



Included:

Form 10-K for the year ended December 31, 2015
Proxy Statement for the year ended December 31, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

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

For the transition period ----- to -----

Commission File Number: 0-28666

American Bio Medica Corporation

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction of
incorporation or organization)

14-1702188

(IRS Employer Identification No.)

122 Smith Road

Kinderhook, New York

(Address of principal executive offices)

12106

(Zip Code)

Registrant's telephone number (including area code) (518) 758-8158

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Securities registered pursuant to Section 12(g) of the Exchange Act:

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 Securities 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 Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 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 of this chapter) is not contained herein, and will not be contained herein, 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, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

- Large accelerated filer Accelerated filer
 Non-accelerated filer Smaller reporting company

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 24,526,753 voting Common Shares held by non-affiliates of the registrant was approximately \$2,334,000 based on the last sale price of the registrant's Common Shares, \$.01 par value, as reported on the OTC Pink Open Marketplace on June 30, 2015.

As of March 29, 2016, the registrant had outstanding 26,475,408 Common Shares, \$.01 par value.

Documents Incorporated by Reference:

(1) Portions of the Registrant's Proxy Statement for the Annual Meeting of Shareholders to be held on June 16, 2016 in Part III of this Form 10-K

(2) Other documents incorporated by reference on this report are listed under Part IV, Item 15(B); Exhibits

American Bio Medica Corporation
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For the year ended December 31, 2015

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This Form 10-K may contain certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained in this Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as “may”, “could”, “should”, “will”, “expect”, “believe”, “anticipate”, “estimate” or “continue” or comparable terminology is intended to identify forward-looking statements. It is important to note that actual results could differ materially from those anticipated from the forward-looking statements depending on various important factors. These important factors include our history of losses, our ability to continue as a going concern, adverse changes in regulatory requirements related to the marketing and use of our products, the uncertainty of acceptance of current and new products in our markets, competition in our markets and other factors discussed in our “Risk Factors” found in Part I, Item 1A.

PART I

ITEM 1. OUR BUSINESS

Form and Year of Organization

American Bio Medica Corporation (the “Company”) was incorporated on April 2, 1986 under the laws of the State of New York under the name American Micro Media, Inc. On September 9, 1992, we filed an amendment to our Articles of Incorporation and changed our name to American Bio Medica Corporation.

Our Business

We develop, manufacture and sell immunoassay tests, primarily for the immediate, point of collection testing (“POCT”) for drugs of abuse (“DOA”) in urine and oral fluids. Our DOA POCT products offer employers, law enforcement, government, health care, laboratory and education professionals, self-contained, cost-effective, user-friendly products capable of accurately identifying illicit drug use within minutes.

In addition to the manufacture and sale of DOA POCT products, we provide bulk test strip manufacturing services to unaffiliated third parties on a contract basis. We do not currently derive a significant portion of our revenues from bulk test strip contract manufacturing. Bulk test strip contract manufacturing could become a greater portion of our revenues in the future, if sales of our current contract-manufacturing customers increase, or if additional applications for our technology are explored.

Our Products

POCT Products for the Detection of DOA in Urine

We manufacture a number of POCT products that detect the presence or absence of certain DOA in urine. We offer a number of standard configurations and we can also produce custom configurations on special order. We also offer different cut-off levels for certain drugs. Cut-off levels are concentrations of drugs or metabolites that must be present in urine or oral fluid specimens before a positive result will be obtained. Our urine-based POCT products test for the following drugs: amphetamines (available in some products with a cut-off level of either 500 ng/mL or 1,000 ng/mL), barbiturates, benzodiazepines, buprenorphine, cocaine (available in some products with a cut-off level of either 150 ng/mL or 300 ng/mL), MDMA (Ecstasy) (available in some products with a cut-off level of either 500 ng/mL or 1,000 ng/mL), methadone, methamphetamines (available in some products with a cut-off level of either 500 ng/mL or 1,000 ng/mL), opiates (available in some products with a cut-off level of either 300 ng/mL or 2000 ng/mL), oxycodone, PCP (phencyclidine), propoxyphene, THC (marijuana) and tricyclic antidepressants.

All of our urine-based POCT products are accurate, cost-effective, easy to use and provide results within minutes. We currently offer the following POCT products for urine-based DOA testing:

Rapid Drug Screen®: The Rapid Drug Screen, or RDS®, is a patented rapid, POCT product that detects the presence or absence of 2 to 10 DOA simultaneously in a single urine specimen. The RDS is available in card only, or as part of a kit that includes a patented collection cup.

Rapid ONE®: The patented Rapid ONE product line consists of single drug tests, each of which tests for the presence or absence of a single drug of abuse in a urine specimen. The Rapid ONE is designed for those situations in which a person is known to use a specific drug. It can also be used with a RDS to allow screening of an additional drug. The Rapid ONE is currently sold in limited markets; primarily markets outside of the United States.

RDS InCup®: The patented RDS InCup is an all-inclusive POCT product that detects the presence or absence of 1 to 12 DOA in a single urine specimen. The RDS InCup incorporates collection and testing of a urine sample in a single step. Each RDS InCup product contains multiple channels, and each channel contains a single drug-testing strip that contains the chemistry to detect a single class of DOA.

Rapid TOX®: Rapid TOX is a cost-effective POCT product in a cassette platform that

simultaneously detects the presence or absence of 2 to 10 DOA in a single urine specimen. Each Rapid TOX contains one or two channels, and each channel contains a single drug-testing strip that contains the chemistry to detect more than one class of DOA.

Rapid TOX Cup® II: The patented Rapid TOX Cup II is an all-inclusive POCT product that detects the presence or absence of 1 to 14 DOA in a single urine specimen. The Rapid TOX Cup II incorporates collection and testing of the urine sample in a single step. Each Rapid TOX Cup II contains multiple channels and each channel contains a single drug-testing strip that contains the chemistry to detect more than one class of drug of abuse. In the first quarter of 2015, we launched a second generation of the original Rapid TOX Cup II. The second generation consists of a smaller cup with smaller test strips. This smaller version results in lower material costs and allows us to be more competitive against foreign manufactured products being sold in our core markets.

Private Label Products

We do provide private labeled versions of certain urine-based products to unaffiliated third parties for sale outside of the United States. As of December 31, 2015, sales of these products were not material.

POCT Products for the Detection of DOA in Oral Fluids:

We manufacture POCT products that detect the presence or absence of DOA in oral fluids. These products are easy to use and provide test results within minutes with enhanced sensitivity and detection. Currently, the assays available on our oral fluid products are amphetamines, barbiturates, benzodiazepines, cocaine, MDMA (Ecstasy), methadone, methamphetamines, opiates, PCP, propoxyphene and THC. Our oral fluid products are currently marketed “for forensic use only”; see “Government Regulations” for information on the regulations related to the sale of our products. All of our oral fluid-based POCT products are accurate, cost-effective, easy to use and provide results within minutes. We currently offer the following POCT products for oral fluid-based DOA testing:

OralStat®: OralStat is a patented and patent pending, innovative POCT product for the detection of DOA in oral fluids. Each OralStat simultaneously tests for 6 or 10 DOA in a single oral fluid specimen.

Private Label Products

We do provide private labeled versions our OralStat product to unaffiliated third parties for sale outside of the United States. As of December 31, 2015, sales of these products were not material.

Other Products

We distribute a number of other products related to the detection of substances of abuse. We do not manufacture these products. We do not derive a significant portion of our revenues from the sale of these products.

Rapid Reader®: The Rapid Reader is a compact, portable unit that uses a high-resolution camera to capture a picture of the results obtained when using an ABMC POCT product. The results are analyzed, interpreted, and sent to a data management system, which enables the user to interpret, store, transmit and print the results. The Rapid Reader system can only be used to interpret and record the results of an ABMC drug test. We obtained 510(k) marketing clearance (“Government Regulations” for a description of 510(k) marketing clearance) from the U.S. Food and Drug Administration (“FDA”) specific to our marketing of the Rapid Reader.

Adulteration and Alcohol: We currently offer a number of POCT products that detect the presence or absence of adulterants and alcohol. One of these products is sold under ABMC-owned trademarks; the Rapid Check® test for adulterants. Some of the adulterant test products we distribute are also incorporated into our urine-based POCT products for DOA. We do not derive a significant portion of our revenues from the sale of these products.

Contract Manufacturing

We provide bulk test strip contract manufacturing services to a number of non-affiliated POCT diagnostic companies. In the year ended December 31, 2015, we manufactured a test for the detection of RSV (Respiratory Syncytial Virus; the most common cause of lower respiratory tract infections in children worldwide), and strip components for a test to detect fetal amniotic membrane rupture. In the year ended December 31, 2015, we did not derive a significant portion of our revenues from contract manufacturing.

Our Markets

Workplace

The Workplace market consists of pre-employment testing of job applicants, and random, cause and post-accident testing of employees. Many employers recognize the financial and safety benefits of implementing drug-free workplace programs, of which drug testing is an integral part. In some states, there are workers' compensation and unemployment insurance premium reductions, tax deductions and other incentives for adopting these programs. The Drug-Free Workplace Act requires some federal contractors and all federal grantees to agree that they will provide drug-free workplaces as a precondition of receiving a contract or grant from a federal agency. Typically if a contractor receives a federal contract of \$100,000 or more, they must enact a drug-free workplace program. Any organization or individual that has been granted a federal contract, regardless of size, must enact a drug-free workplace program. We sell our products in this market through our direct sales force and through a select network of distributors.

Government

The Government market includes federal, state, county and local agencies, including correctional facilities (including juvenile facilities), pretrial agencies, probation, drug courts and parole departments at the federal and state levels. A significant number of individuals on parole or probation, or within federal, state, county and local correctional facilities and jails, have one or more conditions to their sentence, including but not limited to, periodic drug-testing and substance abuse treatment. We sell our products in this market through our direct sales force.

Clinical/Pain Management

The Clinical market includes emergency rooms, physician offices, hospitals and clinics and rehabilitation facilities associated with hospitals. There are a number of medical emergencies associated with adverse reactions, accidental drug ingestions, and misuse or abuse of prescription drugs and over-the-counter medications. To address this issue, drug testing is performed so healthcare professionals are able to ascertain the drug status of a patient before they administer pharmaceuticals or other treatment.

Drug testing is also a useful in pain management as it is one of the major tools of adherence monitoring in the assessment of a patient's predisposition to, and patterns of, misuse/abuse; a vital first step towards establishing and maintaining the safe and effective use of drugs in the treatment of chronic pain. There are many benefits of drug testing in this market; these include reducing the risk for toxicity in patients vulnerable to adverse drug effects, detecting patient non-compliance, reducing the risk of therapeutic failure, and avoiding or detecting drug-drug interaction. Additionally, drug testing enhances the physician's ability to use drugs effectively and minimize costs. Urine is the standard body fluid used in this market for drug screening because it is readily available, it is easily collected, and it is easily handled by laboratory and office personnel. Urine has been preferred over serum sampling because the period of detection of a particular drug in the urine is increased, while drugs and their corresponding metabolites may only be detectable in the serum for a short period of time. Urine drug testing is also less expensive and non-invasive compared to serum testing. Our CLIA waived Rapid TOX product line is particularly appropriate for the pain management market. In the year ended December 31, 2015, we submitted an application to the U.S. Food and Drug Administration ("FDA") requesting over-the-counter clearance of our Rapid TOX Cup II (all-inclusive cup). If we obtain this marketing clearance, our Rapid TOX Cup II product would also be classified as CLIA waived (a classification generally required by customers in the clinical market). We currently sell our urine DOA products in this market through our direct sales force and a number of key distributors. We do not have an exclusive distribution relationship focused on the clinical POCT market, however we continue to look for such a relationship with a global diagnostic company.

Rehabilitation/Drug Treatment

The Rehabilitation/Drug Treatment market includes people in both inpatient and outpatient treatment for substance abuse. Drug testing is a positive aspect of treatment as it aids in relapse prevention and encourages honesty both within the patient and with outside interactions. In addition, being able to accurately gauge the current drug use by patients enrolled in a substance abuse program is essential so, urine drug testing is an integral part of treatment programs, including physician office-based programs. There is typically a high frequency of testing in this market. In many residence programs, patients are tested each time they leave the facility and each time they return. In methadone and buprenorphine maintenance programs, more frequent testing provides a more complete picture of drug use habits, thus helping to direct treatment. There are advantages of point of collection testing in this market, including but not limited to, less handling of the specimen, which will reduce the potential for mistakes, a "greater sense of confidentiality," and quicker results. Our CLIA waived Rapid TOX product line is particularly appropriate for the Rehabilitation/Drug Treatment market. In the year ended December 31, 2015, we submitted an application to the FDA requesting over-the-counter clearance of our Rapid TOX Cup II (all-inclusive cup). If we obtain this marketing clearance, our Rapid TOX Cup II product would also be classified as CLIA waived (a classification generally required by customers in this market segment). We currently sell our urine DOA products in this market through our direct sales force and a number of key distributors.

International

The International market consists of various markets outside of the United States. Although workplace testing is not as prevalent outside of the United States as within, the international Government and Clinical markets are somewhat in concert with their United States counterparts. One market that is significantly more prevalent outside of the United States is roadside drug testing. We sell in this market through a select network of distributors, including a master distributor in the region of Latin American; this distributor's sales are primarily in the Government and Clinical markets, along with some sales in the Workplace market.

Education

The Education market consists of student drug-testing. In June 2002, the Supreme Court ruled that students in extracurricular activities including athletics, band, choir, and other activities could be tested for drugs at the start of the school year and randomly throughout the year. We primarily sell our urine DOA products in this market through our direct sales force.

Our Distribution Methods

We have a two-pronged distribution strategy that focuses on growing our business through direct sales and distributors. Our direct sales team consists of our Director of Sales & Marketing, Director of Latin America Sales, Director of International Sales, Regional Sales Managers, sales consultants and Inside Sales Representatives (collectively our "Direct Sales Team"); all of which are trained professionals that are experienced in DOA testing sales. Our distributors are unaffiliated entities that resell our POCT products either as stand-alone products or as part of a service they provide to their customers.

Our Direct Sales Team and network of distributors sell our products to the Workplace, Government, Clinical/Pain Management, Rehabilitation/Drug Treatment, and Education markets, and we sell primarily through a network of distributors in the International market.

We promote our products through direct mail campaigns, selected advertising, participation at high profile trade shows, and other marketing activities. We expect to continue to recruit and utilize experienced distributors in addition to selling directly in our markets.

Competition

We compete on the following factors:

Pricing: The pricing structure within the POCT market for DOA is highly competitive. Price pressure remains to be the greatest when comparing our pricing with pricing of products manufactured outside of the United States. We continuously evaluate all aspects of our manufacturing and assembly processes to identify areas of cost savings. In the year ended December 31, 2014, we closed down two of the three units we leased in Logan Township, New Jersey and moved certain manufacturing operations up to our (owned) facility in Kinderhook, New York.

The one remaining unit in New Jersey continues to house bulk strip manufacturing and research and development. The New Jersey facility consolidation resulted in increased efficiencies in the year ended December 31, 2015. Cost savings in manufacturing allows us to achieve and/or sustain acceptable gross margins while still providing our customers with cost-competitive products.

Quality: Our products are manufactured, assembled and packaged completely in the United States in accordance with quality system regulations set forth by FDA. Products manufactured outside of the US are manufactured outside of the requirements of quality system regulations set forth by FDA. In our opinion, this results in inferior, sub-par products being offered in the market. Most of our markets require accurate detection near the cut-off level of the test. Given this, we market our products as “aggressive” products; this means that our products are manufactured to detect drug use closer to the cut-off level of the test. The majority of the POCTs on the market today are less aggressive; meaning they are not as sensitive and they will miss positive results. Missing positive results can be extremely troublesome to customer from both an economic and liability perspective.

