Alliqua BioMedical, Inc.
Form 10-K
February 23, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-K

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

For the fiscal year ended: **December 31, 2015**

or

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

For the transition period from _____ to _____

Commission file number: **001-36278**

Alliqua BioMedical, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**58-2349413** (I.R.S. Employer Identification Number)
1010 Stony Hill Road **Yardley, PA** (Address of principal executive office)	**19067** (Zip Code)

Registrant's telephone number, including area code: **(215) 702-8550**

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value	**The NASDAQ Stock Market LLC**

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

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

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

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 þ 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 þ 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, 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. þ

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 þ
Non-accelerated filer ¨ Smaller reporting company þ
(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates, computed by reference to the closing sales price of such stock, as of June 30, 2015 was $122,154,637. (For purposes of determination of the aggregate market value, only directors, executive officers and 10% or greater shareholders have been deemed affiliates.)

The number of shares outstanding of the registrant’s common stock, par value $0.001 per share, as of February 17, 2016 was 27,668,913 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement for the 2016 Annual Meeting of Stockholders, which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Form 10-K relates, are incorporated by reference into Part III of this report.

ALLLIQUA BIOMEDICAL, INC.

TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements," which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predict," "potential," "continue," "expect," "anticipate," "future," "intend," "plan," "belie similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

inadequate capital;

the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;

our ability to obtain reimbursement from third party payers for our products;

our ability to obtain and maintain regulatory approval of our existing products and any future products we may develop;

market acceptance of our existing and future products

loss or retirement of key executives;

our plans to make significant additional outlays of working capital before we expect to generate significant revenues and the uncertainty regarding when we will begin to generate significant revenues, if we are able to do so;

an unfavorable decision on product reimbursement;

adverse economic conditions and/or intense competition;

loss of a key customer or supplier;

entry of new competitors and products;

adverse federal, state and local government regulation;

technological obsolescence of our products;

technical problems with our research and products;

risks of mergers and acquisitions including the time and cost of implementing transactions and the potential failure to achieve expected gains, revenue growth or expense savings;

price increases for supplies and components; and

the inability to carry out research, development and commercialization plans.

For a discussion of these and other risks that relate to our business and investing in shares of our common stock, you should carefully review the risks and uncertainties described under the heading “Item 1A. Risk Factors” in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Our Company

We are a provider of advanced wound care solutions. We have a suite of advanced wound care solutions that enable surgeons, clinicians, and wound care practitioners to address some of the challenges presented by chronic and advanced wounds. We have built this portfolio through our proprietary hydrogel technology platform, targeted acquisitions, and through licensing and distribution agreements with strategic partners that include sorbion GmbH & Co. KG, an affiliate of BSN Medical, Inc., and Celgene Cellular Therapeutics, a subsidiary of Celgene Corporation. Our contract manufacturing business provides custom hydrogels to the OEM market.

Products and Services

Our commercial wound care portfolio, operating within one segment, currently consists of five product categories: Wound Bed Preparation & Stimulation; Human Biologics; Antimicrobial Protection; Exudate Management; and Contract Manufacturing.

Wound Bed Preparation & Stimulation

On May 29, 2015, we completed our acquisition of Celleration, Inc. (“Celleration”), a medical device company focused on developing and commercializing the MIST Therapy® (“MIST Therapy”) therapeutic ultrasound platform for the treatment of acute and chronic wounds. MIST Therapy is a painless, noncontact, low-frequency ultrasound delivered through a saline mist to the wound bed. The MIST Therapy System and UltraMIST® (“UltraMIST”) consist of a small countertop generator and handheld transducer. Attached to the transducer is a single-use disposable applicator, which includes an inlet for sterile saline. As the device is activated, the saline is introduced to the head of the transducer where it is atomized. This saline mist is the medium through which the ultrasonic energy is transmitted to the wound site inducing a non-painful, cool sensation to the patient. The disposable applicator is designed for a single use only in order to avoid infection from patient to patient. Unlike most wound therapies that are limited to treating the wound surface, we believe the gentle wound sound waves of MIST Therapy stimulate the cells within and below the wound bed to accelerate the healing process and reduces bacteria and bioburden.

Human Biologics

In November 2013 we entered into a license, marketing and development agreement with Anthrogenesis Corporation, d/b/a Celgene Cellular Therapeutics (“CCT”), an affiliate of Celgene Corporation, pursuant to which CCT granted us an

exclusive, royalty-bearing license in its intellectual property related to certain placental based products, including the wound care products Extracellular Matrix ("ECM"), a suite of advanced wound management products made from extracellular matrix derived from the human placenta and Biovance®, a decellularized and dehydrated allograft produced from human amniotic membrane for the management of non-infected partial- and full-thickness wounds.

The license agreement permits us to commercialize ECM and Biovance in the United States. The development and application of the intellectual property covered under the license agreement and is managed by a joint steering committee, composed of members of our company and CCT. We pay CCT annual license fees, designated amounts when certain milestone events occur and royalties on all sales of licensed products, with such amounts being variable and contingent on various factors. On September 30, 2014, we and CCT amended the license agreement, pursuant to which we received the right to market Biovance for podiatric and orthopedic applications. On May 5, 2015, the license agreement was further amended, pursuant to which we received the additional right to develop and market CCT's connective tissue matrix product ("CTM"). We expect to initiate sales and marketing efforts for CTM products in 2016. The product will be available in two forms of delivery and we believe will be able to treat deep wounds better than Biovance.

In connection with the Biovance products contemplated by the license agreement, on November 14, 2013, we also entered into a supply agreement with CCT, as subsequently amended on each of April 10, 2014 and September 30, 2014, pursuant to which CCT agreed to supply us with our entire requirement of Biovance for distribution and sale in the United States. On April 10, 2014, we and CCT entered into a supply agreement for ECMs, on substantially the same terms as the supply agreement for Biovance. On April 23, 2014 we initiated our sales and marketing efforts for Biovance at the Spring 2014 Symposium on Advanced Wound Care.

Biovance and CTM are derived from the placenta of normal, full-term pregnancies. After processing these human tissues contain collagen, fibronectin, and other proteins and biochemicals that support wound healing. Additionally, essentially no cells are contained in the finished product (Biovance and CTM are decellularized), which is different from other placenta-based wound care products, and this decellularization contributes to minimization of irritation and inflammation related to immune responses that can hamper wound healing. The extracellular matrix composition of Biovance and CTM form a natural scaffold that when placed in a wound bed, serves as a platform that allows the body's own cells to migrate into and attach. Once attached, the cells release growth factors to signal other activities to progress wound healing. Biovance is intended to be used as a wound cover to support the wound through the healing process or, when implanted, maintains the tissue plains minimizing adhesions and CTM which is intended for use as a biological tissue graft for the repair or replacement of non-infected damaged or deficient soft tissue to treat voids or defects and augment during repair of dehisced or complicated surgical closures and repair of small surgical defects resulting from either medical or surgical conditions including those with exposed vital structures. Biovance is intended for application to open traumatic wounds, complex wounds such as burns, open surgical wounds, Mohs procedure (microscopically controlled surgery for skin cancer), and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers. CTM is intended for augmentation of deficient/inadequate soft tissue and treatment of deep dermal wounds; surgical wounds; soft tissue voids as a result of tunneling wounds, fistula tracts, or dermal undermining. Biovance and CTM may also be used on exposed tendon, muscle, bone, nerve or other vital structures.

We and CCT are still evaluating the development path for ECM based on continued consultation with the FDA. Any further development and commercialization is uncertain at this time.

In January 2016, Human Longevity, Inc. (“HLI”), a genomics-based, technology-driven company, announced its planned purchase of LifebankUSA and other select assets from CCT. We will remain the exclusive commercial partner for the existing pipeline of human placental based products as noted above.

Antimicrobial Protection

In July 2012, we began to market two proprietary products, SilverSeal, a hydrogel wound dressing with silver coated fibers, and Hydress, an over-the-counter hydrogel wound dressing. Our SilverSeal dressing is available in two sizes and our Hydress dressing is available in one size. Both types of dressing are used to provide and maintain a moist wound environment. The benefits of these products include reduced pain, maintenance of a moist wound environment that may speed healing. SilverSeal dressings also provide an antimicrobial barrier. Silver based wound dressings are becoming increasingly prevalent in wound care due to the recent increase of antibiotic-resistant bacteria such as methicillin-resistant Staphylococcus aureus, commonly known as MRSA.

In July 2013, we announced the results from a post-marketing study to assess surgical wound outcomes in patients who have undergone foot and ankle surgery. In this study, those treated with our SilverSeal dressing had a lower incidence of post-operative wound complications, including infections and rupture of the incision lice (dehiscence). In addition, there was a reduction in scar length compared to standard petroleum-based dressing. In this study, patients who had undergone ankle and foot (including forefoot, midfoot or hindfoot) surgery were randomized to receive either SilverSeal or a standard petroleum-based dressing. Patients were monitored for three months following surgery to assess the degree of scarring and the incidence of post-operative wound complications such as superficial or deep infections or dehiscence. Of the nine wound complications observed, eight occurred in patients using the petroleum-based dressing and only one in those using SilverSeal ($p=0.03$). The p-value is the percentage chance that the results of a statistical nature are due to random error (a p-value less than 0.05 [5%] is considered to be significant). Scar length was also reduced to a greater extent in patients using SilverSeal compared to those with a standard petroleum-based dressing. Additional studies should be done to confirm these favorable results.

In May 2014 we acquired Choice Therapeutics, Inc. (“Choice”), a provider of innovative wound care products using proprietary TheraBond 3D® Antimicrobial Barrier Systems (“TheraBond”). The TheraBond product line includes contact dressings, island dressings and wraps. Based on a proprietary and patented manufacturing process, silver is bonded to the entire surface of the nylon fibers of the TheraBond dressing. When the TheraBond products are placed on the wound, bioactive ionic silver is released at a controlled rate. Used largely in burn care, we believe TheraBond promotes an optimal wound healing environment by creating an antimicrobial barrier that helps protect against infection. With its one-piece construction and unique struts between the contact and outer layers, TheraBond enables

efficient transfer of fluid and exudate (excess wound fluid) away from the wound and into an absorptive outer dressing, while providing rapid, sustained antimicrobial protection.

Exudate Management

In September 2013, we entered into a distributor agreement (the "Sorbion Agreement") with Sorbion GmbH & Co KG ("Sorbion"), pursuant to which we became the exclusive distributor of sorbion sachet S, sorbion sana and new products with hydrokinetic fibers as primary dressings in the United States, Canada and Latin America, subject to certain exceptions. The term of the agreement ends on December 31, 2018. Sorbion assigned its rights and obligations of the Sorbion Agreement to BSN Medical, Inc. ("BSN"), an affiliate of Sorbion, in June 2015.

Intended for wound bed preparation (a comprehensive approach to removing barriers to healing and stimulating the healing process), sorbion sachet S is indicated as a primary dressing for moderately to highly exudating wounds such as some surgical wounds, venous leg ulcers and diabetic ulcers. It assists in the removal of slough (dead skin tissue) and toxins, and locks bacteria into the dressing. Sorbion sachet S's hydration response technology combines mechanically modified cellulose fibers with gelling agents; the close interaction of the two components allows for active regulation of the wound climate.

Sorbion sana is indicated as a primary wound dressing and provides another form of wound treatment. It maintains a wound climate which supports healing, supports granulation (the formation of a new connective tissue and tiny blood vessels on the surface of a wound) by protecting tissue and offers a reduction in pain during dressing changes. Sorbion sana consists of an absorbent core with hydration response technology and a three-dimensional outer cover made of polyethylene. Selected materials and an optimized manufacturing process allow the avoidance of glues and adhesives, making the sorbion sana dressings less likely to cause an allergic reaction.

Contract Manufacturing

In connection with our legacy contract manufacturing business, we develop, manufacture and market high water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. We specialize in custom gels by capitalizing on proprietary manufacturing technologies. Our products are manufactured using proprietary and non-proprietary mixing, coating and cross-linking technologies. Together, these technologies enable us to produce gels that can satisfy rigid tolerance specifications with respect to a wide range of physical characteristics (e.g., thickness, water content, adherence, absorption, moisture vapor transmission rate (a measure of the passage of water vapor through a substance) and release rate) while maintaining product integrity. Additionally, we have the manufacturing ability to offer broad choices in selection of liners onto which the gels are coated. Consequently, our customers are able to determine tolerances in moisture vapor transmission rate and active ingredient release rates while personalizing color and texture.

Planned Products and Services

We intend to continue to expand our existing product offerings largely through licensing of products and acquisitions. We believe that our management team will be able to successfully integrate and leverage acquired products so we will have a more comprehensive suite of wound care products. We believe acquiring a product with established sales channels would also help us market our existing products. In evaluating potential acquisition targets, we are looking for technology platforms which enhance our current products, have revenue associated with the technology where possible, and have a strong value proposition in today’s health care climate. In addition to expanding our product offerings through licenses and acquisitions, we also intend to modify our existing products through the expansion of customer options (e.g. additional offerings in different sizes and shapes). As our products, with the exception of the ECM suite, are already cleared by the FDA, we believe that these types of modifications can be made with minor regulatory delay. We believe that these improvements and additional options will enhance our reputation and potentially attract new customers.

Industry and Markets

According to medical market research firm BioMedGPS, LLC SmartTRAK™ data, the U.S. market for wound care management products, which had revenues of approximately $5.9 billion in 2015, is expected to grow to $7.4 billion by 2019, which is a compound annual growth rate of 5% for 2015 to 2019. Growth in the U.S. wound care market will likely come from new therapies that result in decreasing healing times and subsequent cost savings and a growing focus on special populations such as diabetics and the obese.

We intend to target five specific markets within the wound care industry:

Diabetic Ulcers. According to the National Diabetes Clearinghouse ("National Diabetes Fact Sheet, 2014" available at www.cdc.gov), there are over 29 million diabetics in the U.S., or more than 9.3% of the U.S. population. Almost 11.2 million people over the age of 65 are diabetic, which equates to almost 26% of all people in this age group. Furthermore, more than 60% of nontraumatic lower-limb amputations occur in people with diabetes. A study published by Wild, et. al. (*Diabetes Care*, May 2004) estimates that the worldwide number of diabetics is projected to be 366 million people by the year 2030. Boulton, et. al. ("Neuropathic Diabetic Foot Ulcers," *New England Journal of Medicine*, July 2004) reported that diabetic foot ulcers (DFUs) develop in approximately 15% of patients with diabetes and precede 84% of all diabetes-related lower leg amputations. We believe that our wound care products can aid in the healing of these diabetic foot ulcers, thereby lessening the need for amputation.

Pressure Ulcers. Dorner, et. al. ("The Role of Nutrition in Pressure Ulcer Prevention and Treatment," *The National Pressure Ulcer Advisory Panel*, 2009) stated that according to The Joint Commission, more than 2.5 million patients in U.S. acute-care facilities suffer from pressure ulcers. Dorner, et. al. also stated that the prevalence of pressure ulcers in the U.S. is widespread in all settings, with estimates of 10% to 18% in acute care and 2.3% to 28% in long-term care. The study further noted that these pressure ulcers can reduce overall quality of life and may also contribute to premature mortality in some patients, therefore any intervention that may help to prevent or treat them once they occur is important to reduce the cost of pressure ulcer care and improve the quality of life for affected individuals. Park-Lee, et. al. ("Pressure Ulcers Among Nursing Home Residents: United States, 2004," *The National Center for Health Statistics Data Brief*, No. 14, February 2009) reported that 35% of nursing home residents with stage 2 or higher pressure ulcers received special wound care by specially trained professionals. We believe that our wound care products can aid in the treatment of pressure sores and ulcers, thereby increasing quality of life and decreasing the amount of time spent in wound care facilities.

Venous Stasis Ulcers. These wounds are believed to occur due to improper functioning of venous valves, usually of the legs. According to the University of Washington Medical Center (available at www.uwmedicine.org/health-library/Pages/venous-stasis-ulcers.aspx), the main risk of venous stasis ulcers is the spread of infection from a persistent wound. Failure to address the condition appropriately could ultimately result in limb loss. As these ulcers are typically small, they are often undertreated, which leads to larger ulcers which require more complex treatments. Brem, et. al. ("Protocol for the Successful Treatment of Venous Ulcers," *American Journal of Surgery*, July 2004) reported in one study that up to 48% of venous ulcers had recurred by the fifth year after healing. These often chronic ulcers affect up to 2.5 million U.S. citizens annually. We believe that our wound care products can aid in the treatment of venous stasis ulcers and increase the quality of life for those affected.

Post-Surgical Dressings. The study entitled "Number, Rate, and Standard Error of All Listed Surgical and Non-surgical Procedures for Discharges from Short-stay Hospitals, by Selected Procedure Categories: United States, 2009" (Centers for Disease Control and Prevention) reported that in 2009, an estimated 29 million surgical procedures were performed in the U.S. The New York Times (Sack, "Hospital Infection Problem Persists," *The New York Times*, April 13, 2010) cited a report from the Agency for Healthcare Research and Quality in 2010 that the problem of hospital-acquired infections ("HAIs") contributes to an estimated 100,000 deaths annually and concluded that the problem merited "urgent attention". We believe that our wound care products can aid in the prevention of HAIs. In July 2013, we announced the results from a post-marketing study to assess surgical wound outcomes in patients who have undergone foot and ankle surgery. In this study, our SilverSeal dressing was shown to have a lower level of incision complications, including infection, and a greater reduction in scar length compared to standard petroleum-based dressings.

Burns. According to the American Burn Association ("Burn Incidence and Treatment in the United States: 2015 Fact Sheet," available at www.ameriburn.org/resources_factsheet.php), an estimated 486,000 people with burn injuries receive medical treatment on an annual basis. If the burn is second degree or worse, medical attention may be required to reduce the risk of infection, dehydration and other potentially serious consequences. If the burn does result in hospitalization, we believe that our wound care products will benefit the healing process for the patient.

Sales and Marketing

We continue to focus on sales and marketing efforts in the U.S. As of December 31, 2015, we had 43 employees dedicated to sales, all of whom have experience in the wound care industry. Additionally, we have developed an independent network of agents to sell our wound care products through our extensive channel reach through a network of distributors. In addition, we have assembled a Medical Advisory Board to help us target improvements and new applications for our products and assist in our marketing efforts. We also market our advanced wound care products at conferences, trade shows and other educational events.

Customers

One customer accounted for approximately 10% and 23% of our revenue for the years ended December 31, 2015 and 2014, respectively. This customer is a medical device manufacturer and a consumer of our contract manufacturing products. The decrease in this concentration is due to an increase in product revenue, which is consistent with our strategy. We expect that as revenues from the sales of our portfolio of advanced wound care solutions increases, this concentration will continue to abate in 2016.

Proprietary Hydrogel Technologies and Manufacturing

Our hydrogels are manufactured by introducing a hydrophilic polymer into water to create a feed mix. The hydrophilic polymer has a tendency to mix with or dissolve in water. The feed mix is then coated onto a liner and exposed to radiation. The polymers we use, when exposed to radiation, cross-link faster than they degrade, creating a matrix that gives the gels a solid form. Active ingredients such as prescription or over-the-counter medication, skin care or wound-healing ingredients or other materials can be added before or after cross-linking. Materials that do not survive the irradiation process, or are modified by such process, may be added after the cross-linking process is completed. Once the products have been mixed and cross-linked, they form sheets that can either be delivered directly to customers or first cut and shaped according to customer or our specifications, as appropriate. We believe that many of the processes described above are proprietary to us and provide us with competitive advantages, including our production of a high quality product and our increased ability to customize products for customers.

