) consisted of the following:

	February 28, 2017	February 29, 2017
Accrued compensation	$ 70,354	$ 87,969
Accrued interest	6,674	23,520
Net operating loss carryovers	7,257,930	5,555,259
Research and development credits	253,125	130,422
Capital loss carryover	16,663	25,421
Stock compensation	1,537,117	1,491,106
	9,141,863	7,313,697
Depreciation	(90,655)	(76,987)
		7,236,710
Less: Valuation allowance	(9,051,208)	(7,236,710)
Net deferred tax asset	$ -	$ -

In assessing the realization of deferred tax assets, management determines whether it is more likely than not some, or all, of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the carryforward period as well as the period in which those temporary differences become deductible. Management considers the reversal of taxable temporary differences, projected taxable income and tax planning strategies in making this assessment. Based upon historical losses and the possibility of continued taxable losses over the periods that the deferred tax assets are deductible, management believes it is not more likely than not that the Company will realize the benefits of these deferred tax assets and thus recorded a valuation allowance against the entire net deferred tax asset balance. The valuation allowance increased by approximately $1.8 million and $2.0 million in the years ended February 28, 2017 and February 29, 2016, respectively.

At February 28, 2017, the cumulative federal and state net operating loss carry-forwards are approximately $18.7 million and $17.3 million, respectively and, and will expire between 2029 and 2036. At February 28, 2017, the Company has research and development credits amounting to approximately $0.3 million that will start expiring in 2033.

The Internal Revenue Code (“IRC”) limits the amount of net operating loss carryforwards that a company may use in a given year in the event of certain cumulative changes in ownership over a three-year period as described in Section 382 of the IRC. We have not performed a detailed analysis to determine whether an ownership change has occurred. Such a change of ownership could limit our utilization of the net operating losses, and could be triggered by subsequent sales of securities by the Company or its stockholders.

The Company records interest and penalties related to unrecognized tax benefits within income tax expense. The Company had not accrued any interest or penalties related to unrecognized benefits. No amounts were provided for unrecognized tax benefits attributable to uncertain tax positions as of February 28, 2017 and February 29, 2016. The Company is no longer subject to Federal income tax assessment for years before 2013. However, since the Company has incurred net operating losses every year since inception, all of its income tax returns are subject to examination and adjustments by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

NOTE 13 – LICENSE AGREEMENT WITH ASET THERAPEUTICS, LLC

On August 31, 2016, the Company and ASET Therapeutics, LLC ("ASET") entered into a mutual release of claims with respect to the termination of the Memorandum of Understanding dated July 14, 2014, as amended, the License and Development and Commercialization Agreement dated November 25, 2014 and all other related documents and agreements.

The Company assessed the collectability of its notes receivable in connection with two past due promissory notes of ASET in the aggregate principal amount of $125,000 held by the Company (the "ASET Notes"). The Company determined that the probability of repayment of the ASET Notes had decreased significantly and were to be written off. On August 30, 2016, the Company entered into a sale and assignment agreement with a non-affiliated shareholder, whereby the Company sold the ASET Notes for gross proceeds of $12,500. The Company recorded a loss on sale of notes receivable of $112,500 during the year ended February 28, 2017

NOTE 14 – SUBSEQUENT EVENTS

Effective May 24, 2017, Paul Billings, M.D., Ph.D. was appointed as a member of our board of directors.

Exhibit 31

CERTIFICATION PURSUANT TO
RULE 13A-14 OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Douglas A. Hamilton, certify that:

1. I have reviewed this annual report on Form 10-K of MetaStat, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchanged Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

    a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) designed such internal control over financial reporting, caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Douglas A. Hamilton
Douglas A. Hamilton
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

May 30, 2017

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of MetaStat, Inc. (the "Company") on Form 10-K for the period ended February 28, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Hamilton, the President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Douglas A. Hamilton
Douglas A. Hamilton
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

May 30, 2017