Customer and technical support: Customer and technical support are becoming more important in the POCT market. Our customers often need guidance and assistance with certain issues, including but not limited to, test administration, drug cross reactivity and drug metabolism. We provide our customers with continuous customer and technical support on a 24/7/365 basis. We believe that this support gives us a competitive advantage since our competitors do not offer this extended service to their customers.

Raw Materials and Suppliers

The primary raw materials required for the manufacture of our point of collection test strips and our point of collection drug tests consist of antibodies, antigens and other reagents, plastic molded pieces, membranes and packaging materials. We maintain an inventory of raw materials. Currently, most raw materials are available from several sources. We own the molds and tooling for our plastic components that are custom and proprietary. The ownership of these molds affords us flexibility and control in managing the supply chain for these components. We do not own the molds and tooling for plastic components that are “stock” items.

Major Customers

We have a number of customers that in total represent a significant portion of our sales in the years ended December 31, 2015 and December 31, 2014. One of these national account customers represented 26.0% of net sales in the year ended December 31, 2015, and 22.9% of net sales in the year ended December 31, 2014.

Patents and Trademarks/Licenses

As of December 31, 2015, we held 37 patents related to our point of collection drug-testing products, including 12 patents issued in the United States. As of December 31, 2015, we have 1 United States patent application pending and 7 foreign patent applications pending.

To date, we have registered 15 trademarks in the United States, including but not limited to, Rapid Drug Screen, RDS, Rapid ONE, OralStat, Rapid Reader, Rapid TOX, Rapid TOX Cup, InCup, Rapid Check, our website domain, our corporate logos and certain product logos. We have also registered 14 trademarks in countries/regions such as Canada, Mexico, Europe, and the United Kingdom.

Government Regulations

In certain markets, the development, testing, manufacture and sale of our POCTs, and possible additional testing products for other substances or conditions, are subject to regulation by the United States and foreign regulatory agencies. Pursuant to the Federal Food, Drug, and Cosmetic Act, and associated regulations, the FDA regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. A “medical device” is defined as an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animal...”

When a product is a medical device, a 510(k) marketing application must be submitted to the FDA. A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent,

to a legally marketed device that is not subject to premarket approval. Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims. The legally marketed device(s) to which equivalence is drawn is known as the “predicate” device (s). Applicants must submit descriptive data and, when necessary, performance data to establish that a device is substantially equivalent to a predicate device.

Most of our urine-based products are marketed and sold in the Clinical market (in addition to other markets) and therefore, we have obtained 510(k) marketing clearance on our:

- ◆ 9 panel RDS test and our Rapid ONE dipsticks. In addition, the testing strips contained in the RDS InCup are the same as those testing strips contained within the RDS. Therefore, the RDS InCup can be offered in a variety of combinations to meet customer requirements; and
- ◆ Rapid Reader; and
- ◆ Rapid TOX product line; and
- ◆ Rapid TOX Cup II.

Our oral fluid products have never been marketed or sold to the Clinical market (or to any market that would use the products for diagnosis or treatment) and prior to the receipt of a warning letter from FDA in July 2009, it was our belief, and the belief of our industry, that 510(k) marketing clearance was not required to sell in non-clinical markets, including the Workplace market. However, after protracted discussions with FDA and ultimately consenting to their jurisdiction in the Workplace market, on September 3, 2013, we filed our application for 510(k) marketing clearance. In November 2013, we were informed that the FDA determined that our OralStat was not substantially equivalent to the predicate market device (even though OralStat had an overall accuracy rate of 92%). This decision on the part of FDA resulted in our cessation of marketing and selling OralStat to the Workplace market in 2013. We continue to market and sell OralStat to the forensic market and for export outside the United States.

In order to sell our products in Canada, we must comply with ISO 13485:2003, the International Standards Organization’s Directive for Quality Systems for Medical Devices (MDD or Medical Device Directive), and in order to sell our products in the European Union, we must obtain CE marking for our products (in the European Union, a “CE” mark is affixed to the product for easy identification of quality products). Collectively, these standards are similar to the U.S. Federal Regulations enforced by the FDA, and are a reasonable assurance to the customer that our products are manufactured in a consistent manner to help ensure that quality defect-free goods are produced. As of the date of this report, we have received approval and the right to bear the CE mark on our Rapid Drug Screen, Rapid ONE, Rapid TOX, RDS InCup, Rapid TOX Cup II, and OralStat. We received our IS EN ISO 13485:2003 compliance certification in August 2006, updated since to IS EN ISO 13485, 2012 and in 2010 we received our ISO 9001:2008 compliance certification. We have also obtained the license to sell our RDS, Rapid ONE and Rapid TOX products in Canada.

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 established quality standards for laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. As a result, those using CLIA waived tests are not subject to the more stringent and expensive requirements of moderate or high complexity laboratories. In August 2008, we received our CLIA waiver from the FDA related to our Rapid TOX product line. As of the date of this report, the Rapid TOX is the only ABMC POCT product that has been granted a CLIA waiver from the FDA.

Due to the nature of the manufacturing of our point of collection tests and the raw materials used, ABMC does not incur any material costs associated with compliance with environmental laws, nor do we experience any material effects of compliance with environmental laws.

Research and Development (“R&D”)

Our R&D efforts are continually focused on enhancing and/or maintaining the performance and reliability of our drug-testing products. In the year ended December 31, 2015, in addition to the former, efforts in R&D were related to modifications to our Rapid TOX Cup II product line; modifications that will enable us to be slightly more cost-competitive with products made by foreign manufacturers while still maintaining (or further improving) the quality and performance of the product line.

We also took efforts to develop a POCT for K2, or synthetic marijuana, (these efforts were completed in December 2015 and the product was launched in late December 2015). Also included in R&D expense are FDA compliance costs, or costs associated with regulatory efforts taken related to the marketing of our products.

Our R&D expenditures were \$156,000 in the year ended December 31, 2015 and \$228,000 in the year ended December 31, 2014. None of the costs incurred in R&D in either the year ended December 31, 2015 or the year ended December 31, 2014 were borne by a customer.

Manufacturing and Employees

Our facility in Kinderhook, New York houses assembly and packaging of our products in addition to the Company's administration. We continue to primarily outsource the printing of the plastic components used in our products, and we outsource the manufacture of the plastic components used in our products. We manufacture all of our own individual test strips and we manufacture test strips for unaffiliated third parties at our R&D and bulk manufacturing facility in Logan Township, New Jersey. An unaffiliated third party manufactured the Rapid Reader products we currently offer; and unaffiliated third parties also manufacture the adulteration and alcohol products we offer.

As of December 31, 2015, we had 65 employees, of which 63 were full-time and 2 were part-time. None of our employees are covered by collective bargaining agreements, and we believe our relations with our employees are good.

ITEM 1A. RISK FACTORS

ABMC has a history of incurring net losses.

Since our inception and throughout most of our history, we have incurred net losses, including but not limited to, a net loss of \$333,000 incurred in the year ended December 31, 2015. We expect to continue to make substantial expenditures for sales and marketing, product development and other business purposes. Our ability to achieve profitability in the future will primarily depend on our ability to increase sales of our products. Our cessation of selling and marketing our oral fluid test in the Workplace market has severely impacted our revenues over the course of the last 2 fiscal years. Prior to the removal of the product from the Workplace market in the fourth quarter of the year ended December 31, 2013, oral fluid sales accounted for approximately 20% of our annual sales. Future profitability is also dependent on our ability to reduce production and other costs and successfully introduce new products and enhanced versions of our existing products into the marketplace. There can be no assurance that we will be able to increase our revenues at a rate that equals or exceeds expenditures. Our failure to increase sales while maintaining or reducing product costs, general and administrative, sales and marketing and research and development costs would result in the Company incurring additional losses.

We may need additional funding for our existing and future operations.

Our financial statements for the year ended December 31, 2015 were prepared assuming we will continue as a going concern. If sales do not improve, our current cash balances and cash generated from future operations may not be sufficient to fund operations for the next twelve months. Future events, including the expenses and difficulties which may be encountered in establishing and maintaining a substantial market for our products could make cash on hand insufficient to fund operations. If cash generated from operations is insufficient to satisfy our working capital and capital expenditure requirements, we may be required to sell additional equity or debt securities or obtain additional credit facilities. There can be no assurance that such financing will be available or that we will be able to complete financing on satisfactory terms, if at all. Any such equity financing would result in further dilution to existing shareholders.

The POCT market for DOA is highly competitive.

The POCT market for DOA is highly competitive. Several companies produce drug tests that compete directly with our DOA product line, including Alere and its subsidiaries, as well as OraSure Technologies, Inc. In addition to these manufacturers, there are a number of smaller privately held companies, as well as foreign manufacturers, that compete with us. Alere and OraSure are better known and have far greater financial resources, which means they can devote substantially more resources to business and product development and marketing efforts. Our inability to successfully address any competitive risk factors could negatively impact sales and further our profitability.

Two of our customers accounted for more than 10% of our total net sales in the year ended December 31, 2015.

Two of our customers each accounted for more than 10% of our total net sales in the year ended December 31, 2015. Although we have entered into written purchase agreements with these customers, neither customer has minimum purchase obligations and they could stop buying products from us with adequate notice outlined in their contracts. A reduction, delay or cancellation of orders from these customers or the loss of one or both of these customers would reduce our revenues. There can be no assurance that these customers or any of our current customers will continue to place orders, that orders by existing customers will continue at current or historical levels or that we will be able to obtain orders from new customers.

We rely on third parties for raw materials used in our DOA products and in our bulk test strip contract manufacturing processes.

We currently have approximately 50 suppliers that provide us with the raw materials necessary to manufacture our point of collection drug-testing strips and our point of collection tests for DOA. For most of our raw materials, we have multiple suppliers, but there are a few raw materials for which we only have one supplier. The loss of one or more of these suppliers, the non-performance of one or more of their materials or the lack of availability of raw materials could suspend our manufacturing process related to our DOA products. This interruption of the manufacturing process could impair our ability to fill customers' orders as they are placed, putting us at a competitive disadvantage.

Furthermore, we rely on a number of third parties for the supply of raw materials necessary to manufacture the test components we supply to other diagnostic companies under bulk test strip contract manufacturing agreements. For most of these raw materials, we have multiple suppliers, but there are a few raw materials for which we only have one supplier. The loss of one or more of these suppliers could suspend the bulk test strip manufacturing process and this interruption could impair our ability to perform bulk test strip contract manufacturing services.

We have a significant amount of raw material and "work in process" inventory on hand that may not be used in the year ended December 31, 2016 if the expected configuration of sales orders is not received at projected levels.

We had approximately \$1,208,000 in raw material components for the manufacture of our products at December 31, 2015. The non-chemical raw material components may be retained and used in production indefinitely and the chemical raw materials components have lives in excess of 20 years. In addition to the raw material inventory, we had approximately \$399,000 in manufactured testing strips, or other "work in process" inventory at December 31, 2015. The components for much of this "work in process" inventory have lives of 12-24 months. If sales orders received are not for products that would utilize the raw material components, or if product developments make the raw materials obsolete, we may be required to dispose of these unused raw materials. In addition, since the components for much of the "work in process" inventory have lives of 12-24 months, if sales orders within the next 12-24 months are not for products that contain the components of the "work in process" inventory, we may need to discard this expired "work in process" inventory. We have established an allowance for obsolete or slow moving inventory. At December 31, 2015, this allowance was \$432,000. There can be no assurance that this allowance will continue to be adequate for the year ending December 31, 2016 and/or that it will not have to be adjusted in the future.

Possible inability to hire and retain qualified personnel.

We will need additional skilled sales and marketing, technical and production personnel to grow the business. If we fail to retain our present staff or hire additional qualified personnel our business could suffer.

We depend on key personnel to manage our business effectively.

We are dependent on the expertise and experience of our senior management for our future success. The loss of a member of senior management could negatively impact our business and results of operations. Melissa A. Waterhouse serves as our Chief Executive Officer and Principal Financial Officer. We have an employment agreement in place with Ms. Waterhouse, but there can be no assurance that Ms. Waterhouse will continue her employment; and the loss of Ms. Waterhouse could disrupt the business and have a negative impact on business results. We also have a number of other individuals in senior management positions. There can be no assurance that

they too will continue their employment. We do not currently maintain key man insurance on Ms. Waterhouse.

Any adverse changes in our regulatory framework could negatively impact our business.

Although we are unaware of any recent or upcoming changes in regulatory standards related to any of our markets, recent history supports that changes in regulatory requirements could negatively impact our business. In July 2009 we received a warning letter from FDA related to the marketing of our oral fluid products. Prior to the receipt of the warning letter, we (and our industry) believed that when DOA POCTs were sold in non-clinical markets (such as Workplace), they did not fall under the definition of a “medical device”, but when sold in the clinical market, they did fall under the definition of a “medical device.” When a product is a medical device, a 510(k) marketing application must be submitted to the FDA. A 510(k) is a premarketing submission made to the FDA to demonstrate that the device is as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval. We have never marketed or sold our oral fluid products to the clinical market.

After protracted discussions with FDA and ultimately consenting to their jurisdiction in the Workplace market, on September 3, 2013, we filed our application for 510(k) marketing clearance. In November 2013, we were informed that the FDA determined that our oral fluid product was not substantially equivalent to the predicate market device (even though our oral fluid product had an overall accuracy rate of 92%). This decision on the part of FDA resulted in our cessation of marketing and selling our oral fluid product to the Workplace market in 2013. The cost of filing our application for 510(k) clearance was material and had a negative impact on our efforts to improve our financial performance. The inability to market and sell our oral fluid drug tests in the Workplace market negatively impacted our revenues, as oral fluid sales were a material portion of our revenue.

If regulatory standards were to further change in the future, there can be no assurance that the FDA will grant the Company appropriate marketing clearances required to comply with the changes, if and when we apply for them.

We rely on intellectual property rights, and we may not be able to obtain patent or other protection for our technology, products or services.

We rely on a combination of patent, copyright, trademark and trade secret laws, confidentiality procedures and contractual provisions to protect our proprietary technology, products and services. We also believe that factors such as the technological and creative skills of our personnel, new product developments, product enhancements and name recognition are essential to establishing and maintaining our technology leadership position. Our personnel are bound by non-disclosure agreements. However, in some instances, some courts have not enforced all aspects of such agreements.

We seek to protect our proprietary products under trade secret and copyright laws, which afford only limited protection. We currently have a total of 29 patents related to our POCT products. We have additional patent applications pending in the United States, and other countries, related to our POCT products. Certain trademarks have been registered in the United States and in other countries. There can be no assurance that the additional patents and/or trademarks will be granted or that, if granted, they will withstand challenge.

Despite our efforts to protect our proprietary rights, unauthorized parties may attempt to copy aspects of our products or to obtain information that we regard as proprietary. We may be required to incur significant costs to protect our intellectual property rights in the future. In addition, the laws of some foreign countries do not ensure that our means of protecting our proprietary rights in the United States or abroad will be adequate. Policing and enforcement against the unauthorized use of our intellectual property rights could entail significant expenses and could prove difficult or impossible.

Potential issuance and exercise of new options and warrants and exercise of outstanding options and warrants, could adversely affect the value of our securities.