Proprietary Mixing. We believe that we are able to manufacture hydrogel feed mixes with far greater homogeneity than those of our competitors. This manufacturing advantage is critical, especially as it relates to dosages of active ingredients. In addition, our proprietary mixing technology allows for the incorporation of sensitive materials that may degrade if subjected to other types of mixing.

Proprietary Coating. Our proprietary coating technology enables us to properly coat the gels even though the gels are extremely thick and resistant to flow. We have achieved coating tolerances that have allowed us to coat materials as thin as 0.005 of an inch with a margin for error of typically less than 5%. Thickness controls are critical with respect to the performance of many of the end products utilizing our hydrogels, including medical electrodes, transdermal delivery patches and cosmetic patches. We have also developed a coating methodology that minimizes imperfections such as wrinkling in the end product by significantly reducing line tension. We believe that our proprietary know-how allows us to manufacture high quality, consistent products which meet the standards of our customers.

Proprietary Cross-Linking Technology. We cross-link our hydrogels using an electron beam accelerator. Such cross-linking is achieved by introducing a high energy field, created by accelerated electrons, which causes the release of hydrogen atoms and causes carbon molecule covalent bonding. The creation of longer chains of the polymer in the gel increases its molecular integrity, giving the gel characteristics that make it useful in a variety of products.

Our electron-beam cross-linking process is one of three types of cross-linking, that we are aware of, used in the industry. The other types used are ultra-violent cross-linking and chemical cross-linking. We believe that the benefits of electron beam cross-linking include:

allowing for precise control of the amount of polymer cross-linking;

obviating the need for chemical cross-linking agents which may complicate or interfere with other additives or active ingredients; and

providing the ability to manufacture high quality hydrogels on a consistent basis.

The cross-linking of hydrogels can be further modified by varying the percent of polymer cross-linking and the way in which the high energy field is delivered. There are three variables in the use of an electron beam accelerator for cross-linking of hydrogels:

time of exposure of the target material to the electron stream;

voltage (electrical potential); and

amperage (strength of the electrical current).

We believe that our proprietary methods of managing these three variables make it possible to produce high quality gels that can match a wide range of customer specifications.

We own and operate a Radiation Dynamics, Inc. Dynamitron IEA 1500-40 Industrial Electron Accelerator, or RDI Accelerator. The RDI Accelerator has been customized to handle the cross-linking of the type of materials we use, but can also be used for several other potential uses such as coloring gemstones and treating wire, cable and tubing. The replacement cost of the RDI Accelerator and processing equipment is substantial. The delivery and installation

process is time-consuming, with replacement estimated to take 2.5 to 3 years. We estimate that our equipment has a useful life of approximately 20 years and provides annual production capacity in excess of 6,000 hours. We believe that its current utilization is significantly less than capacity. We are also subject to state regulation with respect to electron beam radiation services and facilities. The expansion of our business into the manufacturing and distribution of our products for consumer use will subject us to additional governmental regulation.

Competition

There are several established silver-based wound dressings and other products which are already in the marketplace that compete with SilverSeal and TheraBond. These include Acticoat (sold by Smith & Nephew), Aquacel Ag (sold by ConvaTec), and Silvercel (sold by Acelity). We believe that our low cost of sales will enable us to capture market share from our competitors.

Leading competitors in the tissue-based wound care area that will compete with our biologic products include companies such MiMedx Group, LLC, Osiris, Organogenesis, Derma Sciences, as well as a significant number of smaller companies.

Leading competitors of our sorbion products include Optilock (sold by Medline), Xtrasorb (sold by Derma Sciences), Drawtex (sold by Stead Med) and Enluxtra (sold by Osnovative Systems).

We believe that MIST Therapy has no direct competition in the advanced wound care market. As a result, we believe that MIST Therapy may compete favorably on the basis of broad application. Notwithstanding this, we expect that many physicians and allied professionals to continue to employ other treatment approaches and technologies separately and in combination in an attempt to treat chronic and hard-to heal wounds.

Our ability to establish sales in a market with many larger manufacturers may be difficult. We continue to recruit veterans of the medical device industry to leverage our product offerings into the most beneficial distribution channels. Our competitors may still have greater resources to support their products and may not allow us to take any market share from them.

Sources and Availability of Raw Materials; Principal Suppliers

In general, raw materials essential to our businesses are readily available from multiple sources. For reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. Our policy is to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time.

Carolina Silver is the principal manufacturer utilized in production of our TheraBond dressings. Carolina Silver utilizes a proprietary and patented manufacturing process. Although we have not experienced significant production delays attributable to supply changes, we believe that developing alternative sources of supply used to make TheraBond would be difficult over a short period of time.

We purchase MIST Therapy applicators and the saline bottles/bags included with each applicator from single sources. We purchase the UltraMist System from two suppliers. We and our suppliers purchase many of the components and raw materials in manufacturing the MIST products from numerous suppliers in various countries. We have been able to obtain adequate supplies of such raw materials and components and work closely with suppliers to try to ensure continuity of supply while maintaining high quality and reliability.

Under our Sorbion Agreement with BSN and our supply agreements with CCT, we receive finished goods from these parties.

The Dow Chemical Company and the BASF Corporation are the principal manufacturers of the two polymers, polyethylene oxide and polyvinylpyrrolidone, respectively, that we primarily use in the manufacture of hydrogels.

Because we have no direct control over these suppliers, interruptions or delays in the products and services provided by these parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary products or raw materials, we may be unable to redesign or adapt our technology to work without such raw materials or products or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs or quality control problems, or be unable to sell the applicable products, all of which could have a significant adverse impact on our revenue.

Other than as discussed above, we believe that, due to the size and scale of production of our suppliers, there should be adequate supply of raw materials from our manufacturers.

Patents, Proprietary Rights and Trademarks

We own or license a number of trademarks covering our company and our products. Our policy is to file patent applications to protect technology, inventions and improvements that are important to the development of our business. We also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position.

As of December 31, 2015 we owned 17 issued U.S. patents and 17 issued foreign patents covering aspects of our MIST Therapy platform. Specifically, our issued patents cover both medical and device aspects of wound care using non-contact ultrasound, as well as other clinical applications of non-contact ultrasound.

Pursuant to the Sorbion Agreement, in connection with our exclusive rights to sell Sorbion sachet S, Sorbion sana and new products with hydrokinetic fibers as primary wound dressings, we have the right to use trademarks related to the Sorbion products for sale of the products in the applicable territory. The initial term of the agreement expires on December 31, 2018, unless earlier terminated pursuant to the termination rights under the agreement.

In July 2011, we obtained from Noble Fiber Technologies, LLC an exclusive, worldwide license to use silver-coated fibers marketed under the trademarks X-Static® and SilverSeal® in our manufacture, sale, use and distribution of Hydrogel Wound Dressing identified in 510(k) K040019 and Hydrocolloid Wound Dressing identified in 510(k) K033900. We have an exclusive license until July 2021 with an option to extend for consecutive renewal periods of two years after the initial term.

In November 2013, we entered into a license, marketing and development agreement with CCT, as subsequently amended on each of September 30, 2014 and May 5, 2015, pursuant to which we hold an exclusive, royalty-bearing license in CCT's intellectual property related to certain placental based products, including ECM, CTM and Biovance, to develop and commercialize these products in the United States. The development and application of the intellectual property covered under the license agreement is managed by a joint steering committee, composed of members of us and CCT. Following the commencement of commercial sales of each licensed product, the license agreement requires us to pay CCT certain annual license fees, royalty payments based on a percentage of net sales as well as financial and performance milestone payments, subject to the terms and conditions set forth in the license agreement. The initial term of the license agreement expires on November 14, 2023, unless sooner terminated pursuant to the termination rights under the license agreement, and will automatically renew for additional two-year periods unless either party gives written notice within a specified period prior to the end of a term. The license agreement may be terminated (i) by CCT if we or any of our affiliates challenges the validity, enforceability or scope of certain enumerated CCT patents anywhere in the world; (ii) by either party if there is a final decree that a licensed product infringed on the intellectual property of a third party; (iii) by either party for breach and failure to cure such breach of the license agreement; or (iv) by either party if the other party is the subject of insolvency proceedings, either voluntary or involuntary. In addition, the license agreement is terminable on a product-by-product basis, and not with respect to the entire license agreement (i) by CCT if we fail to meet certain minimum sales thresholds for the second year of commercial sales, and by either CCT or us if we fail to meet certain minimum sales thresholds for the third or any subsequent year of commercial sales and (ii) by either party upon written notice if outside legal counsel recommends discontinuance of commercialization of a product because of significant safety, legal, or economic risk as a result of a claim, demand or action or as a result of a change in the interpretation of law by a governmental or regulatory authority.

Government Regulation

Product Regulation. Under the Federal Food, Drug and Cosmetic Act, medical devices are classified by the FDA into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. While some applications of hydrogels fall under the jurisdiction of the FDA, hydrogels are generally classified as Class I exempt devices and the majority of the hydrogel products that we manufacture are thereby exempt from the FDA filing of any regulatory submissions and/or pre-market notification requirements. To the extent that any FDA regulatory submissions are required, we will be required to file these submissions and maintain all appropriate documentation. With respect to registering the manufacturing facility with the FDA under the Code of Federal Regulations, 21 CFR 820.1, Scope: Part A, it is stated that the regulation does not apply to manufacturers of component parts of finished devices. Currently, hydrogels are sold as component parts to various medical device/cosmetic manufacturers.

We believe that a number of products that our partners are developing will be classified in the US as either Class I or Class II medical devices or Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Class I medical devices are subject to the FDA's general controls, which include compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject

to the FDA's general controls and may also be subject to other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Most Class II devices require pre-market clearance by the FDA through the 510(k) pre-market notification process. When a 510(k) is required, the manufacturer must submit to the FDA a pre-market notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or to another commercially available, similar device which was subsequently cleared through the 510(k) process. By regulation, the FDA is required to clear a 510(k) within 90 days of submission of the application. As a practical matter, clearance often takes longer. HCT/Ps that are regulated under 21 Code of Federal Regulations Part 1271 and Section 361 of the Public Health Service Act ("361 HCT/Ps") and do not require FDA approval or clearance prior to marketing. We are required to follow Good Tissue Practices (GTP) including registration as a storage/distribution facility as well as track the tissue products from receipt to final disposition.

Biovance and CTM are products derived from human tissue. The FDA has specific regulations governing HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into humans. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act and 21 CFR 1271 (361 HCT/Ps) are not subject to pre-market clearance or approval requirements, but are subject to post-market regulatory requirements. To be a 361 HCT/P, a product must meet all four of the following criteria:

- It must be minimally manipulated;
- It must be intended for homologous use;
- It must not be combined with another article; and
- It must not have a systemic effect and not be dependent upon the metabolic activity of living cells for its primary function.

We and CCT believe that Biovance and CTM qualify as a 361 HCT/P. The FDA is in the process of clarifying definitions of homologous use and minimal manipulation in their Guidance for Industry publications.

The FDA has broad post-market regulatory and enforcement powers with respect to medical devices, similar to those for pharmaceutical products. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA's refusal to grant future pre-market clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution. Similarly, the FDA may audit any facility with a registered 361 HCT/P.

If there are any modifications to an approved device such as our Hydrogel Wound Dressing identified in 510(k) K040019 and Hydrocolloid Wound Dressing identified in 510(k) K033900, including changes in indication, manufacturing process or labeling or a change in a manufacturing facility, an applicant must notify the FDA, and in many cases, approval for such changes must be submitted to the FDA. Additionally, the FDA regulates post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements. These regulations include standards or restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities and off-label promotion. Likewise, labeling and advertising of HCT/Ps may be monitored for indication language to be consistent with homologous use. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label (or homologous use). The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these regulations can result in enforcement action, including the issuance of warning letters directing entities to correct deviations from FDA regulations and civil and criminal investigations and prosecutions. These activities could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Quality Assurance Requirements. The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs, medical devices and/or HCT/Ps conform with current good manufacturing (GMP) and/or tissue practices (GTP). The current GMP regulations the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality and purity characteristics required of them. The current GMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device manufacture, from pre-production design validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the Federal Food, Drug and Cosmetic Act. GTPs are narrower in scope than GMPs. GTP requires a quality program to prevent, detect, and correct deficiencies that could increase communicable disease risk. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA also conducts periodic inspections of drug, device and registered HCT/P facilities to assess their current GMP/GTP status. If the FDA were to find serious non-compliant manufacturing or processing practices during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations, financial condition and cash flows. With respect to domestic establishments, the FDA could initiate product seizures or in some instances require product recalls and seek to enjoin a product’s manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with current good manufacturing practices requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an “unacceptable supplier”, thereby disqualifying that company from selling products to federal agencies.

We believe that we and our suppliers and outside manufacturers are currently in compliance with current good manufacturing practices requirements. We are currently registered as a device manufacturer and human tissue distributor with the FDA and we intend to register as a drug facility with the FDA when we are required to do so.

Third-Party Reimbursement

In the United States as well as in foreign countries, sales of our products depends in significant part on the availability of reimbursement from third-party payers. In the U.S. third-party payers consist of government programs such as Medicare, private health insurance plans, managed care organizations and other similar programs. For any product, three factors are critical to reimbursement:

- coding, which ensures uniform description of procedures, diagnoses and medical products;
- coverage, which is the payer's policy describing the clinical circumstances under which it will pay for a given treatment; and
- payment process and amounts.

We believe the availability, as of January 2014, of a Category I CPT code for MIST Therapy has encouraged and will continue to encourage, broader coverage and subsequent use of its MIST Therapy System in the United States. Previously, MIST Therapy was billed under a temporary Category III CPT code, which some payers generally refuse to cover. Each government and private payer, however, makes its own coverage decision.

Access to MIST Therapy is available to Medicare beneficiaries in 46 states. Although private payers will often pay for MIST Therapy when medically necessary and pre-approved, we have not focused on securing private payer coverage decisions for MIST Therapy.

For Medicare-covered patients who are commonly treated in a hospital outpatient department, the payment system is called the Outpatient Prospective Payment System. The facility payment for MIST Therapy is billed under the CPT Code and then categorized for payment under a single Ambulatory payment ("APC"). Each hospital has a specific APC payment based on the hospital's wage index for their geographic location.

If MIST Therapy is delivered by a physician, non-physician practitioner, or physical therapist, a professional payment may be based on the Medicare Physician Fee Schedule ("MPFS"). The MPFS includes both a facility, and, for treatment delivered in a physician's office a non-facility rate. The actual amount will vary by location per the geographic practice cost index adjustment to the national rate. Therapy services are typically paid under the non-facility MPFS payment rate pursuant to Medicare guidelines.

Biovance is currently marketed in hospitals where Diagnosis Related Group Procedures are performed, in the Veteran's Affairs health system, and in hospital outpatient departments as well as Physician offices or other outpatient care centers. Providers of outpatient services will be reimbursed for Biovance by Medicare where there is a local coverage determination by the prevailing Medicare Administrative Contractor ("MAC"). On October 31, 2014, Biovance was assigned a new and unique, Level II Healthcare Common Procedure Coding System product reimbursement Q code (Q4154) by Centers for Medicare and Medicaid Services ("CMS"). The new reimbursement code took effect on January 1, 2015. We currently have reimbursement coverage for Biovance from three of the eight MACs, so customers get reimbursed for Biovance used to treat Medicare beneficiaries in outpatient settings in 25 states.

We have the Healthcare Common Procedural Coding System, or HCPCS, codes, from the Pricing, Data, Analysis, and Coding contractor for CMS, for use when billing for our wound care dressings. HCPCS was established in 1978 to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. HCPCS codes are used by Medicare and monitored by the CMS. They are based on the Current Procedural Technology codes developed by the American Medical Association. We believe that these codes will facilitate reimbursement for the use of our dressings in Medicare patients with applicable wounds.

Environmental Regulation. We are subject to various laws and governmental regulations concerning environmental matters and employee safety and health in the U.S. and other countries. We have made, and continue to make, significant investments to comply with these laws and regulations. We cannot predict the future capital expenditures or operating costs required to comply with environmental laws and regulations. We believe that we are currently compliant with applicable environmental, health and safety requirements in all material respects. However, we cannot assure you that current or future regulatory, governmental, or private action will not have a material adverse effect on our performance, results or financial condition.

In the future, if a loss contingency related to environmental matters, employee safety, health or conditional asset retirement obligations is recognized, we would record a liability for the obligation and it may result in a material impact on net income for the annual or interim period during which the liability is recorded. The investigation and remediation of environmental obligations generally occur over an extended period of time, and therefore we do not know if these events would have a material adverse effect on our financial condition, liquidity, or cash flow, nor can we assure you that such liabilities would not have a material adverse effect on our performance, results or financial condition.

Federal and State Anti-kickback, Self-referral, False Claims and Similar Laws. Our relationships with physicians, hospitals and the marketers of our products are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. Certain states have similar fraud and abuse laws, imposing substantial penalties for violations. Any government investigation or a finding of a violation of these laws would likely result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations. We believe that we are currently compliant with applicable anti-kickback, self-referral, false claims in all material respects.

Research and Development Costs

For the year ended December 31, 2015, we incurred research and development costs of approximately $715,000 related to a randomized controlled trial for our Biovance product in chronic diabetic foot wounds. For the year ended December 31, 2014, we incurred no research and development costs. We bear our own research and development costs and do not directly pass along our research and development costs to our customers.

We intend to commit capital resources to research and development only as our cash resources allow. We have incurred all cost associated with the launch of our proprietary products and will only require research and development expenses for product enhancements and modifications, which we do not expect to be significant.

Employees

As of December 31, 2015 we had 87 full-time employees. Of these employees, 66 are involved with finance, sales, marketing, and administration and 21 are involved with manufacturing, clinical and regulatory matters. Our employees are not represented by a labor union or other collective bargaining groups, and we consider relations with our employees to be good. We currently plan to retain and utilize the services of outside consultants for additional research, testing, regulatory, legal compliance and other services on an as needed basis.

ITEM 1A. RISK FACTORS

There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks described below and the other information included in this Annual Report on Form 10-K, including the consolidated financial statements and related notes. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Risks Relating to Our Company

We have experienced significant losses and expect losses to continue for the foreseeable future.

We have incurred annual net losses of $26.0 million and $25.4 million, respectively, during the years ended December 31, 2015 and 2014. As of December 31, 2015, we had an accumulated deficit of $96.0 million. We expect to incur additional operating losses for the foreseeable future. Although we expect sales to continue to increase in 2016 and beyond from our existing product offerings, there can be no assurance that we will be able to achieve these revenues throughout the year or be profitable in the future.

We will require additional capital in order to execute the longer term aspects of our business plan.

The implementation of our growth strategy will continue to result in an increase in our fixed cost structure. Due to the time delay between outlays for working capital expenditures, such as costs to acquire rights to additional products, the hiring and training of sales agents and personnel, marketing costs, the purchasing of inventory, the billing and collection of revenue, the conducting of a post marketing clinical trial for Biovance, debt service costs, and diligence costs related to merger and acquisition activities, we expect to have a net cash outflow from operating activities as a result of these expenditures. Future results of operations involve significant risks and uncertainties. Factors that could affect our future operating results and cause actual results to vary materially from expectations include, but are not limited to, potential demand for our products, risks from competitors, regulatory approval of our new products, technological change, and dependence on key personnel. In addition, half of the contingent consideration payable to Celleration shareholders will be payable in cash in 2016 and 2017.

In order to complete our future growth strategy, additional equity and/or debt financing will be required. If we are unable to raise additional capital or if we encounter circumstances that place unforeseen constraints on capital resources, we will be required to take even stronger measures to conserve liquidity, which may include, but are not limited to, eliminating all non-essential positions and ceasing all marketing efforts. We would have to curtail business development activities and suspend the pursuit of our business plan. There can be no assurance that we will be successful in improving revenues, reducing expenses and/or securing additional capital in sufficient amounts and on favorable terms.

We have a substantial amount of indebtedness under our $15.5 million principal term loan, which may adversely affect our cash flow and our ability to operate our business.

In order to finance our acquisition of Celleration, on May 29, 2015, we and each of our subsidiaries entered into a credit agreement and guaranty (the "Credit Agreement") with a third-party lender, which provided for a senior, secured term loan in the principal amount of approximately $15.5 million. The full unpaid principal amount of the term loan will mature on May 29, 2019. Prior to maturity, on the last business day of each calendar month following May 29, 2017, we will be required to make monthly principal payments of $225,000,with any remaining unpaid balance of the term loan being payable in cash on the maturity date. The repayment of the term loan and our obligations under the Credit Agreement are secured by a first priority lien on all of our existing and after acquired tangible and intangible assets, including intellectual property. The Credit Agreement also contains certain restrictions that prohibit us and our subsidiaries from engaging in certain transactions and activities, including but not limited to the following:

- entering into, creating, incurring or assuming any indebtedness of any kind, subject to limited exceptions;
- creating or incurring new liens, subject to certain exceptions;
- entering into new acquisitions or investments in other entities, subject to certain exceptions;
- winding up, liquidating or dissolving;
- merging or consolidating with another person or disposing of assets, subject to certain exceptions;
- entering into inbound or outbound licenses, subject to certain exceptions;
- changing the nature of our core business;

· paying cash dividends; and

· repaying, repurchasing or otherwise acquiring shares of our common stock or other equity securities.

Our ability to meet our expenses, debt obligations and other financial covenants under the Credit Agreement will depend on our future performance, which will be affected by financial, business, economic, regulatory and other factors. We will be unable to control many of these factors. We cannot be certain that our earnings will be sufficient to allow us to pay the principal and interest on our debt and meet any other obligations. If we do not have enough money to service our debt, we may be required, but unable to refinance or restructure all or part of our existing debt, sell assets, borrow money or raise equity on terms acceptable to us, if at all, and the lender could foreclose on its security interest and liquidate some or all of our assets, which would harm our business, financial condition and results of operations.

The Credit Agreement also requires us to meet certain financial covenants. Our ability to meet these financial covenants may be affected by events beyond our control. If, as or when required, we are unable to repay, refinance or restructure our indebtedness under, or amend the covenants contained in, the Credit Agreement, the lender could institute foreclosure proceedings against our assets, which would harm our business, financial condition and results of operations.

In addition, as a result of our increased level of indebtedness, demands on our cash resources will continue to increase in the future and could, among other things:

• require us to dedicate a large portion of our cash flow from operations to the servicing and repayment of our debt, thereby reducing funds available for working capital, capital expenditures, research and development expenditures and other general corporate requirements;

• limit our ability to obtain additional financing to fund future working capital, capital expenditures, research and development expenditures and other general corporate requirements;

• limit our flexibility in planning for, or reacting to, changes in its business and the industry in which we operate;

• restrict our ability to make strategic acquisitions or dispositions or to exploit business opportunities;

• place us at a competitive disadvantage compared to our competitors that have less debt;

- adversely affect our credit rating, with the result that the cost of servicing our indebtedness might increase and our ability to obtain surety bonds could be impaired;

- adversely affect the market price of our common stock; and

- limit our ability to apply proceeds from an offering or asset sale to purposes other than the servicing and repayment of debt.

If an event of default occurs under the Credit Agreement, it could result in a material adverse effect on our business, operating results and financial condition, or the loss of our assets as the lender holds a first priority security interest in all of our assets and the assets of our subsidiaries.

Events of default under the Credit Agreement include, but are not limited to, the following:

- failure to pay principal, interest or other amounts, if any, when due;

- any form of bankruptcy or insolvency proceeding instituted by or against us or any of our subsidiaries that is not dismissed in 60 days;

- a default occurring under any debenture, mortgage, credit agreement, indenture or other instrument representing or securing indebtedness in an amount exceeding $250,000;

- we or any of our subsidiaries is party to a change of control;

- the FDA or other governmental authority (i) issues a letter or other communication asserting any of our products lacks a required product authorization, including in respect of CE marks or 510(k)s or 361HCT/P qualification, or (ii) initiates enforcement action or warning against us, any of our products or manufacturing facilities resulting in the discontinuance of marketing, withdrawal of any material products, or delay in the manufacture of any material products, each lasting for more than 90 days;

- a recall of any product that has generated or is expected to generate at least $1,000,000 in revenue in the aggregate over any consecutive twelve (12) month period;

- we or any of our subsidiaries enters into a settlement agreement with the FDA or any other governmental authority that results in aggregate liability as to any single or related series of transactions, incidents or conditions, in excess of $500,000;

- we are in default under our license agreement with CCT or the license agreement is terminated, amended, waived or otherwise modified in a manner materially adverse to the lender's interests; and

- failure to observe or perform any other covenant contained in the Credit Agreement.

If an event of default were to occur, payment of the entire principal amount could be accelerated and become immediately due and payable. The cash that we may be required to pay would most likely come out of our working capital, which may be insufficient to repay the obligation or leave us with insufficient cash to finance our operations. In such event, we may lose some or all of our assets as the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations. We may also be required to file for bankruptcy, sell assets, or cease operations, any of which would put our company, our investors and the value of our common stock, at significant risk.

The pledge of these assets and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the $15.5 million principal term loan, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

A portion of the merger consideration for the acquisition of Celleration is contingent on the occurrence of certain events in the future, which could result in future dilution to our shareholders.

In connection with our acquisition of Celleration, we agreed to pay certain additional consideration to Celleration equity holders that is contingent upon the occurrence of certain events in the future over which we have limited control. In addition, for a period of 18 months after the closing of the merger, we have the right to setoff certain indemnification claims against the contingent consideration in certain circumstances. The exact amounts of cash and shares of our common stock that Celleration equity holders will be entitled to receive as part of the total merger consideration cannot be determined as of the date of this report. The issuance of any additional shares of our common stock as part of the contingent consideration upon the occurrence of certain future events will dilute the ownership position of our current stockholders and may result in fluctuations in the market price of our common stock, including a stock price decrease.

If we fail to meet certain minimum sales thresholds for products licensed pursuant to our agreement with CCT, we could lose our right to license such products.

Our license agreement with CCT is terminable on a product-by-product basis if we fail to meet certain minimum sales thresholds in the second year or any subsequent year following the commencement of commercial sales of each licensed product. We commenced sales of Biovance in April 2014. Therefore, in order to maintain our license for Biovance, we must meet the minimum gross sales amount for Biovance during 2016. If we fail to sell Biovance products in amounts that meet or exceed the minimum sales threshold for the second year of commercial sales, we may cure such minimum sales failure by paying CCT in cash an amount equal to the difference between the annual license fee for the second year of commercial sales and the aggregate royalties which would be due to CCT if gross annual sales of Biovance had satisfied the minimum sales threshold amount. If we do not cure a minimum sales failure with a makeup payment for the second year of commercial sales, CCT may terminate our license with respect to Biovance. No assurance can be given that we will be able to meet the minimum sales threshold for Biovance or that we will have sufficient capital to make the payments required to cure a minimum sales failure. Moreover, if we were required to make such a makeup payment to retain our Biovance license, it could impair our liquidity. We also have no right to cure a minimum sales failure starting in 2017 through a makeup payment. If we were to lose or otherwise become unable to maintain our right to license Biovance or other products from CCT, it could have a material adverse effect on our business, financial condition and results of operations. In addition, any termination of our right to license Biovance or other products under the license agreement with CCT could trigger an event of default under the Credit Agreement that we entered into to finance the cash portion of the purchase price for the Celleration acquisition.

We depend on our executive officers and key personnel.

We believe that our success will depend, in part, upon our ability to retain our executive officers, including David Johnson, our Chief Executive Officer, Brian Posner, our Chief Financial Officer, Nino Pionati our Chief Strategy and Marketing Officer and Brad Barton, our Chief Operating Officer, and other key personnel, and attract additional skilled personnel, which may require substantial additional funds. There can be no assurance that we will be able to find and attract additional qualified employees or retain any such executive officers and other key personnel. Our inability to hire qualified personnel, the loss of services of our executive officers or key personnel, or the loss of services of executive officers or key personnel who may be hired in the future may have a material and adverse effect on our business

Our strategic business plan may not produce the intended growth in revenue and operating income.

Our strategies include making significant investments in sales and marketing programs to achieve revenue growth and margin improvement targets. If we do not achieve the expected benefits from these investments or otherwise fail to execute on our strategic initiatives, we may not achieve the growth improvement we are targeting and our results of operations may be adversely affected.

15

Our acquisition strategy may not produce the intended growth in revenue and operating income.

As part of our strategy for growth, we may make acquisitions and enter into strategic alliances such as joint ventures and joint development agreements. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. Such acquisitions could reduce shareholders' ownership, cause us to incur debt, expose us to liabilities and result in amortization expenses related to intangible assets with definite lives. In addition, acquisitions involve other risks, including diversion of management resources otherwise available for ongoing development of our business and risks associated with entering new markets with which we have limited experience or where distribution alliances with experienced distributors are not available. Our future profitability may depend in part upon our ability to further develop our resources to adapt to these new products or business areas and to identify and enter into satisfactory distribution networks. Moreover, we may fail to realize the anticipated benefits of any acquisition as rapidly as expected or at all, or the acquired business may not perform in accordance with our expectations. We may also incur significant expenditures in anticipation of an acquisition that is never realized. There can be no assurance that difficulties encountered in connection with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

Our future success depends upon market acceptance of our existing and future products.

We believe that our success will depend in part upon the acceptance of our existing and future products by the medical community, hospitals and physicians and other health care providers, third-party payers, and end-users. Such acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective or cost-competitive than other similar products. Ultimately, for our new products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our new products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

We are dependent on significant customers.

Historically, our contract manufacturing business has generated most of our revenue, and much of this revenue is generated from a limited number of clients, who account for a substantial percentage of our total revenues. One customer accounted for approximately 10% and 23% of our revenue for the years ended December 31, 2015 and 2014, respectively. This customer is a medical device manufacturer and a consumer of our contract manufacturing products. The decrease in this concentration is due to an increase in product revenue, which is consistent with our strategy. We expect that as revenues from the sales of our proprietary wound dressings increase, this concentration will continue to abate in 2016. The loss of any of our significant customers would have a significant negative effect on our overall

operations.

We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

the time and resources required to develop and conduct clinical trials and obtain regulatory approvals for our products;

the costs to attract and retain personnel with the skills required for effective operations; and/or

the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

If we do not accurately predict our operating expenses, we may not allocate resources appropriately, which could lead to cash shortfalls and force us to seek additional capital or curtail other projects or initiatives, all of which could have a significant negative effect on our business, results of operations and financial condition.

We operate in a highly competitive industry and face competition from large, well-established medical device manufacturers as well as new market entrants.

Competition from other medical device companies and from research and academic institutions is intense, expected to increase, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we compete with other companies in acquiring rights to products or technologies from those institutions. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, and the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. There can be no assurance that our products will receive market acceptance in a commercially viable period of time, if at all. Furthermore, there can be no assurance that we can develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing or acquiring products and technologies that are more effective than those being developed by us, that would render our products and technologies less competitive or obsolete.

16

Our competitors enjoy several competitive advantages over us, including some or all of the following:

large and established distribution networks in the U.S. and/or in international markets;

greater financial, managerial and other resources for products research and development, sales and marketing efforts and protecting and enforcing intellectual property rights;

significantly greater name recognition;

more expansive portfolios of intellectual property rights;

established relations with physicians, hospitals, other healthcare providers and third party payers;

products which have been approved by regulatory authorities for use in the U.S. and/or Europe and which are supported by long-term clinical data; and

greater experience in obtaining and maintaining regulatory approvals and/or clearances from the FDA and other regulatory agencies.

Our competitors' products will compete directly with our products. In addition, our competitors as well as new market entrants may develop or acquire new treatments, products or procedures that will compete directly or indirectly with our products. The presence of this competition in our market may lead to pricing pressure which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

Certain of our existing and potential future products will require FDA approval before they can be marketed in the United States.

Inherent in the development of new medical products is the potential for delay because product testing, including clinical evaluation, is required before most products can be approved for human use. With respect to medical devices, such as those that we manufacture and market, before a new medical device, or a new use of, or claim for, an existing product can be marketed, unless it is a Class I device, it must first receive either premarket clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act or approval of a premarket approval application, or PMA, from

the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that the proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA approval pathway requires an applicant to demonstrate the safety and effectiveness of the device for its intended use based, in part, on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The premarket approval process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Both the 510(k) and premarket approval processes can be expensive and lengthy and entail significant user fees.

Failure to comply with applicable regulatory requirements can result in, among other things, suspensions or withdrawals of approvals or clearances, seizures or recalls of products, injunctions against the manufacture, holding, distribution, marketing and sale of a product, civil and criminal sanctions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. Meeting regulatory requirements and evolving government standards may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, on a timely basis, if at all, or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

Changes to the FDA approval process or ongoing regulatory requirements could make it more difficult for us to obtain FDA approval of our products or comply with ongoing requirements.

Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current FDA standards of review for approving new medical device products are sometimes more stringent than those that were applied in the past. For example, the FDA is currently evaluating the 510(k) process for clearing medical devices and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k) clearances and additional requirements that may significantly impact the process.

We cannot determine what effect changes in regulations or legal interpretations by the FDA or the courts, when and if promulgated or issued, may have on our business in the future. Changes could, among other things, require different labeling, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, or limitations on product distribution. These changes, or others required by the FDA could have an adverse effect on the sales of these products. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

Should the FDA determine that Biovance does not meet regulatory requirements that permit qualifying HCT/Ps to be processed, stored, labeled and distributed without pre-marketing approval, our supplier may be required by the FDA to stop processing and we may be required to stop distributing Biovance, or to narrow the indications for which Biovance is marketed, which, in turn, could also result in a default under our planned credit facility.

Biovance is a product derived from human tissue. The FDA has specific regulations governing HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into humans. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act and 21 CFR 1271 (361 HCT/Ps) are not subject to pre-market clearance or approval requirements, but are subject to post-market regulatory requirements. To be a 361 HCT/P, a product must meet all four of the following criteria:

- It must be minimally manipulated;
- It must be intended for homologous use;
- It must not be combined with another article; and
- It must not have a systemic effect and not be dependent upon the metabolic activity of living cells for its primary function.

We and Celgene believe that Biovance qualifies as a 361 HCT/P. The FDA is in the process of clarifying definitions of homologous use and minimal manipulation in their Guidance for Industry publications. Should a significant change occur with these updated final documents expected in 2016, and the FDA disagrees with our belief, changes its policy with respect to 361 HCT/P qualifications, or determines that our marketing claims exceed what would be permitted for a 361 product, and Biovance is determined to not qualify as a section 361 HCT/P product, we may have to revise our labeling and other written or oral statements of use or obtain approval or clearance from the FDA before we can continue to market the product in the United States. Furthermore, a communication from the FDA asserting that Biovance does not qualify as a 361 HCT/P product could also trigger an event of default under the Credit Agreement

that we entered into to finance the cash portion of the purchase price for the Celleration acquisition.

Modifications to our current products may require new marketing clearances or approvals or require us to cease marketing or recall the modified products until such clearances or approvals are obtained.

Any modification to a FDA-cleared product that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, requires a new FDA 510(k) clearance or, possibly, a premarket approval. The FDA requires every manufacturer to make its own determination as to whether a modification requires a new 510(k) clearance or premarket approval, but the FDA may review and disagree with any decision reached by the manufacturer. In the future, we may make additional modifications to our products after they have received FDA clearance or approval and, in appropriate circumstances, determine that new clearance or approval is unnecessary. Regulatory authorities may disagree with our past or future decisions not to seek new clearance or approval and may require us to obtain clearance or approval for modifications to our products. If that were to occur for a previously cleared or approved product, we may be required to cease marketing or recall the modified device until we obtain the necessary clearance or approval. Under these circumstances, we may also be subject to significant regulatory fines or other penalties. If any of the foregoing were to occur, our financial condition and results of operations could be negatively impacted.

We and our manufacturers will be required to comply with current GMPs and GTPs and could be subject to suspensions or product withdrawals if found non-compliant.

The FDA regulates the facilities, processes and procedures used to manufacture and market medical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with "current good manufacturing practices," or cGMP, regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects our manufacturing facilities and those of our subcontractors and procedures to assure compliance. The FDA may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility for a particular drug or medical device is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, or a third party contract manufacturing facility faces manufacturing problems, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could adversely affect our business, results of operations, financial condition and cash flow.

We will be subject to ongoing federal and state regulations, and if we fail to comply, our business could be seriously harmed.

Following initial regulatory approval of any products that we may develop, we will be subject to continuing regulatory review, including review of adverse (drug or device) experiences or reactions and clinical results that are reported after our products become commercially available. This would include results from any post-marketing tests or continued actions required by a condition of approval. The manufacturing facilities we may use to make any of our products may become subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often requires FDA approval before the product, as modified, can be marketed. In addition, for products we develop in the future, we and our contract manufacturers may be subject to ongoing FDA requirements for submission of safety and other post-market information. If we or any of our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

issue warning letters;

impose civil or criminal penalties;

suspend or withdraw our regulatory approval;

suspend or terminate any of our ongoing clinical trials;

refuse to approve pending applications or supplements to approved applications filed by us;

impose restrictions on our operations;

close the facilities of our contract manufacturers; and/or

seize or detain products or require a product recall.

Additionally, regulatory review covers a company's activities in the promotion of its medical products, with significant potential penalties and restrictions for promotion of drugs, devices or tissues for an unapproved use. Sales and marketing programs, such as illegal promotions to health care professionals, are under scrutiny for compliance with various mandated requirements. We are also required to submit information on open and completed clinical trials to public registries and databases. Failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined, be forced to remove a product from the market or experience other adverse consequences, including delay, which would materially harm our financial results. Additionally, we may not be able to obtain the labeling claims necessary or desirable for product promotion.

We and our sales personnel, whether employed by us or by others, must comply with various federal and state anti-kickback, self-referral, false claims and similar laws, any breach of which could cause a material adverse effect on our business, financial condition and results of operations.

Our relationships with physicians, hospitals and the marketers of our products are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to liability, or claims of alleged violations. Possible sanctions for violation of these fraud and abuse laws include monetary fines; civil and criminal penalties; exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers' compensation programs and TRICARE, the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents, retirees and their dependents; and forfeiture of amounts collected in violation of such prohibitions. Certain states have similar fraud and abuse laws that also authorize substantial civil and criminal penalties for violations. Any government investigation or a finding of a violation of these laws would likely result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations.