We currently have two non-statutory stock option plans, the Fiscal 2001 Non-statutory Stock Option Plan (the “2001 Plan”) and the 2013 Equity Compensation Plan (the “2013 Plan”). Both plans have been adopted by our Board of Directors and approved by our shareholders. Both the 2001 Plan and the 2013 Plan have options available for future issuance. As of December 31, 2015, there were 1,435,000 options issued and

outstanding under the 2001 Plan. There were no options issued under the 2013 Plan, making the total issued and outstanding options 1,435,000 as of December 31, 2015. Of the total options issued and outstanding, 1,027,000 are fully vested as of December 31, 2015. As of December 31, 2015, there were 2,282,000 options available for issuance under the 2001 Plan and 4,000,000 options available for issuance under the 2013 Plan. We also currently have 2,385,000 warrants issued and outstanding.

If these stock options and warrants are exercised, the common shares issued will be freely tradable, increasing the total number of common shares issued and outstanding. If these shares are offered for sale in the public market, the sales could adversely affect the prevailing market price by lowering the bid price of our securities. The exercise of any of these stock options and warrants could also materially impair our ability to raise capital through the future sale of equity securities because issuance of the common shares underlying the stock options and warrants would cause further dilution of our securities. In addition, in the event of any change in the outstanding shares of our common stock by reason of any recapitalization, stock split, reverse stock split, stock dividend, reorganization consolidation, combination or exchange of shares, merger or any other changes in our corporate or capital structure or our common shares, the number and class of shares covered by the stock options and/or the exercise price of the stock options may be adjusted as set forth in their plans.

Substantial resale of restricted securities may depress the market price of our securities.

There are 3,428,048 common shares presently issued and outstanding as of the date hereof that are “restricted securities” as that term is defined under the Securities Act of 1933, as amended, (the “Securities Act”) and in the future may be sold in compliance with Rule 144 of the Securities Act (“Rule 144”), or pursuant to a registration statement filed under the Securities Act. Rule 144 addresses sales of restricted securities by affiliates and non-affiliates of an issuer. An “affiliate” is a person, such as an officer, director or large shareholder, in a relationship of control with the issuer. “Control” means the power to direct the management and policies of the company in question, whether through the ownership of voting securities, by contract, or otherwise. If someone buys securities from a controlling person or an affiliate, they take restricted securities, even if they were not restricted in the affiliate's hands.

A person who is not an affiliate of the issuer (and who has not been for at least three months) and has held the restricted securities for at least one year can sell the securities without regard to restrictions. If the non-affiliate had held the securities for at least six months but less than one year, the securities may be sold by the non-affiliate as long as the current public information condition has been met (i.e. that the issuer has complied with the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

We are subject to reporting requirements of the Exchange Act. Under Rule 144, if a holder of securities is an affiliate of an issuer subject to Exchange Act reporting requirements, the securities must be held for at least six months. In addition, the number of equity securities sold during any three-month period cannot exceed 1% of the outstanding shares of the same class being sold. The securities must be sold in unsolicited, routine trading transactions and brokers may not receive more than normal commission. Affiliates must also file a notice with the SEC on Form 144 if a sale involves more than 5,000 shares or the aggregate dollar amount is greater than \$50,000 in any three-month period. The sale must take place within three months of filing the Form 144 and, if the securities have not been sold, an amended notice must be filed. Investors should be aware that sales under Rule 144 or pursuant to a registration statement filed under the Securities Act might depress the market price of our securities in any market for such shares.

Our securities are currently trading on the OTC Markets, Inc. (under their OTC Pink® Open Marketplace), and may be subject to SEC “penny stock,” rules, which could make it more difficult for a broker-dealer to trade our common shares, for an investor to acquire or dispose of our common shares in the secondary market and for us to retain or attract market makers.

The SEC has adopted regulations that define a “penny stock” to be any equity security that has a market price per share of less than \$5.00, subject to certain exceptions, such as any securities listed on a national securities exchange or securities of an issuer in continuous operation for more than three years whose net tangible assets are in excess of \$2 million, or an issuer that has average revenue of at least \$6 million for the

last three years. Our common shares are currently trading on the OTC Markets, Inc., under their OTC Pink Open Marketplace. As of the year ended December 31, 2015, our net tangible assets did not exceed \$2 million, however, our average revenue for the last three years exceeded \$6 million, so our securities currently qualify for exclusion from the “penny stock” definitions. However, if our three-year average revenue falls below \$6 million, we would fail to qualify for the exclusion, and our common shares would be subject to “penny stock” rules. For any transaction involving a “penny stock,” unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. For these reasons, a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market. Therefore, broker-dealers may be less willing or able to sell or make a market in our securities because of the penny stock disclosure rules. Not maintaining a listing on a major stock market may result in a decrease in the trading price of our securities due to a decrease in liquidity and less interest by institutions and individuals in investing in our securities, and could also make it more difficult for us to raise capital in the future. Furthermore, listing on the OTCQB may make it more difficult to retain and attract market makers. In the event that market makers cease to function as such, public trading of our securities will be adversely affected or may cease entirely.

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

We incur significant legal, accounting and other expenses as a result of our required compliance with certain regulations implemented by the SEC. Our management and other personnel devote a substantial amount of time to these compliance requirements. Moreover, these rules and regulations result in significant legal and financial compliance costs and make some activities more time-consuming and costly.

More specifically, the Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Our management is required to perform system and process evaluation and testing of the effectiveness of our internal controls over financial reporting, as required by Section 404(a) of the Sarbanes-Oxley Act (as a smaller reporting company, we are exempt from the requirements of Section 404(b) of the Sarbanes-Oxley Act which requiring auditor’s attestation related to internal controls over financial reporting). Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. As a result, our compliance with Section 404(a) may require that we incur substantial accounting expense and expend significant management efforts. We do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to ensure compliance with these regulations and/or to correct such material weaknesses. If we are not able to comply with the requirements of Section 404(a), or if we identify deficiencies in our internal controls over financial reporting, the market price of our common shares could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Inability to comply with financial covenants under our current credit facilities could result in our creditor(s) declaring all amounts owed to them due and payable with immediate effect, or result in the collection of collateral by the creditor(s); both of which would have an adverse material impact on our business and our ability to continue operations.

We have a credit facility with Crestmark Bank consisting of revolving line of credit (the “Crestmark Line of Credit”). The Crestmark Line of Credit is secured by a first security interest in all of our receivables and inventory and security interest in all other assets of the Company (in accordance with permitted prior encumbrances), (together the “Collateral”). So long as any obligations are due under the Crestmark Line of Credit, we must comply with a minimum Tangible Net Worth (“TNW”) covenant. More specifically, as of June 30, 2015 and each quarter thereafter, we must maintain a TNW of at least \$650,000. Additionally, if a quarterly net income is reported, the TNW covenant will increase by 50% of the reported net income. If a quarterly net loss is reported, the TNW covenant will remain the same as the prior quarter’s covenant amount. TNW is defined as: Total Assets less Total Liabilities less the sum of (i) the aggregate amount of non-trade accounts receivables, including accounts receivables

from affiliated or related persons, (ii) prepaid expenses, (iii) deposits, (iv) net lease hold improvements, (v) goodwill and (vi) any other asset that would be treated as an intangible asset under GAAP; plus Subordinated Debt. Subordinated Debt means any and all indebtedness presently or in the future incurred by the Company to any creditor of the Company entering into a written subordination agreement with Crestmark.

Our failure to comply with Crestmark Line of Credit covenant could result in an event of default, which, if not cured or waived, could result in the Company being required to pay higher costs associated with the indebtedness. If we are forced to refinance our debt on less favorable terms, our results of operations and financial condition could be adversely affected by increased costs and rates. We may also be forced to pursue one or more alternative strategies, such as restructuring, selling assets, reducing or delaying capital expenditures or seeking additional equity capital. There can be no assurances that any of these strategies could be implemented on satisfactory terms, if at all.

Inability to meet our operating plans could have a material adverse effect on our future performance.

Although our financial condition has improved over previous recent fiscal years, if events and circumstances occur such that we do not meet our current operating plans, if we are unable to raise sufficient additional equity or debt financing, or our credit facilities are insufficient or not available, we may be required to further reduce expenses or take other steps which could have a material adverse effect on our future performance.

Our ability to repay our current debt will depend primarily upon our future operating performance, which may be affected by general economic, financial, competitive, regulatory, business and other factors beyond our control, including those discussed herein. In addition, we cannot assure you that future borrowings or equity financing will be available for the payment of any indebtedness we may have.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We own our property in Kinderhook, New York. The property currently consists of a 30,000 square foot facility with approximately 22 surrounding acres. Our Kinderhook facility houses administration, customer service, inside sales, assembly and packaging and shipping. We lease (under a long-term, non-cancellable lease) 5,200 square feet of space in Logan Township, New Jersey that houses our bulk test strip manufacturing and research and development. Both facilities are currently adequate and meet the needs of all areas of the Company.

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company is named in legal proceedings in connection with matters that arise during the normal course of business. While the ultimate result of any such litigation cannot be predicted, if the Company is unsuccessful in defending any such litigation, the resulting financial losses could have an adverse effect on the financial position, results of operations and cash flows of the Company. The Company is not aware of any significant litigation loss contingencies for which management believes it is both probable that a liability has been incurred and that the amount of the loss can be reasonably estimated.

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable.

PART II

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

Market Information

Our common shares are currently trading on the OTC Markets, Inc. under their under their OTC Pink® Open Marketplace under the symbol “ABMC”.

The following table sets forth the high and low closing bid prices of our securities as reported by the OTC Pink Open Marketplace in the years ended December 31, 2015 and December 31, 2014. The prices quoted reflect inter-dealer prices, without retail mark-up, markdown, or commission and may not necessarily represent actual transactions.

Year ended December 31, 2015	High	Low
Quarter ending December 31, 2015	\$0.15	\$0.12
Quarter ending September 30, 2015	\$0.14	\$0.12
Quarter ending June 30, 2015	\$0.25	\$0.11
Quarter ending March 31, 2015	\$0.14	\$0.12

Year ended December 31, 2014	High	Low
Quarter ending December 31, 2014	\$0.14	\$0.11
Quarter ending September 30, 2014	\$0.13	\$0.11
Quarter ending June 30, 2014	\$0.13	\$0.11
Quarter ending March 31, 2014	\$0.16	\$0.11

Holders

Based upon the number of record holders and individual participants in security position listings, as of March 29, 2016, there were approximately 2,300 holders of our securities. As of March 29, 2016, there were 26,475,408 common shares outstanding.

Dividends

We have not declared any dividends on our common shares and do not expect to do so in the foreseeable future. Future earnings, if any, will be retained for use in our business.

Securities authorized for issuance under equity compensation plans previously approved by security holders

We currently have 2 Non-statutory Stock Option Plans (the 2001 Plan and the 2013 Plan, collectively the "Plans") that have been adopted by our Board of Directors and subsequently approved by our shareholders. The Plans provide for the granting of options to employees, directors, and consultants (see Part I, Item 1A, Risk Factor titled, "Potential issuance and exercise...").

Securities authorized for issuance under equity compensation plans not previously approved by security holders

Any securities required to be reported under this item have previously been included in either a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

The following table summarizes information as of December 31, 2015, with respect to compensation plans (including individual compensation arrangements) under which our common stock is authorized for issuance:

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 (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans approved by security holders	1,435,000	\$0.14	6,282,000
Equity Compensation Plans not approved by security holders*	2,385,000	\$0.17	NA

*All securities are related to individual compensation arrangements.

Performance Graph

As a smaller reporting company, we are not required to provide the information required under this item.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities; Purchases of equity securities by the issuer and affiliated purchasers

Any securities required to be reported under this item have previously been included in either a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

ITEM 6. SELECTED FINANCIAL DATA

As a smaller reporting company, we are not required to provide the information required under this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information, which we believe is relevant to an assessment and understanding of our financial condition and results of operations. The discussion should be read in conjunction with the financial statements and the notes to the financial statement contained within this Annual Report on Form 10-K. Certain statements contained in this Annual Report on Form 10-K, including, without limitation, statements containing the words "believes", "anticipates", "estimates", "expects", "intends", "projects", and words of similar import, are forward-looking as that term is defined by the Private Securities Litigation Reform Act of 1995 ("1995 Act"), and in releases issued by the United States Securities and Exchange Commission ("SEC"). These statements are being made pursuant to the provisions of the 1995 Act and with the intention of obtaining the benefits of the "Safe Harbor" provisions of the 1995 Act. We caution that any forward-looking statements made within this Annual Report on Form 10-K are not guarantees of future performance and in fact, actual results may differ materially from those results discussed in such forward-looking statements. This material difference can be a result of various factors, including, but not limited to, any risks detailed herein, including the "Risk Factors" section contained in Part I, Item 1A of this Form 10-K, or detailed in our most recent reports on Form 10-Q and Form 8-K and from time to time in our other filings with the SEC and amendments thereto. We are not undertaking any obligation to publicly update any forward-looking statements. Readers should not place undue reliance on these forward-looking statements.

Overview and Plan of Operations

Sales in the year ended December 31, 2015 ("Fiscal 2015") decreased when compared to the year ended December 31, 2014 ("Fiscal 2014"). During Fiscal 2015, we sustained a net loss of \$333,000 from net sales of \$6,317,000, and had cash provided by operating activities of \$230,000. During Fiscal 2014, we sustained a net loss of \$490,000 from net sales of \$7,285,000, and had net cash provided by operating activities of \$98,000.

The improvement in financial results in spite of sales declines is a result of management's cost containment initiatives. Included in those initiatives is the partial consolidation of our manufacturing operations. More specifically, we closed down 2 of the 3 units we were leasing in Logan Township, New Jersey and we moved certain manufacturing operations up to our (owned) facility in Kinderhook, New York. The 1 remaining unit in New Jersey continues to house bulk strip manufacturing and research and development. The cost of the partial consolidation was approximately \$92,000 and most of this expense was incurred in the fourth quarter of Fiscal 2014. We began to see savings (in site costs, shipping, etc) on January 1, 2015. We saw a 100% return on this investment in Fiscal 2015 primarily in the form of increased manufacturing efficiencies, which resulted in better profit margins.

We continuously examine all expenses in efforts to achieve profitability (if sales levels improve) or to minimize losses going forward (if sales continue to decline). The salary and commission deferral program, (started in August 2013) continued throughout Fiscal 2015. The deferral program consists of a 20% salary deferral for our executive officer (Melissa Waterhouse), and our non-executive VP Operations, as well as a 20% commission deferral for a sales consultant, and a 25% commission deferral of employee commissions (the deferral of employee commissions was reduced from 50% to 25% in July 2015, and was subsequently ceased in the January 2016). As of December 31, 2015, we had total deferred compensation owed of \$179,000. Over the course of the program, we have repaid portions of the deferred compensation (with payments totaling \$100,000 in Fiscal 2015. As cash flow from operations allows, we

intend to continue to make paybacks, however the deferral program is continuing and we expect it will continue for up to another 12 months.

In addition, as part of our debt restructuring initiatives, in Fiscal 2015, we refinanced substantially all of our existing debt in efforts to decrease our interest costs and increase cash flow. In March 2015, we entered into a \$1,200,000 Loan and Security Agreement with Cherokee Financial, LLC (the "Cherokee LSA"). The Cherokee LSA refinanced our Series A Debentures, CAM Bridge Loan and our Mortgage Consolidation Loan with First Niagara Bank. The interest rate on the Cherokee loan facility is 8% with a 1% oversight fee while the interest rate on the Series A Debentures and CAM Bridge Loan was 15%, and the interest rate on the First Niagara loan was 8.25%. In June 2015, we entered into an up to \$1,500,000 Loan and Security Agreement with Crestmark Bank that refinanced our line of credit with Imperium. The annual all-in rate (including interest and fees) on the Crestmark Line of Credit is 9.35% (the interest rate component is variable based on WSJ prime). The Imperium line of credit annual all-in rate was 12% (fixed).

We continue to believe that new products and our ability to sell those markets in new markets will be the primary future growth driver. In Fiscal 2015, we took steps to receive a marketing clearance from the FDA to sell an all-inclusive, urine based, drug-testing cup to customers requiring a CLIA waived product. In Fiscal 2015, we also completed development on a new assay for K2, or synthetic marijuana. We also have a number of new assays planned in research and development. We remain focused on selling our point of collection drugs of abuse tests, and growing our business through direct sales and select distributors. We are also making efforts to identify and secure new contract work and possible diversification alternatives.

Our continued existence is dependent upon several factors, including our ability to raise revenue levels and control costs to generate positive cash flows, maintaining our current credit facilities or refinancing our current credit facilities if necessary, and if needed, the ability to obtain working capital by selling additional shares of our common stock.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or "U.S. GAAP". Part IV, Item 15, Note A to our financial statements describes the significant accounting policies and methods used in the preparation of our financial statements. The accounting policies that we believe are most critical to aid in fully understanding and evaluating the financial statements include the following:

Estimates of the fair value of stock options and warrants at date of grant: The fair value of stock options and warrants issued to employees, members of our Board of Directors, consultants and in connection with debt financings is estimated (on the date of grant) based on the Black-Scholes options-pricing model utilizing certain assumptions for a risk free interest rate; volatility; and expected remaining lives of the awards. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. If factors change and we use different assumptions, our equity-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. In estimating our forfeiture rate, we analyzed our historical forfeiture rate, the remaining lives of unvested options, and the amount of vested options as a percentage of total options outstanding. If our actual forfeiture rate is materially different from its estimate, or if we reevaluate the forfeiture rate in the future, the equity-based compensation expense could be significantly different from what we have recorded in the current period.

Inventory and Allowance for Slow Moving and Obsolete Inventory: We maintain an allowance for slow moving and obsolete inventory. If necessary, actual write-downs to inventory are made for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the net realizable value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory allowances or write-downs may be required.

Deferred Income Tax Asset Valuation Allowance: We record a valuation allowance to

reduce our deferred income tax assets to the amount that is more likely than not to be realized. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the deferred income tax asset valuation allowance, in the event we were to determine that we would be able to realize our deferred income tax assets in the future in excess of our net recorded amount, an adjustment to the deferred income tax asset would increase income in the period such determination was made.

RESULTS OF OPERATIONS FOR FISCAL 2015 COMPARED TO FISCAL 2014

Net Sales: Net sales decreased 13.3% to \$6,317,000 in Fiscal 2015, from \$7,285,000 in Fiscal 2014. Government sales.

Government sales declined in Fiscal 2015 when compared to Fiscal 2014 primarily due to the loss of two state contracts early in Fiscal 2015 (both of which switched to using a product manufactured outside of the United States). Our urine-based, all-inclusive drug test (launched in the first quarter of 2015) is allowing us to be more cost competitive in this market. However, Government sales typically have a longer sales cycle; i.e. when dealing with larger government accounts, the time between initial contact with the customer and the receipt of an order is typically longer than smaller municipalities or entities in the private sector.

International sales were also down in Fiscal 2015 when compared to Fiscal 2014. Decreased European sales were offset by an increase in sales in Latin America and other part of the world in Fiscal 2015 when compared to Fiscal 2014.

And finally, contract-manufacturing sales were down slightly in Fiscal 2015 when compared to Fiscal 2014. This stems primarily from decreased sales related to one contract-manufacturing customer, offset by an increase in sales from another contract manufacturing customer.

Gross profit: Gross profit increased to 45.2% of net sales in Fiscal 2015 from 42.1% of net sales in Fiscal 2014. Expense reductions and the partial consolidation of manufacturing operations at the end of Fiscal 2014 have enabled us to somewhat overcome the continued price pressures in our markets, resulting in increased gross profit from sales.

Operating Expenses: Operating expenses for Fiscal 2015 decreased \$198,000, or 6.0%, when compared to operating expense in Fiscal 2014. Research and Development and General and Administrative expenses decreased while Selling and Marketing expenses increased. More specifically:

Research and development ("R&D")

R&D expenses for Fiscal 2015 decreased 35.1%, when compared to R&D expenses incurred in Fiscal 2014. This stems from decreased FDA compliance (due to timing of actions taken to submit a marketing application to the FDA) and utility costs (as a result of the consolidation of the New Jersey facility). These decreases were partially offset by increased supplies (in connection with the K2 assay development). In Fiscal 2015, our R&D department continued to focus their efforts on the enhancement of current products, development of new testing assays, new product platforms and exploration of contract manufacturing opportunities. At the end of Fiscal 2015, we completed the development of a new assay for the detection of K2, or synthetic marijuana.

Selling and marketing

Selling and marketing expenses for Fiscal 2015 increased by 4.8% when compared to selling and marketing expense in Fiscal 2014. Throughout Fiscal 2015, we made investments in selling and marketing. More specifically, we hired new regional sales managers, attended more trade shows, completed the redesign of marketing materials and purchased new trade show equipment. These investments resulted in increases to sales salaries, auto expense, trade show expense and travel expense. These increases were partially offset by a decrease in sales commissions (due to changes in our commission compensation structure and reduced sales levels), postage and consulting expenses.

In Fiscal 2015, our direct sales force continued to focus their efforts in our target markets, which include, but are not limited to, Workplace and Government, as well as focusing on the clinical (i.e. pain management and drug treatment) with our CLIA waived Rapid TOX product line, and focusing on the forensic and international markets for our OralStat® product.

General and administrative ("G&A")

G&A expenses for Fiscal 2015 decreased 8.8%, from Fiscal 2014. In Fiscal 2015 there were expense reductions in salaries and benefits, building rental (due to consolidation of facilities), relocation expense (as consolidation occurred in Fiscal 2014 and did not occur in Fiscal 2015), legal fees, patents and license fees, contract fees and bank service fees (as a result of decreased credit facility fees). These reductions were partially offset by expense increases in shipping supplies, insurance costs, computer supplies (as a result of system upgrades), outside service fees (associated with our ISO certifications) and telephone costs. Share based payment expense also decreased from \$139,000 in Fiscal 2014 to \$34,000 in Fiscal 2015; this reduction stems primarily from decreased option issuance costs.

Other income and expense: Other expense in Fiscal 2015 consisted primarily of interest expense offset by other income associated with a Strategic Manufacturing and Cooperation Agreement with a contract-manufacturing customer, and a gain on a sales tax liability. Other income during Fiscal 2014 consisted primarily of proceeds from the sale of equipment offset by interest expense. During Fiscal 2015 and Fiscal 2014 we incurred interest expense of \$206,000 and \$244,000, respectively, related to our loans with First Niagara Bank, our line of credit with Imperium Commercial Finance LLC, our Series A Debentures and our loan with Cantone Asset Management.

Note: Our loan with First Niagara Bank the Series A Debentures and our loan with Cantone Asset Management was refinanced in March 2015 through a loan with Cherokee Financial, LLC. Our line of credit with Imperium Commercial Finance, LLC was refinanced through a line of credit with Crestmark Bank in June 2015.

LIQUIDITY AND CAPITAL RESOURCES AS OF DECEMBER 31, 2015

Our cash requirements depend on numerous factors, including but not limited to manufacturing costs (such as raw materials, equipment, etc.), selling and marketing initiatives, product development activities, and effective management of inventory levels and production levels in response to sales forecasts. We expect to devote capital resources to continue selling and marketing initiatives and product development/research and development activities. We will examine other growth opportunities including strategic alliances and expect such activities will be funded from existing cash and cash equivalents, issuance of additional equity or additional borrowings, subject to market and other conditions. Our financial statements for the year ended December 31, 2015 were prepared assuming we will continue as a going concern. Although our financial condition has improved when comparing Fiscal 2015 with Fiscal 2014, our current cash balances, together with cash generated from future operations and amounts available under our credit facilities may not be sufficient to fund operations for the next twelve months. Our current line of credit has a term of 3 years, expiring on June 29, 2018 and has a maximum availability of \$1,500,000. However, the amount available under our line of credit is based upon our accounts receivable and inventory. As of December 31, 2015, there were no additional amounts available under our line of credit because we draw any balance available on a daily basis. If sales levels decline further, we will have reduced availability on our line of credit due to decreased accounts receivable balances. In addition, we would expect our inventory levels to decrease if sales levels decline further, and this also means reduced availability on our line of credit. If availability under our line of credit is not sufficient to satisfy our working capital and capital expenditure requirements, we will be required to obtain additional credit facilities, sell additional equity securities. There is no assurance that such financing will be available or that we will be able to complete financing on satisfactory terms, if at all.

As of December 31, 2015, we had the following debt/credit facilities:

Facility	Debtor	Balance as of December 31, 2015
Loan and Security Agreement	Cherokee Financial, LLC	\$1,200,000
Revolving Line of Credit	Crestmark Bank	\$777,000

Working Capital

Our working capital increased \$573,000 to \$886,000 at the end of Fiscal 2015 from \$313,000 at the end of Fiscal 2014. This increase in working capital is primarily a result of an increase in inventory and a decrease in the current portion of our long-term debt

(as a result of our mortgage and debenture refinancing completed in March 2015), which were offset by a decrease in accounts receivable and cash. We have historically satisfied net working capital requirements through cash from operations and bank debt.

Dividends

We have never paid any dividends on our common shares and we anticipate that all future earnings, if any, will be retained for use in our business.

Cash Flows

Cash provided by operations of \$230,000 for Fiscal 2015 is comprised of a net loss of \$333,000 plus an increase in inventory of \$132,000 and reduction in accounts payable, offset by reductions in account receivables of \$139,000 and prepaid expenses of \$45,000. Cash provided by operations of \$98,000 for Fiscal 2014 is comprised of a net loss of \$490,000 plus a reduction in accounts payable and other accrued liabilities of \$393,000, offset by the reduction in inventory of \$304,000, a reduction in accounts receivable of \$72,000 and adding back non cash changes of amortization and depreciation of \$373,000 and a loss on disposal of fixed assets of \$41,000.

Net cash used in investing activities consisting primarily of equipment, molds and patent costs remains relatively low at \$21,000 and \$65,000 in Fiscal 2015 and Fiscal 2014, respectively. Net cash used in investing activities in Fiscal 2014 did include proceeds from the sale of equipment in the amount of \$10,000.

Net cash used in financing activities for Fiscal 2015 consisted of payments on our lines of credit and other debt and deferred finance costs, offset by proceeds from our lines of credit. Net cash used in financing activities for Fiscal 2014 consisted of payments on our line of credit and other debt financing, offset by proceeds from our line of credit and deferred finance costs. At December 31, 2015 and December 31, 2014, we had cash and cash equivalents of \$158,000 and \$352,000, respectively.

Outlook

We do not expect significant increases in expenses in the year ending December 31, 2016 ("2016") and we continue to take steps to ensure that operating expenses and manufacturing costs remain in line with sales levels. In 2016, we are focusing our efforts on improving sales. Such steps include, but are not limited to, obtaining an over-the-counter marketing clearance from FDA for one of our all-inclusive drug testing cups (allowing us to further penetrate Clinical markets such as pain management and drug treatment), and entering into strategic relationships with third parties to offer additional services to our customers (thereby increasing product sales and generating other revenue from the sale of services). In addition, in the year ending December 31, 2016, we will receive our final payment of \$150,000 related to our Strategic Manufacturing and Cooperation Agreement with one of our contract-manufacturing customers.

Although our financial condition has improved over previous recent fiscal years, if events and circumstances occur such that 1) we do not meet our current operating plans to increase sales, 2) we are unable to raise sufficient additional equity or debt financing, or 3) our credit facilities are insufficient or not available, we may be required to further reduce expenses or take other steps which could have a material adverse effect on our future performance.

Our ability to repay our current debt will depend primarily upon our future operating performance, which may be affected by general economic, financial, competitive, regulatory, business and other factors beyond our control, including those discussed herein. In addition, we cannot assure you that future borrowings or equity financing will be available for the payment of any indebtedness we may have.

Our failure to comply with the covenant under our revolving credit facility could result in an event of default, which, if not cured or waived, could result in the Company being required to pay higher costs associated with the indebtedness. If we are forced to refinance our debt on less favorable terms, our results of operations and financial condition could be adversely affected by increased costs and rates. We may also be forced to pursue one or more alternative strategies, such as restructuring, selling assets, reducing or delaying capital expenditures or seeking additional equity capital. There can be no assurances that any of these strategies could be implemented on satisfactory terms, if at all.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Financial Statements are set forth beginning on page F-1.

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

None.

ITEM 9A. CONTROLS AND PROCEDURESEvaluation of Disclosure Controls and Procedures

Management has reviewed the effectiveness of our “disclosure controls and procedures” (as defined in the Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report and have concluded that the disclosure controls and procedures are effective to ensure that material information relating to the Company is recorded, processed, summarized, and reported in a timely manner.

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 Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed 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. Our internal control over financial reporting includes those policies and procedures that:

- (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorization of Management; and
- (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of 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 risk that controls may become inadequate because of changes in conditions, or the degree of compliance may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on that assessment, Management has concluded that our internal control over financial reporting was effective as of December 31, 2015.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the last quarterly period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Independent Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that exempt smaller reporting companies from this requirement.

ITEM 9B. OTHER INFORMATION

None.

PART III**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE**

The information required by this item is contained in our definitive Proxy Statement with respect to our Annual Meeting of Shareholders for the year ended December 31, 2015, under the captions “Discussion of Proposal Recommended by Board”, “Directors that are not Nominees”, “Additional Executive Officers and Senior Management”, “Section 16(a) Beneficial Ownership Reporting Compliance”, “Code of Ethics”, “Nominating Committee”, “Audit Committee” and “Audit Committee Financial Expert” and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is contained in our definitive Proxy Statement

with respect to our Annual Meeting of Shareholders for the year ended December 31, 2015, under the captions “Executive Compensation”, “Compensation of Directors”, “Compensation Committee Interlocks and Insider Participation”, and “Compensation Committee Report”, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is contained within Part II, Item 5. Market for Registrant’s Common Equity, Related Stockholders Matters and Issuer Purchases of Equity Securities earlier in this Annual Report on Form 10-K and in our definitive Proxy Statement with respect to the Annual Meeting of Shareholders for the year ended December 31, 2015, under the caption “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference.

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

The information required by this item is contained in our definitive Proxy Statement with respect to the Annual Meeting of Shareholders for the year ended December 31, 2015, under the captions “Certain Relationships and Related Transactions” and “Independent Directors”, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is contained in our definitive Proxy Statement with respect to the Annual Meeting of Shareholders for the year ended December 31, 2015, under the caption “Independent Public Accountants”, and is incorporated herein by reference.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

- (1) Our financial statements

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Report of Current Independent Registered Public Accounting Firm — UHY, LLP	F-2
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- (2) Financial Statement Schedule

As a smaller reporting company, we are only required to provide financial statements required by Article 8 of Regulation S-X in lieu of financial statements that may be required under Part II, Item 8 of this Annual Report on Form 10-K, and these financial statements are noted under Item 15(a)(1).

- (3) See Item 15(b) of this Annual Report on Form 10-K.