19

The federal Anti-Kickback Statute prohibits any knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by any federal healthcare program, including Medicare.

The scope and enforcement of the healthcare fraud and abuse laws is uncertain and subject to rapid change. There can be no assurance that federal or state regulatory or enforcement agencies will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition and results of operations. Any state or federal investigation, regardless of the outcome, could be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going-forward basis only.

If we engage additional physicians on a consulting basis, the agreements with these physicians will be structured to comply with all applicable laws, including the federal ban on physician self-referrals (commonly known as the “Stark Law”) the federal Anti-Kickback Statute, state anti-self-referral and anti-kickback laws. Even so, it is possible that regulatory or enforcement agencies or courts may in the future view these agreements as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties. Because our strategy includes the involvement of physicians who consult with us on the design of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with our physician advisors who refer or order our products to be in violation of one or more health care fraud and abuse laws. Such government action could harm our reputation and the reputations of our physician advisors. In addition, the cost of noncompliance with these laws could be substantial because we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from state and federal healthcare programs, including Medicare and Medicaid, for non-compliance.

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

Our success depends in part on our ability to protect the proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of trademark laws and confidentiality, noncompetition and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. Our patents and patent applications, if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if it attempts to enforce them, may not necessarily be upheld by the courts. In addition, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be favorable to us. Efforts to enforce any of our proprietary rights could be time-consuming and expensive, which could adversely affect our business and prospects and divert management’s attention.

We are dependent on proprietary know-how.

Our manufacturing know-how as to mixing, coating and cross-linking may be able to be duplicated, even if it is difficult to do so. There is no assurance that, should we apply for intellectual property protection for our intellectual property, we would be able to obtain such protection. Therefore, our competitors may develop or market technologies that are more effective or more commercially attractive than ours.

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

Despite our efforts to protect our proprietary rights, there is no assurance that such protections will preclude our competitors from developing and/or marketing similar products. While we are not aware of any third party intellectual property that would materially affect our business, our failure or inability to obtain patents and protect our proprietary information could result in our business being adversely affected.

If we are not able to establish and maintain successful arrangements with third parties or successfully build our own sales and marketing infrastructure, we may not be able to commercialize our products, which would adversely affect our business and financial condition.

We are currently expanding our sales and marketing capabilities. To commercialize our products, we must continue to develop our own sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services for us. The third parties may not be capable of successfully selling any of our products. We will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all.

We may face intellectual property infringement claims that could be time-consuming, costly to defend and could result in our loss of significant rights and, in the case of patent infringement claims, the assessment of treble damages.

On occasion, we may receive notices of claims of our infringement, misappropriation or misuse of other parties' proprietary rights. We may have disputes regarding intellectual property rights with the parties that have licensed those rights to us. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of its outcome, is expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. In addition, the outcome of such litigation may be unpredictable. If there is a successful claim of infringement against us, we may be required to pay substantial damages—including treble damages if we were to be found to have willfully infringed a third party's patent—to the party claiming infringement, and to develop non-infringing technology, stop selling our products or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, modifying our products to exclude infringing technologies could require us to seek re-approval or clearance from various regulatory bodies for our products, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our technology. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our products or using technology that contains the allegedly infringing intellectual property, which could harm our business.

Our products risk exposure to product liability claims

We are and, if successful in developing, testing and commercializing our products, will increasingly be, exposed to potential product liability risks, which are inherent in the testing, manufacturing and marketing of such products. It is likely we will be contractually obligated, under any distribution agreements that we enter into with respect to products we manufacture, to indemnify the individuals and/or entities that distribute our products against claims relating to the manufacture and sale of products distributed by such distribution partners. This indemnification liability, as well as direct liability to consumers for any defects in the products sold, could expose us to substantial risks and losses. While we have obtained product liability insurance, there can be no assurance that we will be able to maintain such insurance on acceptable terms or that such insurance will provide adequate coverage against potential liabilities. As we begin to sell and distribute our new line of proprietary products, we intend to increase the limits of our product liability insurance. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

Healthcare policy changes, including recent laws to reform the U.S. healthcare system, may have a material adverse effect on us.

Healthcare costs have risen significantly over the past decade. There have been, and continue to be, proposals by legislators, regulators, and third-party payers to keep these costs down. Certain proposals, if passed, would impose limitations on the prices we will be able to charge for our products, or the amounts of reimbursement available for our products from governmental agencies or third-party payers. These limitations could have a material adverse effect on our financial position and results of operations.

Various healthcare reform proposals have emerged at the federal and state levels. We cannot predict the exact effect newly enacted laws or any future legislation or regulation will have on us. However, the implementation of new legislation and regulation may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially. In addition, the enacted excise tax may materially and adversely affect our operating expenses and results of operations.

Decisions in reimbursement levels by governmental or other third-party payers for procedures using our products may have an adverse impact on acceptance of our products.

We believe that our products will be purchased principally by hospitals or physicians, which typically bill various third-party payers, such as state and federal healthcare programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for the products and services provided to their patients. The ability of our customers to obtain appropriate reimbursement for products and services from third-party payers is critical to the success of our business because reimbursement status affects which products customers purchase and the prices they are willing to pay. In addition, our ability to obtain reimbursement approval in foreign jurisdictions will affect our ability to expand our product offerings internationally.

Third-party payers have adopted, and are continuing to adopt, a number of policies intended to curb rising healthcare costs. These policies include:

imposition of conditions of payment by foreign, state and federal healthcare programs as well as private insurance plans, and;

reduction in reimbursement amounts applicable to specific products and services.

Adverse decisions relating to coverage or reimbursement of our products would have an adverse impact on the acceptance of our products and the prices that our customers are willing to pay for them.

We are unable to predict whether foreign, federal, state or local healthcare reform legislation or regulation affecting our business may be proposed or enacted in the future, or what effect any such legislation or regulation would have on our business. Changes in healthcare systems in the U.S. or internationally in a manner that significantly reduces reimbursement for procedures using our products or denies coverage for these procedures would also have an adverse impact on the acceptance of our products and the prices which our customers are willing to pay for them.

It may be difficult to replace some of our suppliers.

In general, raw materials essential to our business are readily available from multiple sources. However, for reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. The Dow Chemical Company and the BASF Corporation are the principal manufacturers of the two polymers, polyethylene oxide and polyvinylpyrrolidone, respectively, that we primarily use in the manufacture of hydrogels. Carolina Silver is the principal manufacturer utilized in production of our TheraBond dressings. Carolina Silver utilizes a proprietary and patented manufacturing process.

We believe that, due to the size and scale of production of our suppliers, there should be adequate supply of these raw materials from these manufacturers. In addition, our policy is to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time. However, there is no guarantee that our inventory will be sufficient to carry us through any disruption in supply. Because we have no direct control over our third-party suppliers, interruptions or delays in the products and services provided by these third parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary raw materials or products, we may be unable to redesign or adapt our technology to work without such raw materials or products or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs or quality control problems.

Under our distribution agreement with Sorbion and our supply agreements with CCT, we receive finished goods from these parties. Because we have no direct control over these suppliers, interruptions or delays in the products and services provided by these parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary products, we would be unable to sell these products, and, therefore, could experience a significant adverse impact on our revenue.

We purchase the UltraMIST system from two sources. Reliance on outside suppliers makes us vulnerable to a number of risks that could impact our ability to manufacture the UltraMIST System and/or disposable applicators, resulting in harm to our business, including:

- inability to obtain an adequate supply in a timely manner or on commercially reasonable terms;
- uncorrected defects that impact the performance, efficacy and safety of its products;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- delays in delivery by our suppliers due to changes in demand from us or other customers; and
- delays in delivery or production stoppage by our supplier due to a shortage of one or more of the components comprising our product.

If the supply of the UltraMIST System or the disposable applicators for the MIST Therapy System or UltraMIST System or saline bottles/bags is interrupted or significantly delayed and we are unable to acquire product from alternate sources in a timely manner and at a commercially reasonable price, our ability to meet our customers' demand would be impaired and our business could be harmed. Identifying and qualifying additional or replacement suppliers for the UltraMIST System or disposable applicators may not be accomplished quickly or at all and could involve significant additional costs. Interruption of supply from our suppliers or failure to obtain additional suppliers would limit its ability to distribute its products and could therefore have an adverse effect on our business.

We are dependent upon third-party local distributors to market and distribute our products in key markets.

We rely on third-party distributors for marketing and distribution of our products in certain markets, both domestically and internationally. Our success in generating sales in markets where we have engaged local distributors depends in part on the efforts of others whom we do not employ. Many of these distributors have only limited personnel, which could impair their ability to successfully market, sell and service our products. Because of limited resources or for other reasons, they may not comply with applicable local regulations or respond promptly to adverse event reporting requirements under U.S. FDA regulations. As a result of such failures to comply with regulatory requirements, we may experience significant loss of revenue, increased costs and damage to our reputation, and our business, financial condition and results of operations could be materially adversely affected. In addition, if a distributor is terminated by us or goes out of business, it may take us a period of time to locate an alternative distributor, to transfer or obtain appropriate regulatory approvals and to train its personnel to market our products, and our ability to sell and service our products in the region formerly serviced by such terminated distributor could be materially adversely affected. Any of these factors could materially adversely affect our revenue from international markets, increase our costs in those markets or damage our reputation.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause its business and reputation to suffer.

In the ordinary course of our business, we use networks to collect and store sensitive data, including intellectual property, proprietary business information and that of its customers, suppliers and business partners, personally identifiable information of our customers and employees, and data relating to patients who use its products. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, its information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and the services we provide to customers, damage our reputation, and cause a loss of confidence in its products and services, which could adversely affect our operating margins, revenues and competitive position.

We are subject to federal and state regulation with respect to electron beam radiation services and facilities.

We are also subject to federal and state regulation with respect to electron beam radiation services and facilities. The expansion of our business into the manufacturing and distribution of our products for consumer use will subject us to additional governmental regulation.

Risks Related to the Common Stock

Our stock price has been and may continue to be volatile, which could result in substantial losses for investors.

The market price of our common stock has been and is likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by us or our competitors;
- additions or departures of key personnel;
- sales of our common stock, particularly under any registration statement for the purposes of selling any other securities, including management shares;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship;
- industry developments;
- economic, political and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market price of our common stock.

Our stock price, and the stock price of many other life science companies, have suffered significant declines over the past 12 months.

Market prices for securities of life sciences companies, particularly companies like ours with limited product revenues, have been highly volatile and have suffered sharp losses over the past 12 months. As a result of these declines, it has become much harder for life sciences companies, like us, to raise money, as needed, in the capital markets. As such, should we desire to sell equity in the future to raise capital, such capital may not be available on favorable terms, or at all. In addition, any such capital raises could be highly dilutive to current stockholders. Depressed valuations of our stock will also make it harder for us to consummate strategic transactions or acquisitions, which have historically been a significant part of our growth strategy, absent significant dilution to our current investors.

We do not expect to pay dividends in the future. As a result, any return on investment may be limited to the value of our common stock.

We currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. As a result, you should not rely on an investment in our securities if you require dividend income. Capital appreciation, if any, of our shares may be your sole source of gain for the foreseeable future. Moreover, you may not be able to re-sell your shares at or above the price you paid for them.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. It also requires an independent registered public accounting firm to test our internal control over financial reporting and report on the effectiveness of such controls. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the U.S. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood

of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our stock trades. This could, in turn, negatively affect our ability to access public debt or equity markets for capital.

Our board of directors can authorize the issuance of preferred stock, which could diminish the rights of holders of our common stock, and make a change of control of us more difficult even if it might benefit our shareholders.

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our shareholders.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price of our common stock.

In addition, if our shareholders sell substantial amounts of our common stock in the public market, upon the expiration of any statutory holding period under Rule 144, upon the expiration of lock-up periods applicable to outstanding shares, or upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an "overhang," in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, could also make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Although we currently have research coverage by securities and industry analysts, you should not invest in our common stock in anticipation that we will increase such coverage. If one or more of the analysts who covers us at any given time downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analyst's ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

As of December 31, 2015 we operated two offices, with our corporate headquarters located in Langhorne, Pennsylvania. Our headquarters in Langhorne is our primary location, where we lease approximately 16,500 square feet of office and manufacturing space. We also maintain an office and warehouse facility in Eden Prairie, Minnesota. In 2016, we will be moving our corporate headquarters to Yardley, Pennsylvania, where we have leased approximately 9,000 square feet of office space. We will still maintain our manufacturing facility in Langhorne, Pennsylvania. We believe that all of our facilities are well maintained and are suitable and adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in lawsuits, investigations and claims that arise in the ordinary course of business. As of the date of this filing, we are not party to any material litigation nor are we aware of any such threatened or pending legal proceedings that we believe could have a material adverse effect on our business, financial condition or operating results.

There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial shareholder of more than 5% of our common stock is an adverse party or has a material interest adverse to our interest.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market for Common Stock

Our common stock has been listed on the NASDAQ Capital Market under the symbol "ALQA" since January 28, 2014. Prior to that date, it was quoted on the OTCQB over-the-counter marketplace.

The following table sets forth, for the periods indicated, the high and low closing prices of our common stock as reported on the NASDAQ Capital Market. The following table also sets forth, for the period of 2014 ending on January 27, 2014, the high and low bid prices of our common stock as reported on the OTCQB. The quotations reflect inter-dealer prices, without retail markup, markdown, or commissions, and may not represent actual transactions.

	High	Low
NASDAQ Capital Market		
2015		
Fourth Quarter	$3.75	$2.05
Third Quarter	$5.55	$3.17
Second Quarter	$5.49	$4.31
First Quarter	$6.23	$4.31
NASDAQ Capital Market		
2014		
Fourth Quarter	$5.30	$3.89
Third Quarter	$6.07	$4.62
Second Quarter	$8.49	$5.50
January 28, 2014 - March 31, 2014	$9.16	$7.86
OTCQB		
2014		
January 1, 2014 - January 27, 2014	$10.02	$6.99

Holders of Record

As of February 17, 2016, there were approximately 241 holders of record of our common stock.

Dividends

We have never paid cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future, but intend to retain our capital resources for reinvestment in our business.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2015.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included in this report. This discussion and analysis contains forward-looking statements based on our current expectations, assumptions, estimates and projections. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those indicated in these forward-looking statements as a result of certain factors, as more fully discussed in Item 1 of this report, entitled "Business," under "Forward-Looking Statements" and Item 1A of this report, entitled "Risk Factors."

Overview

We are a provider of advanced wound care solutions. We have a suite of advanced wound care solutions that enable surgeons, clinicians, and wound care practitioners to address some of the challenges presented by chronic and advanced wounds. We have built this portfolio through our proprietary hydrogel technology platform, targeted acquisitions, and through licensing and distribution agreements with strategic partners that include sorbion GmbH & Co. KG, an affiliate of BSN Medical, Inc., and Celgene Cellular Therapeutics, a subsidiary of Celgene Corporation. Our contract manufacturing business provides custom hydrogels to the OEM market.

Results of Operations

Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

Overview. For the years ended December 31, 2015 and 2014, we had a net loss of $26.0 million and $25.4 million, respectively. Included in the operating loss for the years ended December 31, 2015 and 2014 was non-cash stock-based compensation of $8.6 million and $10.7 million, and fair value adjustments to contingent consideration of ($1.5) million and $232,000, respectively. We expect our future growth to consist of both organic and acquisition growth from product sales.

Revenues, net. For the year ended December 31, 2015 revenues increased by $10.2 million, or 214%, to $15 million from $4.8 million for the year ended December 31, 2014. The increase in our overall revenue was primarily due to increase in product sales.

The components of revenue were as follows for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	2014
Revenues		
Products	$12,905,326	$3,003,520
Contract manufacturing	2,135,603	1,782,611
Total revenues, net	$15,040,929	$4,786,131

Our growth rates for the years ended December 31, 2015 and 2014 were as follows:

	Year Ended December 31,			
	2015		2014	
Revenue growth	$10,254,798		$2,988,386	
% Growth over prior year	214.3	%	166.2	%
Comprised of:				
% of organic growth*	71.8	%	83.0	%
% of acquisition growth**	142.5	%	83.2	%
	214.3	%	166.2	%

*2015 organic revenue growth represents growth from contract manufacturing and sales of our hydrogel, sorbion, and Biovance products as well as TheraBond sales subsequent to May 2015. 2014 organic revenue growth represents growth from contract manufacturing and sales of our hydrogel, sorbion, and Biovance products.

**2015 acquisition revenue growth represents growth from the sale of the MIST Therapy product line acquired in the purchase of Celleration in May 2015 and TheraBond sales through May 2015. 2014 acquisition growth represents growth from the sale of the TheraBond product line acquired in the purchase of Choice Therapeutics in May 2014.

Gross profit. Our gross profit was $9.0 million for the year ended December 31, 2015 compared to gross profit of $1.5 million for the year ended December 31, 2014. The improved results for the year ended December 31, 2015, as compared to 2014 was primarily due to the greater volume of product sales as product revenue typically commands higher gross profit margins. Gross margin on our product sales was approximately 77%, while our overall gross margin was approximately 60% for year ended December 31, 2015. Gross margin on our product sales was approximately 70%, while our overall gross margin was approximately 32% for year ended December 31, 2014. Gross margin for the year ended December 31, 2015 was favorably impacted by our acquisition of MIST Therapy from Celleration. We expect our gross profit to continue to increase as a result of product sales becoming a higher proportion of our total sales.

The components of cost of revenues are as follows for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	2014
Cost of revenues		
Materials and finished products	$3,571,110	$1,376,278
Stock-based compensation	364,384	199,781
Compensation and benefits	865,741	696,868
Depreciation and amortization	644,479	586,945
Equipment, production and other expenses	603,806	411,083
Total cost of revenues	$6,049,520	$3,270,955

Selling, general and administrative expenses. The following table highlights selling, general and administrative expenses by type for the year ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	2014
Selling, general and administrative expenses		
Compensation and benefits	$12,551,870	$7,173,212
Stock-based compensation	8,269,403	10,530,265
Professional fees	2,674,009	2,135,365
Marketing	2,508,516	1,607,016
Depreciation and amortization	2,222,129	493,389
Royalty fees	729,084	516,893
Other expenses	6,225,425	3,698,868
Total selling, general and administrative expenses	$35,180,436	$26,155,008

Selling, general and administrative expenses increased by $9.0 million, to $35.2 million for year ended December 31, 2015, as compared to $26.2 million for year ended December 31, 2014.

Stock-based compensation decreased by $2.3 million, to $8.3 million for the year ended December 31, 2015, as compared to $10.5 million for the year ended December 31, 2014. The decrease in stock-based compensation is primarily due to the vesting of equity awards granted in prior years and lower weighted average estimated fair value of options granted during the year ended December 31, 2015 as compared to the year ended December 31, 2014. This was offset by an increase in awards granted. Compensation and benefits increased by $5.4 million, to $12.6 million for the year ended December 31, 2015, as compared to $7.2 million for the year ended December 31, 2014. The increase in compensation and benefits was primarily due to the increase in the number of full-time employees from 47 at December 31, 2014 to 87 at December 31, 2015. We do not intend to significantly increase our headcount in 2016.