(b) Exhibits

No.	Description of Exhibits
3.5	Bylaws ⁽¹⁾
3.50	Amended and Restated Bylaws ⁽²⁾
3.51	Amended and Restated Bylaws ⁽³⁾
3.6	Fifth amendment to the Certificate of Incorporation (filed as exhibit 3.6 to the Company’s Form SB-2 filed on November 21, 1996 and incorporated herein by reference)
3.7	Sixth amendment to the Certificate of Incorporation ⁽²⁾

No.	Description of Exhibit (continued from previous page)
4.9	2009 Series A Debenture Offering-Form of Debenture Placement Agreement ⁽⁵⁾
4.10	2009 Series A Debenture Offering-Form of Private Placement Memorandum ⁽⁵⁾
4.11	2009 Series A Debenture Offering-Form of Security Purchase Agreement ⁽⁵⁾
4.12	2009 Series A Debenture Offering-Form of Series A Debenture ⁽⁵⁾
4.13	2009 Series A Debenture Offering-Form of Registration Rights Agreement ⁽⁵⁾
4.14	2009 Series A Debenture Offering - Form of Placement Agent Warrant Agreement ⁽⁵⁾
4.17	Fiscal 2001 Nonstatutory Stock Option Plan (filed as part of the Company's Proxy Statement for its Fiscal 2002 Annual Meeting and incorporated herein by reference) ^(a)
4.19	Placement Agent Agreement by and between the Company and Cantone Research, Inc. ⁽⁶⁾
4.20	Bridge Loan Agreement by and between the Company and Cantone Asset Management, LLC ⁽⁶⁾
4.21	Note (Bridge Loan) by and between the Company and Cantone Asset Management, LLC ⁽⁶⁾
4.22	Form of Debenture Amendment between the Company and Debenture Holders ⁽⁷⁾
4.23	Consulting Agreement between the Company and Cantone Asset Management, LLC ⁽⁷⁾
4.24	Agreement between the Company and Monarch Capital ⁽⁷⁾
4.25	2013 Equity Compensation Plan (filed as Appendix A to the Company's Proxy Statement for its fiscal year ended December 31, 2012 and incorporated herein by reference) ^(a)
10.8	Lease dated August 1, 1999/New Jersey facility ⁽⁸⁾
10.38	Employment Contact between the Company and Melissa A. Waterhouse ⁽⁹⁾
10.40	Employment Contract between the Company and Melissa A. Waterhouse ⁽¹⁰⁾
10.41	Amendment No. 9 to New Jersey facility lease, dated December 15, 2014 ⁽¹¹⁾
10.42	Amendment No. 10 to New Jersey facility lease, dated December 21, 2015 ⁽¹²⁾
31.1 & 31.2	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer/ Chief Financial Officer
32.1 & 32.2	Section 1350 Certification of the Chief Executive Officer/Chief Financial Officer
101	The following materials from our Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheet, (ii) Statements of Income (iii) Statements of Cash Flows, (iv) Statements of Changes in Stockholders' Equity and (v) Notes to Financial Statements.

(a) Indicates an employee benefits plan, management contract or compensatory plan or arrangement in which a named executive officer participates.

(1) Filed as the exhibit number listed to the Company's Form 10-SB filed on November 21, 1996 and incorporated herein by reference.

(2) Filed as the exhibit number listed to the Company's Form 10-KSB filed on April 15, 2002 and incorporated herein by reference.

Filed as the exhibit number listed to the Company's Current Report on Form 8-K filed on October 18, 2007 and incorporated herein by reference.

Filed as Exhibit 3.6 to the Company's Form SB-2 filed on November 21, 1996 and incorporated herein by reference

Filed as the exhibit number listed to the Company's Registration Statement on Form S-3 filed on April 15, 2009 and amended on May 5, 2009 and incorporated herein by reference.

Filed as the exhibit number listed to the Company's Current Report on Form 8-K filed with the Commission on July 31, 2012.

Filed as the exhibit number listed to the Company's Current Report on Form 8-K/A-1 filed with the Commission on August 6, 2012.

Filed as the exhibit number listed to the Company's Form 10-KSB filed on August 11, 2000 and incorporated herein by reference.

Filed as the exhibit number listed to the Company's Current Report on Form 8-K filed with the Commission on November 11, 2013.

Filed as the exhibit number listed to the Company's Current Report on Form 8-K filed with the Commission on June 24, 2014.

Filed as the exhibit number listed to the Company's Form 10-K filed on March 31, 2015 and incorporated herein by reference.

(c) Not applicable

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AMERICAN BIO MEDICA CORPORATION

By /s/ Melissa A. Waterhouse

Melissa A. Waterhouse

Chief Financial Officer (Principal Executive Officer)

Principal Financial Officer

Principal Accounting Officer

Date: March 30, 2016

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 30, 2016:

/s/ Melissa A. Waterhouse Chief Executive Officer (Principal Executive Officer)

Melissa A. Waterhouse Principal Executive Officer

Principal Financial Officer

/s/ Richard P. Koskey Chairman of the Board

Richard P. Koskey

/s/ Carl A. Florio Director

Carl A. Florio

/s/ Jean Neff Director and Corporate Secretary

Jean Neff

/s/ Diane J. Generous Director

Diane J. Generous



FINANCIAL STATEMENTS ▪ DECEMBER 31, 2015

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REPORT OF CURRENT INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of American Bio Medica Corporation

We have audited the accompanying balance sheet of American Bio Medica Corporation as of December 31, 2015, and the related statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2015. American Bio Medica Corporation's management is responsible for these financial statements. 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 audit 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of American Bio Medica Corporation as of December 31, 2015 and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that American Bio Medica Corporation will continue as a going concern. As more fully described in Note A, the Company has incurred recurring operating losses and its current cash position and lack of access to capital raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note A. The financial statements do not include any adjustments to reflect the possible effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of this uncertainty. Our opinion is not modified with respect to that matter.

/s/ UHY LLP

Albany, New York
March 30, 2016

REPORT OF PRIOR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
American Bio Medica Corporation.

We have audited the accompanying balance sheet of American Bio Medica Corporation as of December 31, 2014 and the related statements of operations, stockholders' equity, and cash flows for each of the year then ended December 31, 2014. These 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. 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 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 financial position of the Company as of December 31, 2014, and the results of its operations and cash flows for each of the year ended December 31, 2014, in conformity with generally accepted accounting principles in the United States.

The accompanying financial statements have been prepared assuming that American Bio Medica Corporation will continue as a going concern. As more fully described in Note A, the Company has incurred recurring operating losses and will have to obtain additional financing and or refinance certain debts maturing in 2015. These 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 A. The financial statements do not include any adjustments to reflect the possible effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Liggett & Webb, P.A.

New York, New York
March 27, 2015

BALANCE SHEETS

	December 31, 2015	December 31, 2014
<u>ASSETS</u>		
Current assets		
Cash and cash equivalents	\$ 158,000	\$ 352,000
Accounts receivable, net of allowance for doubtful accounts of \$50,000 at December 31, 2015 and \$47,000 at December 31, 2014	672,000	814,000
Inventory, net of allowance of \$432,000 at December 31, 2015 and \$324,000 at December 31, 2014	1,746,000	1,722,000
Current portion of deferred financing	0	43,000
Prepaid expenses and other current assets	40,000	85,000
Total current assets	2,616,000	3,016,000
Property, plant and equipment, net	910,000	983,000
Patents, net	67,000	65,000
Other assets	14,000	14,000
Deferred finance costs, net	190,000	0
Total assets	<u>\$ 3,797,000</u>	<u>\$ 4,078,000</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities		
Accounts payable	\$ 373,000	\$ 410,000
Accrued expenses and other current liabilities	212,000	192,000
Wages payable	292,000	264,000
Line of credit	777,000	979,000
Current portion of long-term debt	75,000	858,000
Total current liabilities	1,729,000	2,703,000
Other liabilities	38,000	68,000
Related party note payable	124,000	124,000
Long-term debt, net of current portion	945,000	213,000
Total liabilities	2,836,000	3,108,000
COMMITMENTS AND CONTINGENCIES		
Stockholders' equity:		
Preferred stock; par value \$.01 per share; 5,000,000 shares authorized, none issued and outstanding at December 31, 2015 and 2014		
Common stock; par value \$.01 per share; 50,000,000 shares authorized; 26,032,930 issued and outstanding as of December 31, 2015, and 23,648,315 issued and outstanding as of December 31, 2014	260,000	236,000
Additional paid-in capital	20,656,000	20,356,000
Accumulated deficit	(19,955,000)	(19,622,000)
Total stockholders' equity	961,000	970,000
Total liabilities and stockholders' equity	<u>\$ 3,797,000</u>	<u>\$ 4,078,000</u>

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

STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2015	For the Year Ended December 31, 2014
Net sales	\$ 6,317,000	\$ 7,285,000
Cost of goods sold	3,462,000	4,223,000
Gross profit	2,855,000	3,062,000
Operating expenses:		
Research and development	148,000	228,000
Selling and marketing	1,164,000	1,111,000
General and administrative	1,769,000	1,940,000
Operating loss	(226,000)	(217,000)
Other income / (expense):		
Interest income	(1,000)	0
Interest expense	(206,000)	(244,000)
Other income, net	102,000	14,000
Loss on disposition of assets, net	0	(41,000)
Net loss before tax	(331,000)	(488,000)
Income tax benefit (expense)	(2,000)	(2,000)
Net loss	\$ (333,000)	(490,000)
Basic and diluted loss per common share	\$ (0.02)	(0.02)
Weighted average number of shares outstanding - basic & diluted	25,676,976	23,336,806

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

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance-December 31, 2013	22,959,822	229,000	20,241,000	(19,132,000)	1,338,000
Shares issued in connection with L:andmark consulting agreement	208,333	2,000	23,000		25,000
Shares issued in connection with Series A Debenture Forbearance	58,575	1,000	6,000		7,000
Shares issued in connection with Landmark consulting agreement extension	421,585	4,000	46,000		50,000
Share based payment expense			40,000		40,000
Net Loss				(490,000)	(490,000)
Balance—December 31, 2014	23,648,315	\$ 236,000	\$ 20,356,000	\$ (19,622,000)	\$ 970,000
Shares issued in connection with Landmark consulting agreement extension	384,615	4,000	46,000		50,000
Shares issued in connection with Cherokee Financial mortgage	2,000,000	20,000	220,000		240,000
Share based payment expense			34,000		34,000
Net Loss				(333,000)	(333,000)
Balance—December 31, 2015	26,032,930	\$ 260,000	\$ 20,656,000	\$ (19,955,000)	\$ 961,000

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

STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2015	Year Ended December 31, 2014
Cash flows from operating activities:		
Net loss	\$ (333,000)	\$ (490,000)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	91,000	111,000
Loss on disposal of fixed assets	0	41,000
Amortization of debt issuance costs	264,000	251,000
Provision for bad debts	3,000	(11,000)
Provision for slow moving and obsolete inventory	108,000	45,000
Share-based payment expense	34,000	139,000
Changes in:		
Accounts receivable	139,000	50,000
Inventory	(132,000)	334,000
Prepaid expenses and other current assets	45,000	(13,000)
Accounts payable	(37,000)	(187,000)
Accrued expenses and other current liabilities	20,000	(203,000)
Wages payable	28,000	31,000
Net cash provided by operating activities	230,000	98,000
Cash flows from investing activities:		
Proceeds from sale of equipment	0	10,000
Purchase of property, plant and equipment	(13,000)	(51,000)
Patent application costs	(8,000)	(24,000)
Net cash used in investing activities	(21,000)	(65,000)
Cash flows from financing activities:		
Proceeds from / (payments on) debt financings	(51,000)	6,509,000
Deferred finance costs	(150,000)	(7,000)
Proceeds from lines of credit	6,600,000	6,509,000
Payments on lines of credit	(6,802,000)	(6,614,000)
Net cash provided by / (used in) financing activities	(403,000)	(327,000)
Net (decrease) / increase in cash and cash equivalents	(194,000)	(294,000)
Cash and cash equivalents – beginning of period	352,000	646,000
Cash and cash equivalents – end of period	\$	\$ 352,000
Supplemental disclosures of cash flow information:		
Non-Cash transactions:		
Common shares issued in connection with debt financings	290,000	0
Settlement of debt	1,026,000	0
Cash paid during the year for interest	\$ 206,000	\$ 241,000
Cash paid for taxes	\$ 0	\$ 0

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

NOTE A - THE COMPANY AND ITS SIGNIFICANT ACCOUNTING POLICIESThe Company:

American Bio Medica Corporation (the "Company") is in the business of developing, manufacturing, and marketing point of collection testing products for drugs of abuse, as well as performing contract manufacturing services for third parties.

Going Concern

The Company's financial statements have been prepared assuming the Company will continue as a going concern, which assumes the realization of assets and the satisfaction of liabilities in the normal course of business. For the year ended December 31, 2015 ("Fiscal 2015"), the Company had a net loss of \$333,000 and net cash provided by operating activities of \$230,000, compared to a net loss of \$490,000 and net cash provided by operating activities of \$98,000 for the year ended December 31, 2014 ("Fiscal 2014"). The Company's cash balances decreased \$194,000 during Fiscal 2015 and decreased \$294,000 during Fiscal 2014.

As of December 31, 2015, the Company had an accumulated deficit of \$19,955,000. Starting in late 2013, and through Fiscal 2014, the Company implemented a number of expense and personnel cuts, implemented a salary and commission deferral program, consolidated certain manufacturing operations of the Company, and refinance debt. More specifically, the salary and commission deferral program consists of a 20% salary deferral for the Company's executive officer (Melissa Waterhouse), and non-executive VP Operations, as well as a 20% commission deferral for a sales consultant, and a 25% commission deferral of employee commissions (the deferral of employee commissions was reduced from 50% to 25% in July 2015, and was subsequently ceased in the January 2016). As of December 31, 2015, the Company had total deferred compensation owed of \$179,000. Over the course of the program, the Company has repaid portions of the deferred compensation (with payments totaling \$100,000 in Fiscal 2015. As cash flow from operations allows, the Company intends to continue to make paybacks, however the deferral program is continuing and the Company expects it will continue for up to another 12 months.

The consolidation was completed at the end of Fiscal 2014. The Company closed down 2 of the 3 units being leased in Logan Township, New Jersey and moved certain manufacturing operations up to the Company's (owned) facility in Kinderhook, New York. The 1 remaining unit in New Jersey continues to house bulk strip manufacturing and research and development. The cost of the partial consolidation was approximately \$92,000 and most of this expense was incurred in the fourth quarter of Fiscal 2014. The Company began to see savings (in site costs, shipping, etc) on January 1, 2015. The Company saw a 100% return on this investment in Fiscal 2015 primarily in the form of increased manufacturing efficiencies, which resulted in better profit margins.

In Fiscal 2015, the Company refinanced substantially all of its existing debt in efforts to decrease its interest costs and increase cash flow. In March 2015, the Company entered into a \$1,200,000 Loan and Security Agreement with Cherokee Financial, LLC (the "Cherokee LSA"). The Cherokee LSA refinanced the Series A Debentures, CAM Bridge Loan and Mortgage Consolidation Loan with First Niagara Bank. The interest rate on the Cherokee loan facility is 8% with a 1% oversight fee while the interest rate on the Series A Debentures and CAM Bridge Loan was 15%, and the interest rate on the First Niagara loan was 8.25%. In June 2015, the Company entered into an up to \$1,500,000 Loan and Security Agreement with Crestmark Bank that refinanced its line of credit with Imperium Commercial Finance. The annual all-in rate (including interest and fees) on the Crestmark Line of Credit is 9.35% (the interest rate component is variable based on WSJ prime). The Imperium line of credit annual all-in rate was 12% (fixed).