Marketing expenses increased by $0.9 million to $2.5 million for the year ended December 31, 2015, as compared to $1.6 million for the year ended December 31, 2014. The increase was primarily due to increased efforts to market our

proprietary and licensed products through tradeshows, sample products, market research, marketing materials and the addition of the MIST Therapy product line. Also included in the year ended December 31, 2015 are marketing expenses related to the rebranding of our TheraBond product line.

Royalty expenses increased by $212,000 to $729,000 for the year ended December 31, 2015, as compared to $517,000 for the year ended December 31, 2014. The increase was primarily due to the scheduled increase in minimum royalties for the exclusive right and license to manufacture and distribute SilverSeal products. The minimum royalty due for the year ended December 31, 2015 is $500,000 compared to $400,000 for the year ended December 31, 2014. Also included in royalty expense for the year ended December 31, 2015 is approximately $229,000 of royalties due in connection with sales of our Biovance product, as compared to $67,000 for the year ended December 31, 2014.

The increase in other selling, general and administrative expense, including professional fees, is primarily in support of our revenue growth. Other selling, general and administrative expenses consist of costs associated with our selling efforts and general management, including recruiting, information technology, travel, training and third party logistics.

Research and product development expenses. During the year ended December 31, 2015, we incurred research and product development expenses of $715,000 related to a randomized controlled trial for our Biovance product in chronic diabetic foot wounds. We expect our research and product development costs to increase over the next few quarters as the controlled trial progresses.

Acquisition-related expenses. During the year ended December 31, 2015, we incurred acquisition-related costs of $2.9 million in connection with due diligence, professional fees, and other expenses related to the acquisition of Celleration, compared to $547,000 related to the acquisition of Choice Therapeutics during the year ended December 31, 2014.

Income tax benefit. During the year ended December 31, 2015, we recorded income tax benefit of approximately $1.7 million. The income tax benefit is related to an adjustment of the allocation of purchase price for the acquisition of Celleration, related to the release of valuation allowances of approximately $1.7 million resulting from the acquisition of Celleration in May 2015.

Liquidity and Capital Resources

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

As of December 31, 2015, we had cash and cash equivalents totaling $26.1 million compared to $16.8 million at December 31, 2014. The increase was largely attributable to net proceeds from the issuance of common stock of $32.2 million, net proceeds from long-term debt of $14.2 million offset by cash used in operating activities of $21.6 million and $14.9 million used to fund the acquisition of Celleration during the year ended December 31, 2015.

Net cash flow used in operating activities was $21.6 million and $13.3 million for the year ended December 31, 2015 and 2014, respectively. Net cash used in operating activities was principally to fund our net cash loss which included $2.9 million of acquisition-related costs related to our acquisition of Celleration and $1.1 million in connection with the payment of severance to two former Celleration executives, subsequent to the close of the transaction. These severance payments resulted in a decrease in accrued expenses. We have also significantly increased our inventory stocking levels in order to meet an anticipated increase in demand for our products.

Net cash used in investing activities was $15.4 million for the year ended December 31, 2015, compared to $2.3 million used in investing activities in the year ended December 31, 2014. Cash used in investing activities primarily relates to the acquisition of Celleration during the year ended December 31, 2015 and Choice Therapeutics during the year ended December 31, 2014.

Net cash flow generated from financing activities was $46.3 million for the year ended December 31, 2015, compared to $20.3 million for the year ended December 31, 2014. During the year ended December 31, 2015, we received net

proceeds from the issuance of common stock of $32.2 million compared to $14.4 million during the year ended December 31, 2014. Additionally, during the year ended December 31, 2015 we received net proceeds from long-term debt of $14.2 million. During the year ended December 31, 2014, we received proceeds from stock option and warrant exercises of $6.6 million. This was offset by the payment of withholding taxes related to vesting of certain restricted awards of $669,000.

At December 31, 2015, current assets totaled $32.7 million and current liabilities totaled $11.8 million, as compared to current assets totaling $19.6 million and current liabilities totaling $4.1 million at December 31, 2014. As a result, we had working capital of $20.9 million at December 31, 2015 compared to working capital of $15.5 million at December 31, 2014.

Our cash requirements have historically been for mergers and acquisitions, product development, clinical trials, marketing and sales activities, finance and administrative costs, capital expenditures and overall working capital. We have experienced negative operating cash flows since inception and have funded our operations primarily from sales of common stock and other securities.

Liquidity Outlook

The implementation of our growth strategy will continue to result in an increase in our fixed cost structure. Due to the time delay between outlays for working capital expenditures, such as costs to acquire rights to additional products, the hiring and training of sales agents and personnel, marketing costs, the purchasing of inventory, the billing and collection of revenue, the conducting of a post marketing clinical trial for Biovance, debt service costs and diligence costs related to merger and acquisition activities, we expect to have a net cash outflow from operating activities and revenues from sales brought in as a result of these expenditures.

The Company has agreed to pay contingent consideration of three and one half times revenue from acquired MIST Therapy products in excess of certain revenue targets for the years ending December 31, 2015 and 2016, payable in equal amounts of cash and the Company’s common stock. This contingent consideration is payable in two installments in March 2016 and March 2017. As of December 31, 2015, the present value of the contingent consideration due in 2016 and 2017 was approximately $5.1 million and $10.9 million, respectively. The long-term portion of the contingent consideration liability, due in 2017, was discounted at a rate of 15.5%.

On May 29, 2015, simultaneously with and related to the closing of the Celleration acquisition, the Company entered into a Credit Agreement and Guaranty (the "Credit Agreement"). The Credit Agreement provided a senior secured term loan in a single borrowing to the Company in the principal amount of $15.5 million. The Credit Agreement (i) has a four-year term, (ii) accrues interest at an annual rate equal to the greater of (a) one-month LIBOR or 1% plus (b) 9.75%, payable monthly (iii) monthly principal payments of $225,000 commencing in May 2017, with the remaining unpaid balance due on the maturity date and (iv) is secured by a first priority lien on substantially all of the Company's assets.

A shelf registration statement on Form S-3 relating to the public offering of the shares of common stock was filed with the SEC and was declared effective on September 25, 2014. This registration statement will enable us to offer and sell to the public from time to time in one or more offerings, up to $100,000,000 of common and preferred stock, debt securities, warrants, units or any combination thereof. The terms of any securities offered under the registration statement, and the intended use of the net proceeds resulting therefrom, will be established at the times of the offerings and will be described in prospectus supplements filed with the SEC at the times of the offerings. There can be no assurance that we will be successful in securing additional capital in sufficient amounts and on terms favorable to us.

On May 4, 2015, we closed an underwritten public offering of 7,582,418 shares of its common stock at a price to the public of $4.55 per share. Proceeds from this offering, net of underwriter fees were approximately $32.2 million. The shares of common stock were issued pursuant to our shelf registration statement on Form S-3. We intend to use the net proceeds from this offering to fund the commercial expansion of its marketed products, to pursue additional product platforms, and for working capital and general corporate purposes.

We believe that our cash on hand will be sufficient to fund our current business for at least the next 12 months, however, we will require additional capital in order to execute the longer term aspects of our business. Our future results of operations involve significant risks and uncertainties. Factors that could affect our future operating results and cause actual results to vary materially from expectations include, but are not limited to, potential demand for our products, unfavorable decisions on product reimbursement, risks from competition, regulatory approval of our new products, technological change, and dependence on key personnel.

Off Balance Sheet Arrangements

As of December 31, 2015, we had no off-balance sheet arrangements in the nature of guarantee contracts, retained or contingent interests in assets transferred to unconsolidated entities (or similar arrangements serving as credit, liquidity or market risk support to unconsolidated entities for any such assets), or obligations (including contingent obligations) arising out of variable interests in unconsolidated entities providing financing, liquidity, market risk or credit risk support to us, or that engage in leasing, hedging or research and development services with us.

Critical Accounting Policies

The preparation of financial statements in accordance with generally accepted accounting principles requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the reporting period. The accounting policies that we believe require more significant estimates and assumptions include valuing equity securities and derivative financial instruments issued in financing transactions, allowance for doubtful accounts, inventory reserves, deferred taxes and related valuation allowances, and the fair values of long lived assets, intangibles, goodwill and contingent consideration. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ significantly from these estimates under different assumptions or conditions. There have been no material changes to these estimates for the periods presented in this Annual Report.

We believe that of our significant accounting policies, which are described below and in Note 2 to our audited consolidated financial statements included in this Item 7 of this Annual Report, the following accounting policies involve a greater degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our financial condition and results of operations.

Goodwill

Goodwill represents the excess purchase price of acquired businesses over the fair values attributed to underlying net tangible assets and identifiable intangible assets. We assess the recoverability of goodwill annually, at the beginning of the fourth quarter of each fiscal year, and between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. Impairment testing for goodwill is done at a reporting unit level. Under Financial Accounting Standards Board “FASB” guidance for goodwill and other intangible assets, a reporting unit is defined as an operating segment or one level below the operating segment, called a component. However, two or more components of an operating segment will be aggregated and deemed a single reporting unit if the components have similar economic characteristics. In 2013, we adopted authoritative accounting guidance that allows us to first assess qualitative factors to determine whether it is necessary to perform the more detailed two-step quantitative goodwill impairment test. We perform the quantitative test if the qualitative assessment determined it is more likely than not that a reporting unit’s fair value is less than its carrying amount. We may elect to bypass the qualitative assessment and proceed directly to the quantitative test for any reporting unit. When performing the quantitative test, an impairment loss is recognized if the carrying amount of the reporting unit’s net assets exceeds the estimated fair value of the reporting unit and the carrying amount of reporting unit goodwill is determined to exceed the implied fair value of that goodwill. The estimated fair value of a reporting unit is calculated using a discounted cash flow model. There were no goodwill impairment charges recorded during the years ended December 31, 2015 or 2014.

Impairment of Long-Lived Assets Subject to Amortization

We amortize intangible assets with finite lives over their estimated useful lives and review them for impairment at least annually or whenever an impairment indicator exists. We continually monitor events and changes in circumstances that could indicate carrying amounts of our long-lived assets, including our intangible assets, may not be recoverable. When such events or changes in circumstances occur, we assess recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the future undiscounted cash flows are less than the carrying amount of these assets, we recognize an impairment loss based on the excess of the carrying amount over the fair value of the assets. There were no long-lived asset impairment charges recorded during the years ended December 31, 2015 or 2014.

Recent Accounting Pronouncements

Recently issued accounting pronouncements are addressed in Note 2 in the Notes to Consolidated Financial Statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLMENTARY DATA

Our Consolidated Financial Statements and the relevant notes to those statements are attached to this report beginning on page F-1.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

***Disclosure Controls and Procedures*.**

We conducted an evaluation of the effectiveness of our "disclosure controls and procedures" ("Disclosure Controls"), as defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2015, the end of the period covered by this Annual Report on Form 10-K. The Disclosure Controls evaluation was done under the supervision and with the participation of management, including our chief executive officer and chief financial officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon this evaluation, our chief executive officer and chief financial officer have concluded that our Disclosure Controls were effective at the reasonable assurance level as of December 31, 2015.

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 the consolidated financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate over time.

Management, including our chief executive officer and chief financial officer, 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 Organizations of the Treadway Commission ("COSO") in *Internal Control—Integrated Framework (2013)*. Based on its assessment and those criteria, management has concluded that we maintained effective internal control over financial reporting as of December 31, 2015.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by Marcum LLP, an independent registered public accounting firm, as stated in their report which is included in this

Annual Report on Form 10-K.

31

Changes in Internal Control over Financial Reporting.

We regularly review our system of internal control over financial reporting to ensure we maintain an effective internal control environment. As we expand, we make changes to our processes and systems to improve controls and we continue to create and enhance the design and documentation of our internal control processes to ensure effective controls over financial reporting.

There have been no changes in our internal control over financial reporting during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information with respect to this item will be set forth in our definitive proxy statement for the 2016 Annual Meeting of Stockholders, which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this report, (our “Proxy Statement”), and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information with respect to this item will be set forth in our Proxy Statement, and is incorporated herein by reference.

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

Information with respect to this item will be set forth in our Proxy Statement, and is incorporated herein by reference.

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

Information with respect to this item will be set forth in our Proxy Statement, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information with respect to this item will be set forth in our Proxy Statement, and is incorporated herein by reference.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

(1) Financial Statements:

(2) Financial Statement Schedules:

None

(3) Exhibits:

See “Index to Exhibits” for a description of our exhibits.

32

SIGNATURES

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

ALLIQUA
BIOMEDICAL, INC.

By: /s/ DAVID JOHNSON
David Johnson
President and Chief
Executive Officer

Date: February 23, 2016

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

Signature	Title	Date
/s/ DAVID JOHNSON David Johnson	President, Chief Executive Officer and Director (principal executive officer)	February 23, 2016
/s/ BRIAN M. POSNER Brian M. Posner	Chief Financial Officer, Treasurer and Secretary (principal financial and accounting officer)	February 23, 2016
/s/ JEROME ZELDIS Jerome Zeldis, M.D., Ph.D.	Chairman of the Board of Directors	February 23, 2016
/s/ JOSEPH LEONE Joseph Leone	Director	February 23, 2016
/s/ ANDREW AFRICK Andrew Africk	Director	February 23, 2016
/s/ GARY RESTANI	Director	February 23, 2016

Gary Restani		
/s/ JEFFREY SKLAR Jeffrey Sklar	Director	February 23, 2016
/s/ MARK WAGNER Mark Wagner	Director	February 23, 2016
Winston Kung	Director	February 23, 2016

Index to Exhibits

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated May 5, 2014, by and between Alliqua, Inc., ALQA Merger Sub, Inc., Choice Therapeutics, Inc. and E. James Hutchens, as the Stockholder Representative, incorporated by reference to Exhibit 2.1 to the Form 8-K filed May 6, 2014.
2.1	Agreement and Plan of Merger, dated June 5, 2014, by and between Alliqua, Inc. and Alliqua BioMedical, Inc., incorporated by reference to Exhibit 2.1 to the Form 8-K filed June 11, 2014.
2.3**	Agreement and Plan of Merger, dated February 2, 2015, by and among Alliqua BioMedical, Inc., ALQA Cedar, Inc., Celleration, Inc. and certain representatives of the stockholders of Celleration, Inc., as identified therein, incorporated by reference to Exhibit 2.1 to the Form 8-K filed February 2, 2015.
3.1	Certificate of Incorporation of Alliqua BioMedical, Inc., incorporated by reference to Exhibit 3.1 to the Form 8-K filed June 11, 2014.
3.2	Certificate of Amendment to Certificate of Incorporation of Alliqua BioMedical, Inc., incorporated by reference to Exhibit 3.3 to the Form 8-K filed June 11, 2014.
3.3	Bylaws of Alliqua BioMedical, Inc., incorporated by reference to Exhibit 3.2 to the Form 8-K filed June 11, 2014.
4.1	Form of Warrant used in connection with February 16, 2012 private placement, incorporated by reference to Exhibit 10.2 to the Form 8-K filed February 21, 2012.
4.2	Form of Warrant used in connection with August 14, 2012 private placement, incorporated by reference to Exhibit 10.2 to the Form 8-K filed August 16, 2012.
4.3	Form of Warrant used in connection with November 8, 2012 private placement, incorporated by reference to Exhibit 10.2 to the Form 8-K filed November 14, 2012.
4.4	Form of Warrant used in connection with February 22, 2013 private placement, incorporated by reference to Exhibit 10.2 to the Form 8-K filed February 25, 2013.
4.5	Form of Warrant used in connection with April and May 2013 private placement, incorporated by reference to Exhibit 10.2 to the Form 8-K filed April 26, 2013.
4.6	Form of Warrant used in connection with June 28, 2013 private placement, incorporated by reference to Exhibit 10.2 to the Form 8-K filed July 5, 2013.
4.7	Form of $0.10 Warrant used in connection with October 22, 2013 private placement, incorporated by reference to Exhibit 10.2 to the Form 8-K filed October 28, 2013.
4.8	Warrant issued to Celgene Corporation on November 18, 2013, incorporated by reference to Exhibit 4.12 to the Form 10-K filed December 31, 2013.
4.9	Form of Warrant used in connection with November 18, 2013 private placement, incorporated by reference to Exhibit 4.13 to the Form 10-K filed December 31, 2013.
4.10	Form of Warrant, dated April 14, 2014, by and between Alliqua, Inc. and certain accredited investors, incorporated by reference to Exhibit 10.2 to the Form 8-K filed April 15, 2014.
10.1+	2001 Incentive Stock Purchase Plan, incorporated by reference to Exhibit 10.2 to the Form S-8 filed on May 8, 2003.
10.2+	Form of Nonstatutory Stock Option Agreement under the 2001 Incentive Stock Purchase Plan, incorporated by reference to Exhibit 10.2 to the Form 10-K/A filed May 16, 2013.
10.3+	Form of Incentive Stock Option Agreement under the 2001 Incentive Stock Purchase Plan, incorporated by reference to Exhibit 10.3 to the Form 10-K/A filed May 16, 2013.
10.4	Form of Subscription Agreement, incorporated by reference to Exhibit 10.3 to the Form 8-K filed on May 17, 2010.

10.5+	Form of Offer Letter, incorporated by reference to Exhibit 10.1 to the Form 8-K filed January 5, 2011.
10.6+	Form of Indemnification Agreement, incorporated by reference to Exhibit 10.2 to the Form 8-K filed January 5, 2011.
10.7	Exclusive License Agreement, dated as of July 15, 2011, by and between Noble Fiber Technologies, LLC and Alliqua Biomedical, Inc., incorporated by reference to Exhibit 10.1 to the Form 8-K filed July 20, 2011.
10.8	Collateral Assignment of 510(k) Rights, dated as of July 15, 2011, by and between Noble Fiber Technologies, LLC and Alliqua Biomedical, Inc., incorporated by reference to Exhibit 10.1 to the Form 8-K filed July 20, 2011.
10.9+	2011 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.1 to the Form 8-K filed December 20, 2011.
10.10	Form of Securities Purchase Agreement, by and among Alliqua, Inc. and certain purchasers set forth therein, incorporated by reference to Exhibit 10.1 to the Form 8-K filed February 21, 2012.
10.11	Securities Purchase Agreement, dated as of August 14, 2012, by and among Alliqua, Inc. and certain purchasers set forth therein, incorporated by reference to Exhibit 10.1 to the Form 8-K filed August 16, 2012.
10.12	Securities Purchase Agreement, dated as of November 8, 2012, by and among Alliqua, Inc. and certain purchasers set forth therein, incorporated by reference to Exhibit 10.1 to the Form 8-K filed November 14, 2012.
10.13+	First Amendment to the 2011 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.1 to the Form 8-K filed December 20, 2012.
10.14+	Form of Nonstatutory Stock Option Agreement under the 2011 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.32 to the Form 10-K/A filed May 16, 2013.