If cash generated from operations is insufficient to satisfy the Company's working capital and capital expenditure requirements, the Company will be required to sell additional equity or obtain additional credit facilities. The Company's ability to repay, acquire new debt, or to refinance its current debt will depend primarily upon its future operating performance, which may be affected by general economic, financial, competitive, regulatory, business and other factors beyond its control, including those discussed herein. In addition, the Company cannot assure you that future borrowings

or equity financing will be available to fund operations.

The Company's failure to comply with the restrictive covenants under its revolving credit facility and other debt instruments could result in an event of default, which, if not cured or waived, could result in the Company being required to repay these borrowings before their due date or pay higher costs associated with the indebtedness. If the Company is forced to refinance these borrowings on less favorable terms, its results of operations and financial condition could be adversely affected by increased costs and rates. The Company may also be forced to pursue one or more alternative strategies, such as restructuring or refinancing its indebtedness, selling assets, reducing or delaying capital expenditures or seeking additional equity capital. There can be no assurances that any of these strategies could be implemented on satisfactory terms, if at all.

The Company's history of operating cash flow deficits, its current cash position and lack of access to capital raise doubt about its ability to continue as a going concern and its continued existence is dependent upon several factors, including its ability to raise revenue levels and control costs to generate positive cash flows, to sell additional shares of the Company's common stock to fund operations and obtain additional credit facilities. Selling additional shares of the Company's common stock and obtaining additional credit facilities may be more difficult as a result of limited access to equity markets and the tightening of credit markets. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amount of or classification of liabilities that might be necessary as a result of this uncertainty.

Significant Accounting Policies:

[1] *Cash equivalents:* The Company considers all highly liquid financial instruments purchased with a maturity of three months or less to be cash equivalents.

[2] *Accounts Receivable:* Accounts receivable consists of mainly trade receivables due from customers for the sale of our products. Payment terms vary on a customer-by-customer basis, and currently range from cash on delivery to net 60 days. Receivables are considered past due when they have exceeded their payment terms. Accounts receivable have been reduced by an estimated allowance for doubtful accounts. The Company estimates its allowance for doubtful accounts based on facts, circumstances and judgments regarding each receivable. Customer payment history and patterns, historical losses, economic and political conditions, trends and individual circumstances are among the items considered when evaluating the collectability of the receivables. Accounts are reviewed regularly for collectability and those deemed uncollectible are written off. At December 31, 2015 and December 31, 2014 the Company had an allowance for doubtful accounts of \$50,000 and \$47,000, respectively.

[3] *Inventory:* Inventory is stated at the lower of cost or market. Work in process and finished goods are comprised of labor, overhead and raw material costs. Labor and overhead costs are determined on a rolling average cost basis and raw materials are determined on an average cost basis. At December 31, 2015 and December 31, 2014, the Company established an allowance for slow moving and obsolete inventory of \$432,000 and \$324,000, respectively.

[4] *Income taxes:* The Company follows ASC 740 "Income Taxes" ("ASC 740") which prescribes the asset and liability method whereby deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and are measured using the enacted laws and tax rates that will be in effect when the differences are expected to reverse. The measurement of deferred tax assets is reduced, if necessary, by a valuation allowance for any tax benefits that are not expected to be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. Under ASC 740, tax benefits are recorded only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon ultimate settlement. Unrecognized tax benefits are tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards.

[5] *Depreciation and amortization:* Property, plant and equipment are depreciated on

the straight-line method over their estimated useful lives; generally 3-5 years for equipment and 30 years for buildings. Leasehold improvements and capitalized lease assets are amortized by the straight-line method over the shorter of their estimated useful lives or the term of the lease. Intangible assets include the cost of patent applications, which are deferred and charged to operations over 19 years. The accumulated amortization of patents is \$166,000 and \$160,000 at December 31, 2015 and December 31, 2014, respectively. Annual amortization expense of such intangible assets is expected to be \$2,000 per year for the next 5 years.

[6] Revenue recognition: The Company recognizes revenue when title transfers upon shipment. Sales are recorded net of estimated discounts and returns. All buyers have economic substance apart from the Company and the Company does not have any obligation for customer acceptance. The Company's price is fixed and determinable at the date of sale. The buyer has paid the Company or is obligated to pay the Company or, in the case of a distributor, the obligation is not contingent on the resale of the product, nor does the Company have any obligation to bring about the resale of the product. The buyer's obligation would not be changed in the event of theft or physical destruction or damage to the product. All distributors have economic substance apart from the Company and their own customers and payment terms are not conditional. The transactions with distributors are on terms similar to those given to the Company's other customers. No agreements exist with the distributors that offer a right of return.

[7] Shipping and handling: Shipping and handling fees charged to customers are included in net sales, and shipping and handling costs incurred by the Company, to the extent of those costs charged to customers, are included in cost of sales.

[8] Research and development: Research and development ("R&D") costs are charged to operations when incurred. These costs include salaries, benefits, travel, supplies, depreciation of R&D equipment and other miscellaneous expenses.

[9] Net loss per common share: Basic loss per common share is calculated by dividing net loss by the weighted average number of outstanding common shares during the period.

Potential common shares outstanding as of December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014
Warrants	2,385,000	3,303,000
Options	1,435,000	1,295,000
Total	3,280,000	4,598,000

For Fiscal 2015 and Fiscal 2014, the number of securities not included in the diluted loss per share was 3,820,000 and 4,598,000, respectively, as their effect was anti-dilutive due to net loss in each year.

[10] Use of estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities 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. Our management believes the major estimates and assumptions impacting our financial statements are the following:

- estimates of the fair value of stock options and warrants at date of grant; and
- estimates of the inventory reserves; and
- deferred tax valuation

The fair value of stock options and warrants issued to employees, members of our Board of Directors, consultants and in connection with debt financings is estimated on the date of grant based on the Black-Scholes options-pricing model utilizing certain assumptions for a risk free interest rate; volatility; and expected remaining lives of the awards. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment.

As a result, if factors change and the Company uses different assumptions, the Company's equity-based compensation expense could be materially different in the

future. In addition, the Company is required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. In estimating the Company's forfeiture rate, the Company analyzed its historical forfeiture rate, the remaining lives of unvested options, and the amount of vested options as a percentage of total options outstanding.

If the Company's actual forfeiture rate is materially different from its estimate, or if the Company reevaluates the forfeiture rate in the future, the equity-based compensation expense could be significantly different from what we have recorded in the current period.

Actual results may differ from estimates and assumptions of future events.

[11] Impairment of long-lived assets: The Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets.

[12] Financial Instruments: The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and other liabilities approximate their fair value based on the short term nature of those items.

Estimated fair value of financial instruments is determined using available market information. In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts.

Accordingly, the estimates of fair value presented herein may not be indicative of the amounts that could be realized in a current market exchange.

ASC Topic 820, "Fair Value Measurements and Disclosures" ("ASC Topic 820") establishes a hierarchy for ranking the quality and reliability of the information used to determine fair values. ASC Topic 820 requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted market prices in active markets for identical assets or liabilities.

Level 2: Unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices are observable for the asset or liability.

Level 3: Unobservable inputs for the asset or liability.

The Company endeavors to utilize the best available information in measuring fair value. Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The following methods and assumptions were used by the Company in estimating its fair value disclosures for financial instruments:

Cash and Cash Equivalents—The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value due to the short-term maturity of these instruments.

Line of Credit and Long-Term Debt—The carrying amounts of the Company's borrowings under its line of credit agreement and other long-term debt approximates fair value, based upon current interest rates, some of which are variable interest rates.

[13] Accounting for share-based payments and stock warrants: In accordance with the provisions of ASC Topic 718, "Accounting for Stock Based Compensation", the Company recognizes share-based payment expense for stock options and warrants. The weighted average fair value of options granted during Fiscal 2015 and Fiscal 2014 was \$0.14 and \$0.12, respectively. (See Note H [2] – Stockholders' Equity)

The Company accounts for derivative instruments in accordance with ASC Topic 815 "Derivatives and Hedging" ("ASC Topic 815"). The guidance within ASC Topic 815 requires the Company to recognize all derivatives as either assets or liabilities on the statement of financial position unless the contract, including common stock warrants,

settles in the Company's own stock and qualifies as an equity instrument. A contract designated as an equity instrument is included in equity at its fair value, with no further fair value adjustments required; and if designated as an asset or liability is carried at fair value with any changes in fair value recorded in the results of operations. The weighted average fair value of warrants issued was \$0.17 in both Fiscal 2015 and Fiscal 2014. (See Note H [3] – Stockholders' Equity)

[14] Concentration of credit risk: The Company sells its drug-testing products primarily to United States customers and distributors. Credit is extended based on an evaluation of the customer's financial condition.

At December 31, 2015, one customer accounted for 25.43% of the Company's net accounts receivable. A substantial portion of this balance was collected in the first quarter of the year ending December 31, 2016. Due to the longstanding nature of our relationship with this customer and contractual obligations, the Company is confident it will recover these amounts.

At December 31, 2014, one customer accounted for 42.6% of the Company's net accounts receivable. These amounts were collected in Fiscal 2015.

The Company has established an allowance for doubtful accounts of \$50,000 and \$47,000 at December 31, 2015 and December 31, 2014, respectively, based on factors surrounding the credit risk of our customers and other information.

Two of the Company's customers accounted for 25.99% and 15.39% of net sales of the Company in Fiscal 2015.

One of the Company's customers accounted for approximately 22.9% of net sales of the Company in Fiscal 2014.

The Company maintains certain cash balances at financial institutions that are federally insured and at times the balances have exceeded federally insured limits.

[15] Reporting comprehensive income: The Company reports comprehensive income in accordance with the provisions of ASC Topic 220, "Reporting Comprehensive Income" ("ASC Topic 220"). The provisions of ASC Topic 220 require the Company to report the change in the Company's equity during the period from transactions and events other than those resulting from investments by, and distributions to, the shareholders. For Fiscal 2015 and Fiscal 2014, comprehensive income was the same as net income.

[16] Reclassifications: Certain items have been reclassified from the prior years to conform to the current year presentation.

[17] New accounting pronouncements:

In December 2015, FASB issued Accounting Standards Update ("ASU") No 2015-17, "Income Taxes". This update addresses simplification of the presentation of deferred income taxes. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this Update apply to all entities that present a classified statement of financial position. The current requirement is that deferred tax liabilities and assets, net of a tax-paying component of an entity be offset and presented as two amounts; one current and one long-term. The amendments in this Update are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the effects of adopting this ASU.

In August 2015, FASB issued ASU No 2015-15, "Imputation of Interest". This update adds SEC paragraphs pursuant to the SEC Staff Announcement at a June 2015 Emerging Issues Task Force meeting about the presentation and subsequent measurement of debt issuance costs associated with line of credit arrangements. More specifically, additional paragraphs were added because the guidance in ASU No 2015-03 does not address presentation or subsequent measurement of debt issuance costs related to line-of-credit arrangements. Given the absence of authoritative guidance within Update 2015-03 for debt issuance costs related to line-of-credit arrangements, the SEC staff would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of

whether there are any outstanding borrowings on the line-of-credit arrangement.

In August 2015, FASB issued ASU No 2015-14, "Revenue from Contracts with Customers". This update defers the effective dates of ASU No. 2014-09 (originally issued in June 2014) for public business entities by one year, or until annual reporting periods beginning after December 15, 2017, including interim reporting periods within the reporting period. ASU No. 2014-09 gives entities a single comprehensive model to use in reporting information about the amount and timing of revenue resulting from contracts to provide goods or services to customers. The proposed ASU, which would apply to any entity that enters into contracts to provide goods or services, would supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance throughout the Industry Topics of the Codification. Additionally, the update would supersede some cost guidance included in Subtopic 605-35, Revenue Recognition – Construction-Type and Production-Type Contracts. The update removes inconsistencies and weaknesses in revenue requirements and provides a more robust framework for addressing revenue issues and more useful information to users of financial statements through improved disclosure requirements. In addition, the update improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. The Company is continuing to review the provisions of this ASU to determine if there will be any impact on its results of operations, cash flows or financial condition.

In April 2015, the FASB issued ASU 2015-03, "Simplifying the Presentation of Debt Issuance Costs" this Update as part of its initiative to reduce complexity in accounting standards (the Simplification Initiative). The Board received feedback that having different balance sheet presentation requirements for debt issuance costs and debt discount and premium creates unnecessary complexity. Recognizing debt issuance costs as a deferred charge (that is, an asset) also is different from the guidance in International Financial Reporting Standards (IFRS), which requires that transaction costs be deducted from the carrying value of the financial liability and not recorded as separate assets. Additionally, the requirement to recognize debt issuance costs as deferred charges conflicts with the guidance in FASB Concepts Statement No. 6, Elements of Financial Statements, which states that debt issuance costs are similar to debt discounts and in effect reduce the proceeds of borrowing, thereby increasing the effective interest rate. Concepts Statement 6 further states that debt issuance costs cannot be an asset because they provide no future economic benefit. To simplify presentation of debt issuance costs, the amendments in this Update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this Update. For public business entities, the amendments in this Update are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company will adopt this ASU in the first quarter of the year ending December 31, 2016.

In January 2015, the FASB issued ASU No 2015-01, "Income Statement – Extraordinary and Unusual Items". This ASU is part of FASB's initiative to reduce complexity in the account standards by eliminating the concept of extraordinary items from GAAP. The amendments eliminate the requirements for reporting entities to consider whether an underlying event or transaction is extraordinary, however, the presentation and disclosure guidance for items that are unusual in nature or occur infrequently is retained and is expanded to include items that are both unusual in nature and infrequently occurring. This update applies to all entities and is effective for fiscal years, and interim periods within the fiscal year, beginning after December 15, 2015. The Company will adopt this ASU in the first quarter of the year ending December 31, 2016 but does not expect any impact from the adoption.

Any other new accounting pronouncements recently issued, but not yet effective, have been reviewed and determined to be not applicable. As a result, the adoption of such new accounting pronouncements, when effective, is not expected to have a material impact on the financial position of the Company.

NOTE B - INVENTORY

Inventory is comprised of the following:

	December 31, 2015	December 31, 2014
Raw Materials	\$ 1,208,000	\$ 1,136,000
Work in Process	399,000	390,000
Finished Goods	571,000	520,000
Allowance for slow moving and obsolete inventory	(432,000)	(324,000)
	<u>\$ 1,746,000</u>	<u>\$ 1,722,000</u>

NOTE C - PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, at cost, are as follows:

	December 31, 2015	December 31, 2014
Land	\$ 102,000	\$ 102,000
Buildings and improvements	1,352,000	1,347,000
Manufacturing and warehouse equipment	2,064,000	2,056,000
Office equipment (incl. furniture and fixtures)	412,000	412,000
	<u>3,930,000</u>	<u>3,917,000</u>
Less accumulated depreciation	(3,020,000)	(2,934,000)
	<u>\$ 910,000</u>	<u>\$ 983,000</u>

Depreciation expense was \$86,000 and \$109,000 in Fiscal 2015 and Fiscal 2014, respectively.