10.15+	Form of Incentive Stock Option Agreement under the 2011 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.33 to the Form 10-K/A filed May 16, 2013.
10.16+	Executive Employment Agreement, dated as of February 4, 2013, between Alliqua, Inc. and David Johnson, incorporated by reference to Exhibit 10.1 to the Form 8-K filed February 7, 2013.
10.17+	Indemnification Agreement, dated as of February 4, 2013, in favor of David Johnson, incorporated by reference to Exhibit 10.3 to the Form 8-K filed February 7, 2013.
10.18	Securities Purchase Agreement, dated as of February 22, 2013, by and among Alliqua, Inc. and certain purchasers set forth therein, incorporated by reference to Exhibit 10.1 to the Form 8-K filed February 25, 2013.
10.19	Securities Purchase Agreement, dated as of April 11, 2013, by and among Alliqua, Inc. and certain purchasers set forth therein, incorporated by reference to Exhibit 10.1 to the Form 8-K filed April 26, 2013.
10.20	Securities Purchase Agreement, dated as of June 28, 2013, by and among Alliqua, Inc. and certain purchasers set forth therein, incorporated by reference to Exhibit 10.3 to the Form 8-K filed July 5, 2013.
10.21+	Offer Letter to Brian Posner, dated July 19, 2013, incorporated by reference to Exhibit 10.1 to the Form 8-K filed September 9, 2013.
10.22+	Nonqualified Stock Option Agreement, dated September 3, 2013, between Brian Posner and Alliqua, Inc., incorporated by reference to Exhibit 10.2 to the Form 8-K filed September 9, 2013.
10.23^	Distributor Agreement, dated September 23, 2013, by and between Sorbion GmbH & Co KG and Alliqua Biomedical, Inc., incorporated by reference to Exhibit 10.5 to the Form 10-Q filed November 12, 2013.
10.24^	License, Marketing and Development Agreement, dated as of November 14, 2013, by and between Anthrogenesis Corporation, d/b/a CCT, and Alliqua, Inc., incorporated by reference to Exhibit 10.48 to the Form 10-K filed December 31, 2013.
10.25^	Supply Agreement, dated as of November 14, 2013, by and between Anthrogenesis Corporation and Alliqua, Inc., incorporated by reference to Exhibit 10.49 to the Form 10-K filed December 31, 2013.
10.26	Stock Purchase Agreement, dated as of November 14, 2013, by and between Celgene Corporation and Alliqua, Inc., incorporated by reference to Exhibit 10.50 to the Form 10-K filed December 31, 2013.
10.27	Securities Purchase Agreement, dated as of November 18, 2013, by and among Alliqua, Inc. and certain purchasers set forth therein, incorporated by reference to Exhibit 10.51 to the Form 10-K filed December 31, 2013.
10.28	First Amendment to Executive Employment Agreement dated December 20, 2013, by and between Alliqua, Inc. and David Johnson, incorporated by reference to Exhibit 10.1 to the Form 8-K filed December 27, 2013.
10.29	Nonqualified Stock Option Agreement dated December 20, 2013, by and between Alliqua, Inc. and David Johnson, incorporated by reference to Exhibit 10.2 to the Form 8-K filed December 27, 2013.
10.30+	Option Cancellation and Release Agreement, dated January 6, 2014, by and between Alliqua, Inc. and Richard Rosenblum, incorporated by reference to Exhibit 10.1 to the Form 8-K filed January 10, 2014.
10.31+	Option Cancellation and Release Agreement, dated January 6, 2014, by and between Alliqua, Inc. and David Stefansky, incorporated by reference to Exhibit 10.2 to the Form 8-K filed January 10, 2014.
10.32+	Form of Restricted Stock Award Agreement under the 2011 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.62 to the Form 10-K filed December 31, 2013.
10.33+	Form of Restricted Stock Award Agreement for 2013 Executive Bonuses under the 2011 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.63 to the Form 10-K filed December 31, 2013.
10.34+	Form of Nonqualified Stock Option Agreement (outside of any incentive plan), incorporated by reference to Exhibit 99.8 to the Form S-8 filed January 23, 2014.
10.35+	General Release and Severance Agreement, dated March 14, 2014, by and between Alliqua, Inc. and James Sapirstein, incorporated by reference to Exhibit 10.1 to the Form 8-K filed March 19, 2014.
10.36	Form of Securities Purchase Agreement, dated April 14, 2014, by and between Alliqua, Inc. and certain accredited investors, incorporated by reference to Exhibit 10.1 to the Form 8-K filed April 15, 2014.

10.37	Form of Letter Agreement, dated April 11, 2014, by and between Alliqua, Inc. and certain holders of warrants to purchase Common Stock of Alliqua, Inc., incorporated by reference to Exhibit 10.3 to the Form 8-K filed April 15, 2014.
10.38	Warrant Exchange Agreement, dated April 30, 2014, by and among Alliqua, Inc. and certain holders of warrants to purchase Common Stock of Alliqua, Inc., incorporated by reference to Exhibit 10.1 to the Form 8-K filed May 6, 2014.
10.39+	Alliqua BioMedical, Inc. 2014 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.1 to the Form 8-K filed June 11, 2014.
10.40^	Supply Agreement, dated April 10, 2014, by and between Alliqua, Inc. and Anthrogenesis Corporation, d/b/a Celgene Cellular Therapeutics, incorporated by reference to Exhibit 10.4 to the Form 10-Q filed August 11, 2014.
10.41^	First Amendment to Supply Agreement, dated April 10, 2014 by and between Alliqua, Inc. and Anthrogenesis Corporation, d/b/a Celgene Cellular Therapeutics, incorporated by reference to Exhibit 10.5 to the Form 10-Q filed August 11, 2014.
10.42^	First Amendment to License, Marketing and Development Agreement, dated September 30, 2014, by and between Alliqua, Inc. and Anthrogenesis Corporation, d/b/a Celgene Cellular Therapeutics, incorporated by reference to Exhibit 10.1 to the Form 10-Q filed November 5, 2014.
10.43^	Second Amendment to Supply Agreement, dated September 30, 2014, by and between Alliqua, Inc. and Anthrogenesis Corporation, d/b/a Celgene Cellular Therapeutics, incorporated by reference to Exhibit 10.2 to the Form 10-Q filed November 5, 2014.

10.44	Voting Agreement, dated February 2, 2015, by and between Alliqua BioMedical, Inc. and each of the stockholders of Celleration, Inc., as identified therein, incorporated by reference to Exhibit 10.1 to Amendment No. 1 to Registration Statement on Form S-4 filed on April 2, 2015.
10.45	Commitment Letter, dated February 2, 2015, by and between Perceptive Credit Opportunities Fund, LP and Alliqua BioMedical, Inc., incorporated by reference to Exhibit 10.2 to Amendment No. 1 to Registration Statement on Form S-4 filed on April 2, 2015.
10.46	Side Letter Agreement to Commitment Letter, dated March 10, 2015, by and between Perceptive Credit Opportunities Fund, LP and Alliqua BioMedical, Inc., incorporated by reference to Exhibit 10.3 to Amendment No. 1 to Registration Statement on Form S-4 filed on April 2, 2015.
10.47^	Second Amendment to the License, Marketing and Development Agreement, dated April 30, 2015, by and between Alliqua BioMedical, Inc. and Anthrogenesis Corporation, d/b/a Celgene Cellular Therapeutics, incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 6, 2015.
10.48+	First Amendment to the Alliqua BioMedical, Inc. 2014 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 6, 2015.
10.49+	Form of Incentive Stock Option Agreement under the 2014 Long-Term Incentive Plan, incorporated by reference to Exhibit 99.3 to the Form S-8 filed August 6, 2015.
10.50+	Form of Nonqualified Stock Option Agreement under the 2014 Long-Term Incentive Plan, incorporated by reference to Exhibit 99.4 to the Form S-8 filed August 6, 2015.
10.51+	Form of Restricted Stock Award Agreement under the 2014 Long-Term Incentive Plan, incorporated by reference to Exhibit 99.5 to the Form S-8 filed August 6, 2015.
10.52+	Form of Restricted Stock Unit Agreement under the 2014 Long-Term Incentive Plan, incorporated by reference to Exhibit 99.6 to the Form S-8 filed August 6, 2015.
10.53	Credit Agreement and Guaranty, dated May 29, 2015, by and among Alliqua BioMedical, Inc., Perceptive Credit Opportunities Fund, LP and those certain subsidiary guarantors party thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 1, 2015.
10.54	Pledge and Security Agreement, dated May 29, 2015, by and among Alliqua BioMedical, Inc., Perceptive Credit Opportunities Fund, LP and those certain subsidiary guarantor party thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 1, 2015.
10.55	Warrant, dated May 29, 2015, by and between Alliqua BioMedical, Inc. and Perceptive Credit Opportunities Fund, LP, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 1, 2015.
10.56+	Employment Agreement, dated June 3, 2015, by and between Alliqua BioMedical, Inc. and Nino Pionati, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2015.
10.57+	Employment Agreement, dated June 5, 2015, by and between Alliqua BioMedical, Inc. and Brian Posner, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2015
10.58+	Employment Agreement, dated June 5, 2015, by and between Alliqua BioMedical, Inc. and Bradford Barton, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2015.
10.59	First Amendment to Distributor Agreement, dated July 31, 2015, by and between Alliqua BioMedical, Inc. and BSN Medical, Inc., an affiliate of Sorbion GmbK & Co KG, incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 5,

	2015.
21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm to the Form 10-K.
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements

* Filed herewith.

**Certain exhibits and schedules have been omitted and the Company agrees to furnish supplementally to the Securities and Exchange Commission a copy of any omitted exhibits upon request.

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

+ Management contract or compensatory plan or arrangement.

ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of the

Board of Directors and Shareholders of

Alliqua BioMedical, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Alliqua BioMedical, Inc. and Subsidiaries (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements are free of material misstatement. 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 audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Alliqua BioMedical, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Alliqua BioMedical, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2015, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013) and our report dated February 23, 2016 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Marcum LLP

Marcum LLP

New York, NY

February 23, 2016

F-2

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Audit Committee of the

Board of Directors and Shareholders of

Alliqua BioMedical, Inc. and Subsidiaries

We have audited Alliqua BioMedical, Inc. and Subsidiaries' (the "Company") internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013). The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

In our opinion, Alliqua BioMedical, Inc. and Subsidiaries maintained, in all material aspects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended of the Company and our report dated February 23, 2016 expressed an unqualified opinion on those financial statements**.**

/s/ Marcum LLP

Marcum LLP

New York, NY

February 23, 2016

ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2015	December 31, 2014
ASSETS:		
Current Assets:		
Cash and cash equivalents	$26,080,384	$16,770,879
Accounts receivable, net	2,516,808	968,616
Inventory, net	3,132,538	1,411,748
Prepaid expenses and other current assets	942,015	477,824
Total current assets	32,671,745	19,629,067
Improvements and equipment, net	1,846,809	1,434,027
Intangible assets, net	33,893,694	4,387,293
Goodwill	21,166,412	4,100,295
Other assets	172,868	173,042
Total assets	$89,751,528	$29,723,724
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$2,637,971	$1,757,742
Accrued expenses and other current liabilities	3,129,976	2,067,859
Contingent consideration, current	5,146,585	-
Warrant liability	860,651	304,223
Total current liabilities	11,775,183	4,129,824
Long-term debt, net	12,126,390	-
Contingent consideration, long-term	11,881,313	2,931,598
Deferred tax liability	1,468,066	67,000
Other long-term liabilities	75,733	84,071
Total liabilities	37,326,685	7,212,493
Commitments and Contingencies		
Stockholders' Equity		
Preferred Stock, par value $0.001 per share, 1,000,000 shares authorized, no shares issued and outstanding	-	-
Common Stock, par value $0.001 per share, 45,714,286 shares authorized; 27,668,913 and 16,202,689 shares issued and outstanding as of December 31, 2015 and 2014, respectively	27,669	16,203
Additional paid-in capital	148,456,703	92,537,742
Accumulated deficit	(96,059,529)	(70,042,714)

Total stockholders' equity	52,424,843	22,511,231
Total liabilities and stockholders' equity	$89,751,528	$29,723,724

The accompanying notes are an integral part of these consolidated financial statements.

ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2015	2014
Revenue, net of returns, allowances and discounts	$15,040,929	$4,786,131
Cost of revenues	6,049,520	3,270,955
Gross profit	8,991,409	1,515,176
Operating expenses		
Selling, general and administrative	35,180,436	26,155,008
Research and product development	715,074	-
Acquisition-related	2,875,586	546,970
Change in fair value of contingent consideration liability	(1,473,700)	231,598
Total operating expenses	37,297,396	26,933,576
Loss from operations	(28,305,987)	(25,418,400)
Other income (expense)		
Interest expense	(1,564,990)	(384)
Interest income	41,675	30,739
Change in value of warrant liability	2,094,784	(43,390)
Total other income (expense)	571,469	(13,035)
Net loss before income tax	(27,734,518)	(25,431,435)
Income tax benefit (expense)	1,717,703	(14,000)
Net loss	$(26,016,815)	$(25,445,435)
Basic and diluted net loss per common share	$(1.13)	$(1.74)
Weighted average shares used in computing basic and diluted net loss per common share	23,061,931	14,628,981

The accompanying notes are an integral part of these consolidated financial statements.

ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2013	11,484,191	$11,484	$58,538,491	$(44,597,279)	$13,952,696
Issuance of common stock for the purchase of Choice Therapeutics, Inc.	273,368	274	1,992,580		1,992,854
Issuance of common stock for cash, net of issuance costs of $602,500	2,139,287	2,139	14,370,364	-	14,372,503
Exercise of common stock options, net of tendered shares	306,403	307	1,371,607	-	1,371,914
Exercise of warrants, net of issuance costs of $267,174	977,313	977	5,224,610	-	5,225,587
Cashless exercise of warrants	211,295	211	(211)	-	-
Extinguishment of warrant liability	-	-	672,632	-	672,632
Issuance of common stock for services	23,396	23	195,315	-	195,338
Stock-based compensation (A)	836,491	837	10,841,060	-	10,841,897
Net settlement on vesting of restricted stock awards	(98,023)	(98)	(668,657)	-	(668,755)
Warrant exchange	48,968	49	(49)	-	-
Net loss	-	-	-	(25,445,435)	(25,445,435)
Balance, December 31, 2014	16,202,689	$16,203	$92,537,742	$(70,042,714)	$22,511,231
Issuance of common stock for the purchase of Celleration, Inc.	3,168,229	3,168	15,204,332	-	15,207,500
Issuance of common stock for cash, net of issuance costs of $2,303,461	7,582,418	7,582	32,188,958	-	32,196,540

Exercise of common stock options	75,919	76	332,195	-	332,271
Cashless exercise of warrants	8,970	9	(9)	-	-
Extinguishment of warrant liability	-	-	31,498	-	31,498
Stock-based compensation	720,000	720	8,633,067	-	8,633,787
Net settlement on vesting of restricted stock awards	(89,312)	(89)	(471,080)	-	(471,169)
Net loss	-	-	-	(26,016,815)	(26,016,815)
Balance, December 31, 2015	27,668,913	$27,669	$148,456,703	$(96,059,529)	$52,424,843

(A) Includes $307,189 that was part of accrued expenses as of December 31, 2013 and for the year then ended, which was credited to equity upon the issuance of 34,086 restricted common shares during the year ended December 31, 2014.

The accompanying notes are an integral part of these consolidated financial statements.

ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2015	2014
Operating Activities		
Net loss	$(26,016,815)	$(25,445,435)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,866,608	1,080,334
Amortization of deferred lease incentive	(8,338)	(8,337)
Loss on disposal of property and equipment	4,211	-
Deferred income tax (benefit) expense	(1,717,703)	14,000
Provision for doubtful accounts	107,874	-
Provision for inventory obsolescence	58,159	(75,486)
Stock-based compensation expense	8,633,787	10,534,708
Amortization of debt issuance and discount costs	565,225	-
Stock issued for services rendered	-	195,338
Change in value of warrant liability	(2,094,784)	43,390
Fair value adjustment of contingent consideration liability	(1,473,700)	231,598
Changes in operating assets and liabilities:		
Accounts receivable	(779,476)	(800,198)
Inventory	(1,437,806)	(437,832)
Prepaid expenses and other current assets	(257,270)	(387,837)
Accounts payable	571,614	937,639
Accrued expenses and other current liabilities	(639,275)	826,659
Net Cash Used in Operating Activities	(21,617,689)	(13,291,459)
Investing Activities		
Payment for distribution rights	-	(333,333)
Purchase of improvements and equipment	(426,510)	(6,596)
Acquisition of business, net of cash acquired	(14,947,813)	(1,999,526)
Net Cash Used in Investing Activities	(15,374,323)	(2,339,455)
Financing Activities		
Net proceeds from issuance of common stock	32,196,540	14,372,503
Net proceeds from long-term debt	14,243,875	-
Proceeds from the exercise of stock options	332,271	1,371,914
Proceeds from the exercise of warrants	-	5,225,587
Payment of withholding taxes related to stock-based employee compensation	(471,169)	(668,755)
Net Cash Provided by Financing Activities	46,301,517	20,301,249
Net Increase in Cash and Cash Equivalents	9,309,505	4,670,335
Cash and Cash Equivalents - Beginning of period	16,770,879	12,100,544

Cash and Cash Equivalents - End of period	$26,080,384	$16,770,879
Supplemental Disclosure of Cash Flows Information		
Cash paid during the period for:		
Interest	$999,750	$384
Non-cash investing and financing activities:		
Extinguishment of warrant liability due to cashless warrant exercise	$31,498	$672,632
2013 Bonus awarded in equity	-	307,189
Warrant exchange	-	49
Acquisition of business:		
Current assets, excluding cash and cash equivalents	$1,424,480	$408,548
Improvements and equipment	411,492	-
Intangibles	31,952,000	2,683,000
Goodwill	17,066,117	3,674,326
Liabilities assumed	(2,006,527)	(73,494)
Deferred tax liability	(3,122,249)	-
Contingent consideration	(15,570,000)	(2,700,000)
Issuance of common stock for acquisition	(15,207,500)	(1,992,854)

The accompanying notes are an integral part of these consolidated financial statements.

ALLIQUA BIOMEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business and Basis of Presentation

Alliqua BioMedical, Inc. (the "Company") is a provider of advanced wound care solutions. The Company has a suite of advanced wound care solutions that enable surgeons, clinicians, and wound care practitioners to address some of the challenges presented by chronic and advanced wounds.

Principles of Consolidation

The accompanying consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiary, AquaMed Technologies, Inc. All significant inter-company transactions and accounts have been eliminated in consolidation.

Reclassifications

Certain amounts in prior periods have been reclassified to conform to the current year presentation. Such reclassifications did not have a material effect on the Company's financial condition or results of operations as previously reported.

2. Summary of Significant Accounting Policies

Use of Estimates in the Financial Statements

The preparation of the consolidated financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. These estimates and assumptions include valuing equity securities and derivative financial instruments issued in financing transactions, allowance for doubtful accounts, inventory reserves, deferred

taxes and related valuation allowances, and the fair values of long lived assets, intangibles, goodwill and contingent consideration. Actual results could differ from the estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. The Company's balance of cash and cash equivalents at December 31, 2015 and 2014 consisted principally of bank deposits. From time to time, the Company's cash account balances may be uninsured or in deposit accounts that exceed Federal Deposit Insurance Corporation guarantee limit. The Company reduces its exposure to credit risk by maintaining its cash deposits with major financial institutions and monitoring their credit ratings.