NOTE D - ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2015	December 31, 2014
Accounting fees	\$ 65,000	\$ 51,000
Interest payable	13,000	26,000
Accounts receivable credit balances	6,000	4,000
Sales tax payable	37,000	21,000
Other expenses	25,000	51,000
Other current liabilities	66,000	39,000
	<u>\$ 212,000</u>	<u>\$ 192,000</u>

NOTE E - DEBT AND LINE OF CREDIT

The Company's Line of Credit and Debt consisted of the following as of December 31, 2015 and December 31, 2014:

	December 31, 2015	December 31, 2014
Loan and Security Agreement with Cherokee Financial, LLC⁽¹⁾: 5 year note at an annual interest rate of 8% plus a 1% annual oversight fee, interest only and oversight fee paid quarterly with first payment being due on May 15, 2015, annual principal reduction payment of \$75,000 due each year beginning on February 15, 2016, with a final balloon payment being due on February 15, 2020. Loan is collateralized by a first security interest in building, land and property.	\$1,200,000	\$ 0
Crestmark Line of Credit⁽²⁾: 3 year line of credit with interest payable at a variable rate based on WSJ Prime plus 2% with a floor or 5.25%; loan fee of 0.5% annually & monthly maintenance fee of 0.3% on actual loan balance from prior month. Early termination fee of 3% if terminated in year 1 and 2% if terminated in year 2 or after (and prior to natural expiration). Loan is collateralized by first security interest in receivables and inventory.	777,000	0
First Niagara⁽¹⁾: Mortgage payable in equal monthly installments of \$13,199 including interest at 8.25%, collateralized by the building, land and personal property.	0	348,000
Debenture financing⁽¹⁾: \$523,000 in principal amount of Series A Debentures; interest at 15% per annum from August 1, 2013 through January 31, 2015, payable quarterly.	0	523,000
Bridge Loan with Cantone Asset Management, LLC⁽¹⁾: Interest rate of 15% payable upon loan maturity;	0	200,000
Imperium Line of Credit⁽²⁾: Interest payable in arrears for the preceding calendar month on the first day of each calendar month at a rate of 8% per annum plus "PIK" interest at a 2% per annum. Unused line fee equal to 2% of the maximum amount available under the line, less the aggregate amounts outstanding to Imperium, payable on the first day of each calendar month. Collateral Monitoring Fee of \$2,500 due on the first day of each month. Success fee if Imperium terminates due to an event of default, or if we terminate and pre-pay all amounts due to Imperium prior to the stated expiration date of January 16, 2016.	0	1,076,000
	<u>1,977,000</u>	<u>2,147,000</u>
Less debt discount (Debenture and line of credit financings)	(180,000)	(97,000)
Total debt	<u>\$ 1,797,000</u>	<u>\$ 2,050,000</u>
Current portion	\$ 852,000	\$ 1,837,000
Long-term portion	\$ 945,000	\$ 213,000

(1) On March 26, 2015, the Company entered into a Loan and Security Agreement (“LSA”) with Cherokee Financial, LLC (the “Cherokee LSA”). The purpose of the Cherokee LSA was to refinance the Series A Debentures and Cantone Asset Management LLC Bridge Loan (both of which matured on February 1, 2015) and the Mortgage Consolidation Loan with First Niagara Bank at a better interest rate.

(2) On June 29, 2015, the Company entered into a Loan and Security Agreement with Crestmark Bank. The purpose of the Crestmark LSA was to refinance the Company’s line of credit with Imperium at a better interest rate.

At December 31, 2015, the following are the debt maturities for each of the next five years:

2016	\$ 852,000 ⁽³⁾
2017	75,000
2018	75,000
2019	75,000
2020	720,000
	\$ 1,797,000

(3) Although the Crestmark Line of Credit does not mature until June 29, 2018, the balance on the line of credit is included in the debt maturity for 2016 given the “demand” nature of the line of credit.

LOAN AND SECURITY AGREEMENT WITH CHEROKEE FINANCIAL, LLC.

On March 26, 2015, the Company entered into a LSA with Cherokee Financial, LLC (the “Cherokee LSA”). The purpose of the Cherokee LSA was to refinance, at a better interest rate, the Company’s Series A Debentures and Cantone Asset Management Bridge Loan (both of which matured on February 1, 2015), as well as the Company’s Mortgage Consolidation Loan with First Niagara Bank. The loan is collateralized by a first security interest in real estate and machinery and equipment. Under the Cherokee LSA, the Company was provided the sum of \$1,200,000 in the form of a 5-year Note at an annual interest rate of 8%. The Company will make interest only payments quarterly on the Cherokee Note, with the first interest payment due on May 15, 2015. The Company also is also required to make an annual principal reduction payment of \$75,000 on each anniversary of the date of the closing with the first principal reduction payment being due (and paid) on February 15, 2016. A final balloon payment is due on March 26, 2020. In addition to the 8% interest, the Company will pay Cherokee Financial, LLC a 1% annual fee (in cash and paid contemporaneously with payment of quarterly interest) for oversight and administration of the loan. The Company can pay off the Cherokee Note at anytime with no penalty; except that a 1% administration fee would be required to be paid to Cherokee Financial, LLC to close out all participations.

The Company issued 1.8 million restricted shares of the Company’s common stock to Cherokee Financial LLC for payment of fees. The Company also is also required to issue an additional 600,000 restricted shares to Cherokee Financial LLC on March 19, 2016, however, if the Company has repaid the Cherokee Note in full prior to this date, the Company is not obligated to issue these additional shares.

As placement agent for the transaction, CRI received a 5% cash fee on the \$1.2 million, or \$60,000, and 200,000 restricted shares of the Company’s common stock. The Company also is required to issue an additional 196,000 restricted shares of the Company’s common stock to CRI on March 19, 2016 as an additional placement agent fee and expense allowance, however, if the Company has repaid the Cherokee Note in full prior to this date, the Company is not obligated to issue these additional shares.

The Company received net proceeds of \$80,000 after \$1,015,000 of debt payments, \$60,000 in placement agent fees, \$19,000 in legal fees, \$19,000 in expenses, \$3,000 in state filing fees and \$4,000 in interest expense (for 8% interest on \$511,000 in new participations received from February 24, 2015 through March 25, 2015). With the exception of the interest expense, the Company will be amortizing these expenses over the term of the Cherokee LSA, or 5 years as deferred finance and debt issuance costs. From these net proceeds, in April 2015, the Company also paid \$15,000 in interest expense related to 15% interest on \$689,000 in Series A Debentures and CAM Bridge Loan for the period of February 1, 2015 through March 25, 2015.

Fiscal 2015 includes \$58,000 in expense related to the Cherokee LSA, and Fiscal 2014

includes \$0 in expense. The Company recognized \$74,000 in interest expense in Fiscal 2015, and \$0 in interest expense in Fiscal 2014. At December 31, 2015 the Company had \$13,000 in accrued interest expense related to the Cherokee LSA.

As of December 31, 2015, the balance on the Cherokee LSA was \$1,200,000.

LINE OF CREDIT WITH CRESTMARK BANK (“CRESTMARK”)

On June 29, 2015 (the “Closing Date”), the Company entered into a three-year Loan and Security Agreement (“LSA”) with Crestmark, a new Senior Lender, to refinance the Company’s Line of Credit with Imperium Commercial Finance, LLC (“Imperium”). The Crestmark Line of Credit is used for working capital and general corporate purposes.

Under the LSA, Crestmark is providing the Company with a Line of Credit of up to \$1,500,000 (“Maximum Amount”) with a minimum loan balance requirement of \$500,000. The Line of Credit is secured by a first security interest in the Company’s inventory, and receivables and security interest in all other assets of the Company (in accordance with permitted prior encumbrances).

The Maximum Amount is subject to an Advance Formula comprised of: 1) 90% of Eligible Accounts Receivables (excluding, receivables remaining unpaid for more than 90 days from the date of invoice and sales made to entities outside of the United States), and 2) up to 40% of eligible inventory plus up to 10% of Eligible Generic Packaging Components not to exceed the lesser of \$500,000 (“Inventory Sub-Cap Limit”), or 100% of the Eligible Accounts Receivable. The Inventory Sub-Cap Limit is being reduced by \$10,000 per month starting August 1, 2015 until the Inventory Sub-Cap Limit is permanently reduced to \$350,000.

So long as any obligations are due to Crestmark, the Company must comply with a minimum Tangible Net Worth (“TNW”) Covenant. Under the LSA, as of June 30, 2015 and at all times thereafter, the Company must maintain a TNW of at least \$650,000 (the original TNW covenant was \$1,650,000 but the covenant was subsequently amended). Additionally, if a quarterly net income is reported, the TNW covenant will increase by 50% of the reported net income. If a quarterly net loss is reported, the TNW covenant will remain the same as the prior quarter’s covenant amount. TNW is defined as: Total Assets less Total Liabilities less the sum of (i) the aggregate amount of non-trade accounts receivables, including accounts receivables from affiliated or related persons, (ii) prepaid expenses, (iii) deposits, (iv) net lease hold improvements, (v) goodwill and (vi) any other asset that would be treated as an intangible asset under GAAP; plus Subordinated Debt. Subordinated Debt means any and all indebtedness presently or in the future incurred by the Company to any creditor of the Company entering into a written subordination agreement with Crestmark.

If the Company terminates the LSA prior to its 3 year term, an early exit fee is due as follows: 3% of the Maximum Amount (plus any additional amount owed to Crestmark at time of termination) if terminated in year 1, and 2% if terminated in year 2 or anytime thereafter.

In the event of a default of the LSA, which includes but is not limited to, failure of the Company to make any payment when due and non-compliance with the TNW covenant, permits Crestmark to charge an Extra Rate. The Extra Rate is the Company’s then current interest rate plus 12.75% per annum.

Under the LSA, interest on the Crestmark Line of Credit is at a variable rate based on the Wall Street Journal Prime Rate plus 2% with a floor of 5.25%. As of the date of this report, the interest rate on the Crestmark Line of Credit is 5.25%. In addition to the interest rate, on the Closing Date and on each one-year anniversary date thereafter, the Company will pay Crestmark a Loan Fee of 0.50%, or \$7,500, and a Monthly Maintenance Fee of 0.30% of the actual average monthly loan balance from the prior month will be paid to Crestmark. When these additional fees are considered, the rate on the Crestmark is 9.35% annually (the Imperium Line of Credit rate was 12% when all fees were considered).

In addition to the Loan Fee paid to Crestmark on the Closing Date, the Company had to pay a Success Fee (i.e. early termination fee) to Imperium in the amount of \$50,000 on the Closing Date, and a Broker’s Fee of 5%, or \$75,000, to Landmark Pegasus Inc. Prior to the Closing, the Company paid \$12,000 in due diligence fees to Crestmark. The Company also incurred \$3,000 of its own legal costs related to the Crestmark Line of Credit. With the exception of the early term fee (\$50,000) paid to Imperium (which was expensed fully in the Fiscal 2015), these expenses are all being amortized over the term

of the Crestmark Line of Credit, or three years. The Company recognized \$54,000 of these costs in Fiscal 2015. The Company recognized \$0 of costs in Fiscal 2014.

The Company recognized \$41,000 in interest expense related to the Crestmark Line of Credit in Fiscal 2015, and \$0 in interest expense in Fiscal 2014. Given the nature of the administration of the Crestmark Line of Credit, at December 31, 2015, the Company had \$0 in accrued interest expense related to the Crestmark Line of Credit.

As of December 31, 2015, the balance on the Crestmark Line of Credit was \$777,000

FIRST NIAGARA: MORTGAGE CONSOLIDATION LOAN

On April 28, 2014, the Company entered into a Third Amendment to the Loan Agreement (the “Third Mortgage Consolidation Loan Amendment”) with First Niagara Bank. The Mortgage Consolidation Loan continued to be secured by the Company’s facility in Kinderhook, New York as well as various pieces of machinery and equipment. Under the Third Mortgage Consolidation Loan Amendment, the Mortgage Consolidation Loan was recast into a 3-year fully amortizing note through May 1, 2017. The interest rate of the amended facility was decreased from 9.25% to 8.25%, and the monthly payment was reduced from \$14,115 to \$13,199. The Company was required to pay First Niagara a renewal fee of 1% of the principal balance as of April 1, 2014, or \$4,200. No principal reduction payment was required. All other terms of the Mortgage Consolidation Loan remained unchanged, including compliance with a covenant. The Mortgage Consolidation Loan was satisfied in full on March 27, 2015 via a refinancing with Cherokee Financial, LLC.

Interest expense recognized was \$5,000 in Fiscal 2015 and \$32,000 in Fiscal 2014. The balance on the Mortgage Consolidation Loan was \$0 at December 31, 2015 and \$348,000 at December 31, 2014, respectively.

DEBENTURE FINANCING/BRIDGE LOAN

In August 2008, the Company completed an offering of Series A Debentures (“Series A Debentures”) and received gross proceeds of \$750,000. The Series A Debentures’ original interest rate was 8% and the original maturity date was August 1, 2012. In 2012, \$645,000 in Series A Debentures were extended to August 2013 at an increased interest rate of 15%. In 2013, \$634,500 in Series A Debentures were extended to August 2014 at the same interest rate of 15%. Throughout the extensions indicated previously, certain holders did not wish to extend their investment. Given this, the Company entered into bridge loans with Cantone Asset Management, LLC (CAM), one for \$150,000 in 2012 and another for \$200,000 in 2013. Both bridge loans were at an interest rate of 15% (however, the interest on the 2013 bridge loan was paid in advance in the form of 300,000 restricted common shares of ABMC stock). The Company incurred \$87,000 in costs related to the 2013 debenture extension, as well as \$76,000 in expense related to warrants issued to debenture holder who extended for another 12 months. The Company amortized \$0 in costs and warrant expense in Fiscal 2015, and \$65,000 in costs and \$44,000 in warrant expense in Fiscal 2014. As of December 31, 2015, there was \$0 in unrecognized costs and warrant expense with 0 months remaining.

On February 7, 2014, the Company paid \$91,000 to certain Debenture Holders; bringing the balance due to Debenture Holders to \$543,000. The Series A Debentures and the 2013 bridge loan matured on August 1, 2014 and the Company was unable to pay back the Series A Debentures principal of \$543,000 and/or the \$200,000 related to the 2013 Bridge Loan (together the “Debenture Debt”). The Company was however able to continue to make interest payments on the Debenture Debt. All but one of the 27 Series A Debenture holders agreed to forbear from exercising remedies of default related to the non-payment of principal until February 1, 2015. The Company repaid the principal of \$20,000 to this one Series A Debenture holder bringing the balance on the Debentures to \$523,000. The maturity of the 2013 bridge loan was also extended to February 1, 2015.

Throughout the course of the debenture financings, the Company utilized Cantone Research, Inc (“CRI”) as the placement agent and also used CRI’s assistance in obtaining forbearance agreements from debenture holders. CRI received placement agent fees, expense allowance fees and other fees for these services and these fees were recognized throughout 2008 and 2013. The last fee (in 2014; for assisting the Company in obtaining forbearance agreements from the holders) was 2% of the forbearing amount and was paid with \$7,000 in cash and 1% in 58,575 restricted shares of the

Company’s common stock. A stock price of \$0.12 per share was used to determine the number of restricted shares to be issued to CRI. The Company also reimbursed CRI’s legal fees of \$1,000. The Company amortized these costs (totaling \$15,000) over the course of the forbearance period, or over 6 months. The Company recognized \$0 in expense in Fiscal 2015, and \$13,000 in expense in Fiscal 2014. As of December 31, 2015, there is \$0 in unrecognized expense with 0 month remaining.

The Company recognized \$22,000 in interest expense in Fiscal 2015, and \$107,000 in interest expense in Fiscal 2014 related to the Debenture Financing/Bridge Loan. The Company had \$0 in accrued interest expense at December 31, 2015. As of December 31, 2015, the balance on the Debenture Debt/Bridge Loan was \$0.

LINE OF CREDIT WITH IMPERIUM

On January 16, 2013 (the “Imperium Closing Date”), the Company entered into a 3-year Loan and Security Agreement (“LSA”) with Imperium, a Senior Lender.

Under the LSA, the Company was provided with a revolving loan facility (the “Imperium Line of Credit”), which was secured by a first security interest in all receivables, inventory, and intellectual property rights along with a second security interest in machinery and equipment (together the “Collateral”). On March 6, 2014, Imperium amended the Borrowing Base of the Imperium Line of Credit. More specifically, the amount available under the Imperium Line of Credit was capped to the lower of (i) \$1,000,000, or (ii) 100% of the eligible outstanding accounts receivable. The Imperium facility also originally included a supplemental advance that was a discretionary facility secured by the same Collateral as the Imperium Line of Credit.

Under the LSA, so long as any obligations were due to Imperium, the Company was required to maintain certain minimum EBITDA (Earnings Before Interest, Taxes Depreciation and Amortization) requirements. The Company did not comply with this covenant starting in the First Quarter of 2013. The Company received a waiver from Imperium for the three months ended March 31, 2013 (for which the Company paid a fee of \$10,000). No further formal waivers were issued, but no notice of default was received either.

The Company incurred \$435,000 in costs related to the Imperium Line of Credit, and these costs were being amortized over the term of the facility (3 years). On June 29, 2015, all indebtedness due to Imperium was paid in full and Imperium’s security in the Company’s assets was terminated. The Company was required to pay fee of \$50,000 to Imperium in the form of an early termination fee.

The Company recognized \$137,000 in costs in Fiscal 2015 (of which \$69,000 was accelerated costs due to the early termination of the line of credit), and \$138,000 in costs in Fiscal 2014. The Company incurred \$39,000 in interest expense in Fiscal 2015, and \$103,000 in interest expense in Fiscal 2014. As of December 31, 2015, the Company had \$0 in accrued interest related to the Imperium Line of Credit, and the balance of the Imperium Line of Credit was \$0.

NOTE F – INCOME TAXES

A reconciliation of the U.S. Federal statutory income tax rate to the effective income tax rate is as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2014
Tax expense at federal statutory rate	34%	34%
State tax expense, net of federal tax effect	5%	5%
Permanent timing differences	(0%)	(4%)
Deferred income tax asset valuation allowance	(39%)	(35%)
Effective income tax rate	0%	0%

Significant components of the Company's deferred income tax assets are as follows:

As of December 31, 2015, the prior three years remain open for examination by the

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The valuation allowance for deferred income tax assets as of December 31, 2015 and December 31, 2014 was \$5,066,000 and \$4,736,000, respectively. The net change in

	Year Ended December 31, 2015	Year Ended December 31, 2014
Inventory	\$ 22,000	\$ 13,000
Inventory allowance	169,000	126,000
Allowance for doubtful accounts	19,000	18,000
Accrued compensation	38,000	78,000
Research and development tax credit	0	10,000
Stock based compensation	236,000	0
Deferred wages payable	22,000	0
Net operating loss carry-forward	4,560,000	4,491,000
Total gross deferred income tax assets	5,066,000	4,736,000
Less deferred income tax assets valuation allowance	(5,066,000)	(4,736,000)
Net deferred income tax assets	<u>\$ 0</u>	<u>\$ 0</u>

the deferred income tax assets valuation allowance was \$330,000 for Fiscal 2015. The net change in the deferred income tax assets valuation allowance was \$182,000 for Fiscal 2014. The Company believes that it is more likely than not that the deferred tax assets will not be realized.

NOTE H – STOCKHOLDERS' EQUITY

[1] Stock option plans: The Company currently has two non-statutory stock option plans, the Fiscal 2001 Non-statutory Stock Option Plan (the "2001 Plan") and the 2013 Equity Compensation Plan (the "2013 Plan"). Both plans have been adopted by our Board of Directors and approved by our shareholders. Both the 2001 Plan and the 2013 Plan have options available for future issuance. Any common shares issued as a result of the exercise of stock options would be new common shares issued from our authorized issued shares.

[2] Stock options: During Fiscal 2015 and Fiscal 2014, the Company issued options to purchase 340,000 and 80,000 shares of common stock, respectively. Options issued in Fiscal 2015 were all issued under the 2001 Plan; 90,000 options were issued to non-employee members of our board of directors and 250,000 options were issued to our Chief Executive Officer, Melissa Waterhouse. Options issued in Fiscal 2014 were issued under the 2001 Plan; that is 80,000 options were issued to non-employee members of our Board of Directors.

As of December 31, 2015, there were 1,435,000 options issued and outstanding under the 2001 Plan. There were no options issued under the 2013 Plan, making the total issued and outstanding options 1,435,000 as of December 31, 2015. Of the total options issued and outstanding, 1,027,000 are fully vested as of December 31, 2015. As of December 31, 2015, there were 2,282,000 options available for issuance under the 2001 Plan and 4,000,000 options available for issuance under the 2013 Plan.

Stock option activity for Fiscal 2015 and Fiscal 2014 is summarized as follows: (the figures contained within the tables below have been rounded to the nearest thousand)

	Year Ended December 31, 2015			Year Ended December 31, 2014		
	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value as of December 31, 2014	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value as of December 31, 2013
Options outstanding at beginning of year	1,295,000	\$0.27		3,316,000	\$ 0.44	
Granted	340,000	\$0.12		80,000	\$ 0.12	
Exercised	0	NA		0	NA	
Cancelled/expired	<u>(200,000)</u>	<u>\$0.90</u>		<u>(2,101,000)</u>	<u>\$ 0.53</u>	
Options outstanding at end of year	<u>1,435,000</u>	<u>\$0.14</u>	<u>\$16,400</u>	<u>1,295,000</u>	<u>\$ 0.27</u>	<u>\$9,400</u>
Options exercisable at end of year	<u>1,027,000</u>	<u>\$0.15</u>		<u>946,000</u>	<u>\$ 0.31</u>	

The following table presents information relating to stock options outstanding as of December 31, 2015:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Shares	Weighted Average Exercise Price
\$0.07 - \$0.09	280,000	\$0.09	4.92	280,000	\$0.09
\$0.12 - \$0.16	720,000	\$0.13	8.40	312,000	\$0.13
\$0.18 - \$0.26	432,000	\$0.20	6.36	432,000	\$0.20
\$1.00 - \$1.05	3,000	\$1.05	0.45	3,000	\$1.05
TOTAL	<u>1,435,000</u>	<u>\$0.27</u>	<u>6.27</u>	<u>1,027,000</u>	<u>\$0.31</u>

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The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the grants issued during Fiscal 2015 and Fiscal 2014:

	<u>Year Ended December 31</u>	
	<u>2015</u>	<u>2014</u>
Volatility	64%	73%
Expected term (years)	10 years	10 years
Risk-free interest rate	1.92% - 2.33%	2.64%
Dividend yield	0%	0%

The Company recognized \$34,000 in share based payment expense related to stock options in Fiscal 2015 and, \$40,000 in share based payment expense related to stock options in Fiscal 2014. As of December 31, 2015, there was approximately \$32,000 of total unrecognized share based payment expense related to stock options. This cost is expected to be recognized over a period ranging from 2 to 29 months.

[3] Warrants:

Warrant activity for Fiscal 2015 and Fiscal 2014 is summarized as follows. Any common shares issued as a result of the exercise of warrants would be new common shares issued from our authorized issued shares.

	<u>Year Ended December 31, 2015</u>			<u>Year Ended December 31, 2014</u>		
	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value as of December 31, 2015</u>	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value as of December 31, 2014</u>
Warrants outstanding at beginning of year	3,303,000	\$0.17		3,303,000	\$ 0.17	
Granted	0	NA		0	NA	
Exercised	0	NA		0	NA	
Cancelled/expired	<u>918,000</u>	<u>\$0.15</u>		<u>(0)</u>	<u>\$ 0.17</u>	
Warrants outstanding at end of year	<u>2,385,000</u>	<u>\$0.16</u>	<u>None</u>	<u>3,303,000</u>	<u>\$ 0.17</u>	<u>None</u>
Warrants exercisable at end of year	<u>2,385,000</u>	<u>\$0.17</u>		<u>3,303,000</u>	<u>\$ 0.17</u>	

The Company recognized \$100,000 in debt issuance and deferred finance costs related to the issuance of these warrants outstanding in Fiscal 2015, and \$144,000 in debt issuance and deferred finance costs related to the issuance of these warrants outstanding in Fiscal 2014. As of December 31, 2015, there was \$0 of total unrecognized debt issuance costs associated with the issuance of the above warrants outstanding due to accelerated amortization of expense in the second quarter of Fiscal 2015 (as a result of early termination of the Imperium line of credit).

NOTE I – COMMITMENTS, CONTINGENCIES AND OTHER MATTERS

[1] **Operating leases:** The Company leases office and R&D/production facilities in New Jersey under long-term, non-cancellable operating leases. Effective December 31, 2014, the Company closed down 2 of the 3 units we were leasing, and moved certain manufacturing operations up to the Company's (owned) facility in Kinderhook, New York. In December 2015, the Company extended the lease for the 1 remaining unit for another 2-year term, or through December 31, 2017.

The future minimum rent due in 2016 and 2017 under the lease extension is \$32,000 each year. The Company also leased office support equipment through October 2014. At December 31, 2015, the future minimum rental payments under these operating leases are as follows:

2016	\$32,000
2017	32,000
	<u>\$ 64,000</u>

Rent expense was \$122,000 in both Fiscal 2014 and Fiscal 2013.

[2] **Employment agreements:** On October 30, 2013, Melissa A. Waterhouse, our (former) Executive Vice President, Regulatory Affairs, Chief Compliance Officer and Corporate Secretary was appointed as our interim Chief Executive Officer/Chief Financial Officer. Ms. Waterhouse was appointed as our Chief Executive Officer/Principal Financial Officer on June 20, 2014. We have an employment agreement in place with Ms. Waterhouse that provides for a \$160,000 annual salary and is for a term of one year. It automatically renews unless either party gives advance notice of 60 days. The employment agreement contains severance provisions; in the event the Company terminates Waterhouse's employment for any reason other than cause (which is defined under the employment agreement), Waterhouse would receive severance pay equal to 12 months of her base salary at the time of termination, with continuation of all medical benefits during the twelve-month period at the Company's expense. In addition, Waterhouse may tender her resignation and elect to exercise the severance provision if she is required to relocate more than 50 miles from the Company's New York facility as a continued condition of employment, if there is a substantial change in the responsibilities normally assumed by her position, or if she is asked to commit or conceal an illegal act by an officer or member of the board of directors of the Company. In the case of a change in control of the Company, Waterhouse would be entitled to severance pay equal to two times her base salary under certain circumstances.

[3] Legal: From time to time, the Company is named in legal proceedings in connection with matters that arose during the normal course of business. While the ultimate outcome of any such litigation cannot be predicted, if we are unsuccessful in defending any such litigation, the resulting financial losses could have an adverse effect on the financial position, results of operations and cash flows of the Company. We are aware of no significant litigation loss contingencies for which management believes it is both probable that a liability has been incurred and that the amount of the loss can be reasonably estimated.

[4] Financial Advisory Agreement: The Company has entered into a Financial Advisory Agreement with Landmark Pegasus, Inc. ("Landmark"). Under the Financial Advisory Agreement Landmark will provide certain financial advisory services to the Company for a minimum period of 6 months (which period originally commenced on January 17, 2014 and was extended in August 2014 and again on January 10, 2015). As consideration for these services, the Company paid Landmark retainer fees consisting of restricted shares of common stock and the Company will pay Landmark a "success fee" for the consummation of each and any transaction closing during the term of the Financial Advisory Agreement and for 24 months thereafter, inclusive of a sale or merger, between the Company and any party first introduced to the Company by Landmark, or for any other transaction not originated by Landmark but for which Landmark provides substantial support in completing during the term of the Agreement. For certain transactions, the success fee will be paid part upon consummation of a transaction and part paid over a term of not more than five years; all other transactions would be paid upon consummation of the transaction. There is no material relationship between the Company and Landmark, other than with respect to the Agreement.

NOTE K- SEGMENT AND GEOGRAPHIC INFORMATION

The Company operates in one reportable segment.

Information concerning net sales by principal geographic location is as follows:

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	Year Ended December 31, 2015	Year Ended December 31, 2014
United States	\$ 5,613,000	\$ 6,585,000
North America (not domestic)	143,000	157,000
Europe	131,000	132,000
Asia/Pacific Rim	45,000	79,000
South America	384,000	331,000
Africa	1,000	1,000
	\$ 6,317,000	\$ 7,285,000

EXHIBIT 31.1/EXHIBIT 31.2

RULE 13a-14(a)/15d-14(a) CERTIFICATION

I, Melissa A. Waterhouse, certify that:

1. I have reviewed this annual report on Form 10-K of American Bio Medica Corporation;
2. Based on my knowledge, this annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;
4. The registrant's other certifying officers 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 controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the small business issuer 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 annual report is being prepared;
 - b) designed such internal control over financial reporting, or 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; and
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
 - d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the small business issuer'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 officers 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/ Melissa A. Waterhouse

Melissa A. Waterhouse
Chief Executive Officer (Principal Executive Officer)
Principal Financial Officer
Principal Accounting Officer

Date: March 30, 2016

EXHIBIT 32.1/EXHIBIT 32.2

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 American Bio Medica Corporation (the "Company") on Form 10-K for the period ending December 31, 2015 as filed with the Securities and Exchange Commission on March 30, 2016 (the "Report"), I, Melissa A. Waterhouse, Chief Executive Officer and Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 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 results of operations of the Company.

/s/ Melissa A. Waterhouse

Melissa A. Waterhouse
Chief Executive Officer (Principal Executive Officer)
Principal Financial Officer
Principal Accounting Officer

March 30, 2016

EXHIBIT 10.42

LEASE AMENDMENT NO. 10

This Lease Amendment made and entered into this 23rd day of December, 2015, by and between Whitesell Enterprises, hereinafter referred to as ("Landlord") and American Bio Medica Corporation, hereinafter referred to as ("Tenant");

WHEREAS, Landlord leased to Tenant that certain premises known as Units 3, 4 and 6 at 603 Heron Drive, Logan Township, Gloucester County, New Jersey, consisting of 14,406 square feet, (the "Premises") pursuant to a Multi-Tenant Industrial Lease dated July 7, 1999; subsequently amended by Lease Amendment No. 1 dated August 17, 1999, Lease Amendment No. 2 dated May 23, 2001, Lease Amendment No. 3 dated August 20, 2002, Lease Amendment No. 4 dated October 9, 2006, Lease Amendment No. 5 dated January 19, 2007, Lease Amendment No. 6 dated December 1, 2011, Lease Amendment No. 7 dated December 12, 2012 and Lease Amendment No. 8 dated December 4, 2013, and Lease Amendment No. 9 dated December 15, 2014 (the "Lease"), the terms and conditions being more particularly described therein; and

WHEREAS, Landlord and Tenant wish to amend the Lease;

NOW THEREFORE, in consideration of the sum of One Dollar (\$1.00), the promises and undertakings contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant intending to be legally bound, hereby agree to amend the Lease as follows:

Tenant shall renew the term of the lease at Unit 4, consisting of 5,238 square feet, for a period of two (2) years commencing January 1, 2016 and expiring December 31, 2017.

Base Rent for the renewal term shall be \$6.00 per square foot net, \$31,428.00/year, \$2,619.00/month.

Tenant's pro rata share shall be decreased to 12.11%.

Except as modified by this Lease Amendment, all other terms and conditions of the original Lease shall remain in full force and effect.

LANDLORD: WHITESELL ENTERPRISES

By: Whitesell Construction Co., Inc., Authorized Agent

By /S/ Thomas J. Heitzman

Thomas. J. Heitzman, Executive Vice President

TENANT: AMERICAN BIO MEDICA CORPORATION

By /S/ Melissa A. Waterhouse

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PROXY STATEMENT

Year Ended December 31, 2015

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