Accounts Receivable

Trade accounts receivable are stated at the amount the Company expects to collect and do not bear interest. The Company considers the following factors when determining the collectability of specific customer accounts: customer credit-worthiness, past transaction history with the customer, current economic industry trends, and changes in customer payment terms. The Company's accounts receivable balance is a result of product sales and contract manufacturing. These receivables have historically been paid timely. Due to the nature of the accounts receivable balance, the Company believes there is no significant risk of collection. If the financial condition of the Company's customers were to deteriorate, adversely affecting their ability to make payments, allowances for doubtful accounts would be required. The allowance for doubtful accounts was approximately $175,000 as of December 31, 2015 and de minimis as of December 31, 2014.

Inventory

Inventory is valued at the lower of cost or market on a first-in, first-out basis. Reserves for inventory obsolescence are based on expiration date and are utilized to account for slow-moving inventory.

Improvements and Equipment

Improvements and equipment are recorded at cost. Depreciation of equipment is computed utilizing the straight-line method over the estimated useful lives of the assets. Amortization of leasehold improvements is computed utilizing the straight-line method over the shorter of the remaining lease term or estimated useful life. Repairs and maintenance costs are expensed as incurred. Additions and betterments are capitalized.

Intangible Assets

Intangible assets primarily consist of developed technology, customer lists/relationships, non-compete agreements and trade names and trademarks and are amortized ratably over a range of one to seven years which approximates customer attrition rate and technology obsolescence.

Goodwill and Indefinite Life Assets

The Company records goodwill and other indefinite-lived assets in connection with business combinations. Goodwill, which represents the excess of acquisition cost over the fair value of the net tangible and intangible assets of acquired companies, is not amortized. Indefinite-lived assets are stated at fair value as of the date acquired in a business combination.

Goodwill and Other Indefinite-Lived Intangible Asset Impairment

The Company accounts for goodwill and intangible assets in accordance with the accounting guidance which requires that goodwill and other intangibles with indefinite lives be tested for impairment annually or on an interim basis if events or circumstances indicate that the fair value of an asset has decreased below its carrying value. The Accounting Standards Codification ("Codification") requires that goodwill be tested for impairment at the reporting unit level (operating segment or one level below an operating segment). Application of the goodwill impairment test requires judgment, including the identification of reporting units, assigning assets and liabilities to reporting units, assigning goodwill to reporting units, and determining the fair value. Significant judgment is required to estimate the fair value of reporting units which includes estimating future cash flows, determining appropriate discount rates and other assumptions. Changes in these estimates and assumptions could materially affect the determination of fair value and/or goodwill impairment.

When testing goodwill for impairment, the Company may assess qualitative factors for some or all of its reporting units to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that the fair value of a reporting unit is less than its carrying amount, including goodwill. Alternatively, the Company may bypass this qualitative assessment for some or all of our reporting units and perform a detailed quantitative test of impairment (step 1). If the Company performs the detailed quantitative impairment test and the carrying amount of the reporting unit exceeds its fair value, the Company would perform an analysis (step 2) to measure such impairment. The first step is to identify the existence of a potential impairment by comparing the fair value of a reporting unit (the estimated fair value of a reporting unit is calculated using a discounted cash flow model) with its carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, the reporting unit's goodwill is considered not to be impaired and performance of the second step of the quantitative goodwill impairment test is unnecessary. In 2015, the Company first performed a qualitative assessment to identify and evaluate events and circumstances to conclude whether it is more likely than not that the fair value of the Company's reporting unit is less than its carrying amount. Based on the Company's qualitative assessment, for one of its reporting units, the Company was required to perform step 1 of the quantitative analysis. The Company's annual goodwill impairment test during 2015, for this unit, performed under step 1 of the quantitative analysis did not deem an impairment existed as of December 31, 2015.

In accordance with the Codification, the Company reviews the carrying value of its intangibles and other long-lived assets for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of long-lived assets is measured by comparing the carrying amount of the asset or asset group to the undiscounted cash flows that the asset or asset group is expected to generate. If the undiscounted cash flows of such assets are less than the carrying amount, the impairment to be recognized is measured by the amount by which the carrying amount of the asset or asset group, if any, exceeds its fair market value. No impairment was deemed to exist for either unit under the qualitative method and/or the quantitative method as of December 31, 2015 or 2014.

Asset Impairments

The Company reviews for and records impairment losses on long-lived assets (excluding goodwill and other indefinite-lived intangible assets). The Company continually evaluates whether events or changes in circumstances might indicate that the remaining estimated useful life of long-lived assets may warrant revision, or that the remaining balance may not be recoverable. When factors indicate that long-lived assets should be evaluated for possible impairment, the Company uses an estimate of the related undiscounted cash flows in measuring whether the long-lived asset should be written down to fair value. Measurement of the amount of impairment would be based on generally accepted valuation methodologies, as deemed appropriate. As of December 31, 2015, Company management believed that no revision to the remaining useful lives or write-down of the Company's long-lived assets was required, and similarly, no such revisions were required for the year ended December 31, 2015 or 2014.

Fair Value of Financial Instruments

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, accounts receivable and accounts payable and accrued expenses approximate fair value based on the short-term maturity of these instruments.

Fair value is defined as the price that would be received upon selling an asset or the price paid to transfer a liability on the measurement date. It focuses on the exit price in the principal or most advantageous market for the asset or liability in an orderly transaction between willing market participants. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair values are as follows:

Level 1: Observable prices in active markets for identical assets and liabilities.

Level 2: Observable inputs other than quoted prices in active markets for identical assets and liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, title and risk of loss have passed to the customer, there is a fixed or determinable sales price, and collectability of that sales price is reasonably assured. The Company also recognizes revenue under a variety of rental programs of the MIST Therapy system. Rental revenue is recognized on a monthly basis of the term of the rental agreement. Deposits received on product orders are recorded as deferred revenue until revenues are generally earned when the products are shipped to customers.

Cost of Goods Sold and Selling, General and Administrative Expenses

Costs associated with the production and procurement of product are included in cost of goods sold, including shipping and handling costs such as inbound freight costs, purchasing and receiving costs, inspection costs and other product procurement related charges. All other expenses, excluding interest and income taxes, are included in selling, general and administrative expenses, as the predominant expenses associated therewith are general and administrative in nature.

Advertising Expenses

Advertising and marketing costs are expensed as incurred. Advertising expenses for the years ended December 31, 2015 and 2014 were approximately $2.5 million and $1.6 million, respectively.

Shipping and Handling

Certain shipping and handling costs are paid for by the Company. Shipping and handling costs amounted to approximately $161,000 and $53,000 as of December 31, 2015 and 2014, respectively, and are included in cost of revenues.

Research and Development

All research and product development costs are expensed as incurred. For the year ended December 31, 2015, the Company incurred research and development costs of approximately $715,000 related to a randomized controlled trial for our Biovance product in chronic diabetic foot wounds. For the fiscal year ended December 31, 2014, the Company incurred no research and development costs.

Income Taxes

The Company accounts for income taxes pursuant to the asset and liability method which requires the Company to recognize current tax liabilities or receivables for the amount of taxes it estimates are payable or refundable for the current year and deferred tax assets and liabilities for the expected future tax consequences attributable to temporary differences between the financial statement carrying amounts and their respective tax bases of assets and liabilities and the expected benefits of net operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period enacted. A valuation allowance is provided when it is more likely than not that a portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which related temporary differences become deductible.

The Company adopted the provisions of Accounting Standards Codification Topic 740 (“ASC 740”) related to the accounting for uncertainty in income taxes recognized in an enterprise's consolidated financial statements. ASC 740 prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns.

The benefit of tax positions taken or expected to be taken in the Company's income tax returns are recognized in the financial statements if such positions are more likely than not of being sustained upon examination by taxing authorities. Differences between tax positions taken or expected to be taken in a tax return and the benefit recognized and measured pursuant to the interpretation are referred to as “unrecognized benefits”. A liability is recognized (or amount of net operating loss carryover or amount of tax refundable is reduced) for an unrecognized tax benefit because it represents an enterprise’s potential future obligation to the taxing authority for a tax position that was not recognized as a result of applying the provisions of ASC 740. Interest costs and related penalties related to unrecognized tax benefits are required to be calculated, if applicable. The Company’s policy is to classify assessments, if any, for tax related interest as interest expense and penalties as selling, general and administrative expenses. No interest or penalties were recorded during the years ended December 31, 2015 and 2014. As of December 31, 2015 and December 31, 2014, no liability for unrecognized tax benefits was required to be reported. The Company does not expect any significant changes in its unrecognized tax benefits in the next year.

Common Stock Purchase Warrants

The Company assesses classification of common stock purchase warrants at each reporting date to determine whether a change in classification between assets and liabilities or equity is required. The Company’s free standing derivatives consist of warrants to purchase common stock that were issued pursuant to a securities purchase agreement in 2012

and in connection with a credit agreement entered into in 2015. The Company evaluated the common stock purchase warrants to assess their proper classification in the consolidated balance sheet and determined that the common stock purchase warrants contain exercise reset provisions. Accordingly, these instruments have been classified as warrant liabilities in the accompanying consolidated balance sheets as of December 31, 2015 and 2014. The Company re-measures warrant liabilities at each reporting and exercise date, with changes in fair value recognized in earnings for each reporting period.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on interim financial reporting dates and vesting dates until the service period is complete. The fair value amount is then recognized over the period services are required to be provided in exchange for the award, usually the vesting period. The Company recognizes stock-based compensation expense on a graded-vesting basis over the requisite service period for each separately vesting tranche of each award. Stock-based compensation expense is reflected within cost of revenues and operating expenses in the consolidated statements of operations. The Company recognizes stock-based compensation expense for awards with performance conditions if and when the Company concludes that it is probable that the performance condition will be achieved. The Company reassesses the probability of vesting at each reporting period for awards with performance conditions and adjusts stock-based compensation expense based on its probability assessment.

Net Loss Per Common Share

Basic net loss per common share is computed based on the weighted average number of shares of common stock outstanding during the periods presented. Common stock equivalents, consisting of stock options, warrants and non-vested restricted stock, were not included in the calculation of the diluted loss per share because their inclusion would have been anti-dilutive.

The total common shares issuable upon the exercise of stock options, warrants and non-vested restricted stock are as follows:

	As of December 31,	
	2015	2014
Stock options	6,230,549	4,817,660
Warrants	3,372,550	2,675,121
Non-vested restricted stock	691,725	188,149
Total	10,294,824	7,680,930

Recent Accounting Pronouncements

In January 2016, the FASB issued Accounting Standards Update 2016-01, “Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities” (“ASU 2016-01”), which addresses certain aspects of recognition, measurement, presentation and disclosure of financial statements. This guidance will be effective in the first quarter of fiscal year 2019 and early adoption is not permitted. The Company is currently evaluating the impact that this guidance will have on its financial statements.

In November 2015, the FASB issued Accounting Standards Update 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes” (“ASU 2015-17”), an update to accounting guidance to simplify the presentation of deferred income taxes. The guidance requires an entity to classify all deferred tax liabilities and assets as noncurrent in the balance sheet. The guidance requires an entity to classify all deferred tax liabilities and assets, along with any valuation allowance, as noncurrent in the balance sheet. The guidance is effective for public companies with annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is permitted. The Company has elected to early adopt ASU 2015-17 during the year ended December 31, 2015 with retrospective application. The adoption of ASU 2015-17 did not have a material impact on the Company's consolidated financial statements.

In September 2015, the FASB issued Accounting Standards Update 2015-16, “Business Combinations (Topic 805): Simplifying the Accounting for Measurement Period Adjustments” (“ASU 2015-16”), an update to accounting guidance to simplify the accounting for business combinations. The guidance requires an acquirer to recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The updated guidance eliminates the requirement to retrospectively account for these adjustments and restate prior period financial statements. The standard is effective for annual reporting periods beginning after December 15, 2015, which for the Company will commence with the year beginning January 1, 2016. Prospective application is required. The adoption will have an impact on the Company’s consolidated financial statements if it is the acquirer in a business combination that includes measurement-period adjustments.

In July 2015, the FASB issued Accounting Standards Update 2015-11," Inventory (Topic 330) Simplifying the Measurement of Inventory" ("ASU 2015-11"). Currently, all inventory is measured at the lower of cost or market. ASU 2015-11 changes the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. The standard is effective for annual reporting periods beginning after December 15, 2015, which for the Company will commence with the year beginning January 1, 2016. Prospective application is required. The Company does not believe the implementation of this standard will have a material impact on the Company's consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs" ("ASU 2015-03"). ASU 2015-03 requires that debt issuance costs be presented as a direct deduction from the carrying amount of the related debt liability, consistent with the presentation of debt discounts. Prior to the issuance of ASU 2015-03, debt issuance costs were required to be presented as deferred charge assets, separate from the related debt liability. The Company early-adopted ASU 2015-03 during the year ended December 31, 2015, and applied its provisions retrospectively. The adoption of ASU 2015-03 did not have an impact on the Company's consolidated financial statements.

In May 2014, the FASB issued a new revenue recognition standard entitled "Revenue from Contracts with Customers" under Accounting Standards Update 2014-09. The core principle of the new guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. New disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers are also required. The standard is effective for annual reporting periods beginning after December 15, 2017, which for the Company will commence with the year beginning January 1, 2018. Entities must adopt the new guidance using one of two retrospective application methods. The Company is currently evaluating the standard to determine the impact of its adoption on the consolidated financial statements.

In June 2014, the FASB issued Accounting Standards Update 2014-12, “Compensation — Stock Compensation: Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period” (“ASU 2014-12”). ASU 2014-12 requires that a performance target that affects vesting of share-based payments and that could be achieved after the requisite service period be treated as a performance condition that affects vesting and as such, should not be reflected in estimating the grant-date fair value of the award. ASU 2014-12 is effective for annual and interim periods beginning after December 15, 2015. This standard is not expected to have a material effect on the Company’s financial position, results of operations or cash flows.

3. Acquisitions

Acquisition of Celleration, Inc.

On May 29, 2015, the Company acquired all outstanding equity interest of Celleration, Inc. (“Celleration”), a medical device company focused on developing and commercializing the MIST Therapy® therapeutic ultrasound platform for the treatment of acute and chronic wounds for an aggregate purchase price of approximately $46.3 million. The purchase price consists of an initial cash payment of approximately $15.5 million (including working capital adjustments of approximately $0.3 million), 3,168,229 shares of the Company’s common stock and contingent consideration with an estimated acquisition date fair value of approximately $15,570,000. This acquisition complements the Company’s growth strategy aimed at providing a portfolio of advanced wound care solutions.

The Company has agreed to pay contingent consideration of three and one half times revenue from acquired MIST Therapy products in excess of certain revenue targets for the years ending December 31, 2015 and 2016, payable in equal amounts of cash and the Company’s common stock. This contingent consideration is payable in two installments in March 2016 and March 2017. The fair value of this liability is based on future sales projections of MIST Therapy. At the date of acquisition and as of December 31, 2015, the cash flow projection was discounted using a weighted average cost of capital of 12.5%. These fair value measurements were based on significant inputs not observed in the market and thus represented a Level 3 measurement. In addition, the Company has agreed to pay contingent consideration subject to the approval of MIST Therapy products by the National Institute for Health and Care Excellence (“NICE”) of the United Kingdom prior to January 1, 2017. This consideration consists of $500,000 of the Company’s common stock upon receipt of such approval and 20% of incremental net sales in the United Kingdom from the acquired MIST Therapy products for the years ending December 31, 2016, 2017, and 2018. The estimated fair value of this liability is based on future sale projections of the MIST Therapy product and probability of receiving NICE approval. These fair value measurements were based on significant inputs not observed in the market and thus represented a Level 3 measurement. The contingent consideration is re-measured to fair value at each reporting date until the contingency is resolved, and those changes in fair value are recognized in earnings. For the year ended December 31, 2015, the adjustments resulted in a net increase of approximately $450,000 to the Company’s acquisition-related contingent consideration liability and corresponding increase in operating expenses. As of December 31, 2015, the current and long-term portion of the contingent consideration was approximately $5.1 million and $10.9 million, respectively.

The assets and liabilities of the acquired business were included in the Company's consolidated balance sheet based upon estimated fair values on the date of acquisition as determined in the purchase price allocation, using available information and making assumptions management believes are reasonable. The consolidated statements of operations include the results of the Celleration's operations subsequent to the acquisition date. The Company's allocation of purchase price for this acquisition is included in the table below, which summarizes the estimated fair value of the assets acquired and liabilities assumed at the date of acquisition:

Consideration:	
Common stock	$15,207,500
Cash paid	15,476,191
Fair value of contingent consideration	15,570,000
Total consideration	46,253,691
Cash	528,378
Trade receivables	876,590
Inventory	341,143
Other current assets	206,747
Improvements and equipment	411,492
Tradenames	3,601,000
Technology	27,143,000
Customer relationships	1,208,000
Goodwill	17,066,117
Accounts payable	(308,615)
Accrued expenses and other liabilities	(1,697,912)
Deferred tax liability	(3,122,249)
Net assets acquired	$46,253,691

The Company recorded intangible assets of approximately $32.0 million, which included technology of $27.1 million and customer relationships of $1.2 million, which are both amortizable over ten years, as well as tradenames of $3.6 million, which has an indefinite life. The Company recorded approximately $17.1 million of goodwill in connection with this acquisition, which is not expected to be deductible for tax purposes. The acquisition complements the Company’s growth strategy aimed at providing a portfolio of advanced wound care solutions.

The Company funded the cash portion and related costs of the Celleration acquisition with the net proceeds received under the senior secured term loan described below in Note 9 - Debt.

Revenues included in the consolidated statement of operations for the year ended December 31, 2015 from this acquisition for the period subsequent to the closing of the transaction was approximately $6.1 million. The net income or loss attributable to this acquisition cannot be identified on a stand-alone basis because it has been fully integrated into the Company's operations.

During the year ended December 31, 2015, the Company incurred acquisition-related costs related to Celleration of approximately $2.9 million in connection with due diligence, professional fees, and other expenses.

Acquisition of Choice Therapeutics, Inc.

On May 5, 2014, the Company acquired all outstanding equity interest of Choice Therapeutics, Inc., a provider of innovative wound care products using proprietary TheraBond 3D® Antimicrobial Barrier Systems. This acquisition complements the Company's growth strategy aimed at providing a portfolio of advanced wound care solutions. The Company's initial cash payment for this acquisition was $2.0 million and approximately $2.0 million in shares of common stock. In addition, the Company may pay up to $5.0 million, payable in the form of the Company's common stock, in contingent consideration which may be earned based upon the acquired company achieving specific performance metrics over the three twelve month periods, ended April 30, 2017. The fair value of this liability is based on future sales projections of TheraBond 3D® product under various potential scenarios. At the date of acquisition and as of December 31, 2015, the cash flow projection was discounted using a weighted average cost of capital of 15.5%. These fair value measurements were based on significant inputs not observed in the market and thus represented a Level 3 measurement. The contingent consideration is re-measured to fair value at each reporting date until the contingency is resolved, and those changes in fair value are recognized in earnings. For the year ended December 31, 2015, the adjustment resulted in a decrease of approximately $2.0 million to the Company's acquisition-related contingent consideration liability and corresponding offset to operating expenses. The decrease in the fair value of the liability during the year ended December 31, 2015 is due to lower than expected sales of the TheraBond product. For the year ended December 31, 2014, the adjustment resulted in an increase to the Company's acquisition-related contingent consideration liability of $232,000 and corresponding increase to operating expense. The long-term portion of the contingent consideration was approximately $1.0 million and $2.9 million as of December 31, 2015 and 2014, respectively.

The assets and liabilities of the acquired business were included in the Company's consolidated balance sheet based upon estimated fair values on the date of acquisition as determined in the purchase price allocation, using available information and making assumptions management believes are reasonable. The consolidated statements of operations include the results of the Choice operations beginning May 6, 2014. The Company's allocation of purchase price for this acquisition is included in the table below, which summarizes the estimated fair value of the assets acquired and liabilities assumed at the date of acquisition:

Consideration:	
Common stock	$1,992,854
Cash paid	2,000,000
Fair value of contingent consideration	2,700,000
Total consideration	6,692,854
Cash	474
Inventory	396,961
Other assets	11,587
Tradenames	111,000
Technology	2,396,000
Customer relationships	176,000
Goodwill	3,674,326
Other liabilities	(73,494)
Net assets acquired	$6,692,854

The amortization period of intangible assets acquired ranges from 3 to 12 years. The Company recorded approximately $3.7 million of goodwill in connection with this acquisition, reflecting the strategic fit and revenue and earnings growth potential of this business.

Revenues included in the consolidated statement of operations for the year ended December 31, 2014 from this acquisition for the period subsequent to the closing of the transaction was approximately $1.5 million. Loss from operations included in the consolidated statement of operations for the year ended December 31, 2014 from this acquisition for the period subsequent to the closing of the transaction was approximately $136,000. Also included in the loss from operations in the year ended December 31, 2014 is approximately $232,000 relating to adjustments to the fair value of contingent consideration described below, and approximately $200,000 of amortization relating to intangibles.

Pro Forma Results

The following unaudited pro forma financial information summarizes the results of operations for year ended December 31, 2015 and 2014, as if the acquisitions had been completed as of January 1, 2014. The pro forma results were calculated applying the Company's accounting policies and include the effects of adjustments related to the amortization charges from the acquired intangibles and long-term debt. The unaudited pro forma information does not purport to be indicative of the results that would have been obtained if the acquisitions had actually occurred at the beginning of the year prior to acquisition, nor of the results that may be reported in the future.

	Years Ended December 31,	
	2015	2014
Revenues	$19,130,107	$14,165,549
Net loss	$(30,677,311)	$(34,602,957)
Net loss per share	$(1.26)	$(1.92)

4. Inventory

Inventory consists of the following:

	December 31,	
	2015	2014
Raw materials	$241,432	$197,514
Work in process	227,773	489,431
Finished goods	2,722,586	725,897
Less: Inventory reserve	(59,253)	(1,094)
Total	$3,132,538	$1,411,748

5. Improvements and Equipment, net

Improvements and equipment consist of the following:

		December 31,	
	Useful Life (Years)	2015	2014
Machinery and equipment	10	$3,620,658	$2,869,453
Office furniture and equipment	3-10	88,208	51,439
Leasehold improvements	(A)	253,401	228,021
		3,962,267	3,148,913
Less: Accumulated depreciation and amortization		(2,115,458)	(1,714,886)
Improvements and equipment, net		$1,846,809	$1,434,027

(A) Leasehold improvements are amortized over the shorter of the remaining lease term or estimated useful life.

Depreciation and amortization expense was $421,000 and $318,000 for the years ended December 31, 2015 and 2014, respectively.

6. Intangible Assets

The gross carrying amount and accumulated amortization of intangible assets are as follows:

		December 31, 2015		
	Useful Life (Years)	Gross Amount	Accumulated Amortization	Net Carrying Amount
Intangible assets subject to amortization:				
Technology	10	$32,539,000	$ (4,057,675)	$28,481,325
Customer relationships	9-12	1,984,000	(448,893)	1,535,107
Distribution rights	5.27	400,000	(173,071)	226,929
Tradename	3	111,000	(61,667)	49,333
Non-compete	1	208,333	(208,333)	-
Total intangible assets subject to amortization		35,242,333	(4,949,639)	30,292,694
Indefinite-lived intangible assets:				
Tradename	Indefinite	3,601,000	-	3,601,000
Total indefinite-lived intangible assets		3,601,000	-	3,601,000
Total intangible assets		$38,843,333	$ (4,949,639)	$33,893,694

		December 31, 2014		
	Useful Life (Years)	Gross Amount	Accumulated Amortization	Net Carrying
Technology	10	$5,396,000	$ (1,934,733)	$3,461,267
Customer relationships	9-12	776,000	(308,871)	467,129
Distribution rights	5.27	400,000	(96,880)	303,120
Tradename	3	111,000	(24,667)	86,333
Non-compete	1	208,333	(138,889)	69,444
		$6,891,333	$ (2,504,040)	$4,387,293

Amortization expense attributable to intangible assets for the year ended December 31, 2015 and 2014 was approximately $2.4 million and $763,000, respectively.

Amortization expense in each of the five years and thereafter subsequent to December 31, 2015 related to the Company’s intangible assets is expected to be as follows:

	Expected Amortization Expense
2016	$3,557,446
2017	3,532,779
2018	3,518,804
2019	3,169,256
2020	3,144,256
Thereafter	13,370,153
Total	$30,292,694

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2015	2014
Salaries, benefits and incentive compensation	$2,146,258	$1,528,229
Professional fees	701,534	228,426
Royalty fees	51,690	100,537
Deferred revenue	92,374	78,523
Other	138,120	132,144
Total accrued expenses and other current liabilities	$3,129,976	$2,067,859

8. Operating Leases

The Company has an obligation for its corporate offices and commercial manufacturing facility located in Langhorne, Pennsylvania through 2026. The remaining minimum lease payments as of December 31, 2015 were $2.1 million. In conjunction with the acquisition of Celleration in May 2015, the Company also assumed a lease for office space in Eden Prairie, Minnesota through 2016. The remaining minimum lease payments as of December 31, 2015 were $29,000. In 2015, the Company entered into a lease for new office space in Yardley, Pennsylvania through 2023. The remaining minimum lease payments as of December 31, 2015 were $1.6 million.

Total rent expense was $282,000 and $207,000 for the years ended December 31, 2015 and 2014, respectively.

Future minimum lease payments, excluding expense reimbursements, under noncancelable operating leases in each of the five years and thereafter subsequent to December 31, 2015 are as follows:

2016	$376,690
2017	422,197
2018	426,416
2019	430,634
2020	434,852
Thereafter	1,601,659
Total	$3,692,448

9. Debt

Senior Secured Term Loan Facility

On May 29, 2015, simultaneously with and related to the closing of the Celleration acquisition, the Company entered into a Credit Agreement and Guaranty (the "Credit Agreement") with Perceptive Credit Opportunities Fund, L.P. ("Perceptive"). The Credit Agreement provided a senior secured term loan in a single borrowing to the Company in the principal amount of $15.5 million. The Credit Agreement (i) has a four-year term, (ii) accrues interest at an annual rate equal to the greater of (a) one-month LIBOR or 1% plus (b) 9.75%, (iii) is interest only for the first 24 months, followed by monthly amortization payments of $225,000, with the remaining unpaid balance due on the maturity date and (iv) is secured by a first priority lien on substantially all of the Company's assets. In connection with the Credit Agreement, the Company incurred approximately $1.3 million of debt issuance costs, which includes legal expenses and the loan commitment, placement and exit fee, discussed below. The debt issuance costs are being amortized over the term of the loan on a straight-line basis, which approximates the effective interest method. During the year ended December 31, 2015, the Company recorded amortization of debt issuance costs of $169,000, which is included in interest expense.

In connection with the entry into the Credit Agreement, a five-year warrant (the "Warrant") to purchase 750,000 shares of common stock, par value of $0.001 per share at an exercise price of $5.5138 per share (the "Exercise Price") was issued to Perceptive. The Company granted Perceptive customary demand and piggy-back registration rights with respect to the shares of common stock issuable upon exercise of the Warrant. The warrant contains a weighted average anti-dilution feature whereby the Exercise Price is subject to reduction if the Company issues shares of common stock (or securities convertible into common stock) in the future at a price below the current Exercise Price. As a result, the warrant was determined to be a derivative liability. The warrant had an issuance date fair value of approximately $2.7 million which was recorded as a debt discount. During the year ended December 31, 2015, the Company recorded amortization of debt discount of $397,000, which is included in interest expense. See Note 15 – Fair Value Measurement for additional details.

The Credit Agreement requires the Company to prepay the outstanding principal amount of the term loan with 100% of the net cash proceeds received from specified asset sales, issuances or sales of equity and incurrences of borrowed money indebtedness, subject to certain exceptions. In addition, the Company may voluntarily prepay the term loan upon five days prior written notice to Perceptive. The Company will incur an incremental fee for any repayments or prepayments other than the required monthly principal payments made prior to the third anniversary of the Closing Date. The Company is required to pay an exit fee when the term loan is paid in full equal to the greater of 1% of the outstanding principal balance immediately prior to the final payment and $100,000.

The Credit Agreement contains customary affirmative and negative covenants and events of default for a secured financing arrangement, including limitations on additional indebtedness, liens, asset sales and acquisitions, among others. In addition to other customary events of default, any termination of that certain License, Marketing and Development Agreement between the Company and CCT, as amended, will constitute an event of default under the Credit Agreement.

Debt consists of the following:

	December 31, 2015
Long-term debt	$ 15,500,000
Unamortized debt issuance and discount costs	(3,373,610)
Long-term debt, net	$ 12,126,390

10. Commitments and Contingencies

License Agreement

On July 15, 2011, the Company entered into a license agreement with Noble Fiber Technologies, LLC, whereby the Company has the exclusive right and license to manufacture and distribute “SilverSeal Hydrogel Wound Dressings” and “SilverSeal Hydrocolloid Wound Dressings”. The license is granted for ten years with an option to be extended for consecutive renewal periods of two years after the initial term. Royalties are to be paid equal to 9.75% of net sales of licensed products. The agreement calls for minimum royalties to be paid each calendar year as follows: 2015 - $500,000 and 2016 - $600,000. Total royalties charged to selling, general and administrative expense for the years ended December 31, 2015 and 2014 were $500,000 and $400,000, respectively. $497,000 is included in accounts payable as of December 31, 2015 in connection with this agreement. The Company expects to incur the minimum royalty in 2016.

Sorbion Distributor Agreement

In September 2013, the Company entered into a distributor agreement (the "Sorbion Agreement") with Sorbion GmbH & Co KG, pursuant to which the Company became the exclusive distributor of sorbion sachet S, sorbion sana and new products with hydrokinetic fibers as primary dressings in the United States, Canada and Latin America, subject to certain exceptions. The term of the agreement ends on December 31, 2018. Sorbion assigned its rights and obligations of the Sorbion Agreement to BSN Medical, Inc. ("BSN"), an affiliate of Sorbion, in June 2015. In July 2015, the Company entered into an amendment to the Sorbion Agreement with BSN to provide for pricing in U.S. Dollars instead of Euros.

In order to maintain its exclusivity, the Company must purchase minimum amounts of product. The Company has met the minimum purchase amount requirement for the 2015 calendar year of $1.1 million. For calendar years 2016 and 2017, the minimum annual purchase amounts noted below will be converted from Euros to U.S. Dollars with the exchange rate in effect on the last day of the preceding calendar year, provided that the exchange rate is not more than five percent greater or less than the exchange rate from Euros to U.S. Dollars of 1.10. If the exchange rate is five percent greater or less than 1.10, the rate will be rounded as necessary so that it is no more than five percent greater or five percent less.

Calendar Year	Minimum Annual Purchase Amount
2016	2,500,000 Euros
2017	4,000,000 Euros

If the Company fails to purchase products in amounts that meet or exceed the minimum annual purchase amount for a calendar year, it may cure such minimum purchase failure by paying BSN in cash an amount equal to the minimum annual purchase amount for such calendar year less the amount the Company paid to BSN for the products purchased for such calendar year. If the Company does not cure a minimum purchase failure with a makeup payment for a calendar year, BSN may terminate the Company's exclusivity with respect to the products and grant the Company non-exclusive rights with respect to the products. If the Company does not cure a minimum purchase failure for two subsequent calendar years, BSN may terminate the agreement. The Company will not be required to meet the minimal annual purchase amount if BSN fails to supply the Company with the products in accordance with the agreement. BSN may also terminate the Company's exclusivity with respect to the products if the Company does not cure a material breach of the agreement within 30 days. The Company has the right to use the trademarks related to the products. The Company has the ability to sell the products under their respective trademarked names and at prices determined by the Company. The Company is eligible for certain discounts with respect to the purchase and shipping of the products if its orders of the products are above certain amounts.

Celgene License, Marketing and Development and Supply Agreement

In November 2013, the Company entered into a License, Marketing and Development Agreement (the "License Agreement") with Anthrogenesis Corporation, d/b/a Celgene Cellular Therapeutics ("CCT"), an affiliate of Celgene Corporation ("Celgene"), pursuant to which CCT granted the Company an exclusive, royalty-bearing license in its intellectual property for certain placental based products, including ECM, an extracellularmatrix derived from the human placenta, and Biovance®, CCT's proprietary wound coverings produced from decellularized, dehydrated human amniotic membrane, to develop and commercialize ECM and Biovance in the United States. The Company is required to pay CCT annual license fees, designated amounts when certain milestone events occur and royalties on all sales of licensed products, with such amounts being variable and contingent on various factors. The initial term of the License Agreement ends on November 14, 2023, unless sooner terminated pursuant to the termination rights under the License Agreement, and will extend for additional two-year terms unless either party gives written notice within a specified period prior to the end of a term. The License Agreement may be terminated (i) by CCT if the Company or any of its affiliates challenges the validity, enforceability or scope of certain enumerated CCT patents anywhere in the world; (ii) by either party if there is a final decree that a licensed product infringed on the intellectual property of a third party; (iii) by either party for breach of the License Agreement, if the breach is not cured within a specified period after receiving written notice of the breach; or (iv) by either party if the other party is the subject of insolvency proceedings, either voluntary or involuntary. In addition, the License Agreement is terminable on a product-by-product basis, and not with respect to the entire License Agreement (i) by CCT in the second year of the License Agreement, and by either CCT or the Company in the third year of the License Agreement and beyond, if the Company fails to meet certain sales thresholds and (ii) by either party upon written notice if outside legal counsel recommends discontinuance of commercialization of a product because of significant safety, legal, or economic risk as a result of a claim, demand or action or as a result of a change in the interpretation of law by a governmental or regulatory authority. The License Agreement also contains mutual confidentiality and indemnification obligations for

the Company and CCT. In September 2014, the Company entered into a First Amendment to the License Agreement (the "Amended License Agreement"), pursuant to which the Company received the right to market Biovance for podiatric and orthopedic applications. The Amended License Agreement also amends certain terms and the related schedule for milestone payments to CCT. In May 2015, the Company amended its exclusive licensing agreement with CCT, which granted the Company the right to develop and market CCT's connective tissue matrix product ("CTM").

In November 2013, the Company also entered into a Supply Agreement (the "Biovance Supply Agreement") with CCT, pursuant to which CCT shall supply the Company with the Company's entire requirements of Biovance for distribution and sale in the United States. The Biovance Supply Agreement will be terminated automatically upon the termination of the License Agreement and may otherwise be terminated (i) by CCT upon six months' prior written notice, (ii) by the Company upon six months' prior written notice if CCT fails to deliver at least a specified portion of a firm purchase order by the required delivery date specified in the order on at least a specified number of occasions in a specified period; (iii) by either party for breach of the Biovance Supply Agreement, if the breach is not cured within a specified period after receiving written notice of the breach; or (iv) by either party if the other party is the subject of insolvency proceedings, either voluntary or involuntary. On April 10, 2014, the Company and CCT entered into an amendment to the Biovance Supply Agreement in order to amend the pricing schedule.

In April 2014, the Company entered into a Supply Agreement (the "ECM Supply Agreement") with CCT, pursuant to which CCT shall, as soon as reasonably practicable after the date that CCT obtains regulatory clearance or approval in the United States for any of CCT's extracellular matrix products derived from the human placenta (each an "ECM"), supply and sell to the Company all of the Company's requirements of ECM, in finished form and final packaging, for exploitation in the United States under the License Agreement. The ECM Supply Agreement will automatically terminate upon the termination or expiration of the License Agreement and may otherwise be terminated (i) by CCT upon six months' prior written notice, (ii) by the Company upon six months' prior written notice if CCT fails to deliver at least a specified portion of a firm purchase order by the required delivery date specified in the order on at least a specified number of occasions in a specified period; (iii) by either party for breach of the ECM Supply Agreement, if the breach is not cured within a specified period after receiving written notice of the breach; or (iv) by either party if the other party is the subject of insolvency proceedings, either voluntary or involuntary. The ECM Supply Agreement also contains mutual confidentiality and indemnification obligations for the Company and CCT.

In January 2016, Human Longevity, Inc.'s ("HLI"), a genomics-based, technology-driven company, announced the planned purchase of LifebankUSA and other select assets from CCT. The Company will remain the exclusive commercial partner for the existing pipeline of human placental based products as noted above.

Litigation, Claims and Assessments

The Company is subject to periodic lawsuits, investigations and claims that arise in the ordinary course of business. The Company is not party to any material litigation as of December 31, 2015.

11. Stockholders' Equity

Preferred Stock

The Company has authorized 1,000,000 shares of preferred stock, $0.001 par value per share, which may be divided into series and with preferences, limitations and relative rights determined by the Board of Directors.

Common Stock Issuances

On April 14, 2014, the Company entered into a securities purchase agreement pursuant to which the Company issued an aggregate of 2,139,287 shares of common stock, and five year warrants (which were determined to be equity instruments) to purchase an aggregate of 427,858 shares of common stock at an exercise price of $10.50 per share, in exchange for aggregate consideration of $15.0 million. The warrants became exercisable on October 15, 2014. In connection with the financing, the Company paid $598,500 in placement agent fees. Administrative fees for the escrow agent of $4,000 were also deducted from gross proceeds.

On May 4, 2015, the Company closed an underwritten public offering of 7,582,418 shares of its common stock at a price to the public of $4.55 per share. Proceeds from this offering, net of issuance costs were $32.2 million. The shares of common stock were issued pursuant to the Company's shelf registration statement on Form S-3 previously filed with the Securities and Exchange Commission and declared effective on September 25, 2014.

2011 Plan

The Company maintains the 2011 Long-Term Incentive Plan (the "2011 Plan") that provides for the granting of stock options, restricted stock units ("RSUs"), restricted stock and other awards to employees, directors and others. A total of 1,828,571 shares of common stock have been authorized for issuance under the 2011 Plan, of which, as of December 31, 2015, 150,670 shares were available for future issuances.

2014 Plan

On April 10, 2014 and June 5, 2014, the Company's Board of Directors and the Company's shareholders approved the 2014 Long-Term Incentive Plan (the "2014 Plan"), respectively. The 2014 Plan provides for the granting of stock options, RSUs, restricted stock and other awards to employees, directors and others. On February 26, 2015 and May 6, 2015, the Company's Board of Directors and the Company's shareholders approved an amendment to the 2014 Plan to increase the total number of shares of common stock authorized for issuance under the 2014 Plan by an additional 3,500,000 shares from the previous amount of 2,000,000 shares. A total of 5,500,000 shares of common stock are reserved for award under the 2014 Plan, of which, as of December 31, 2015, 2,936,655 shares were available for future issuances.

Stock-Based Compensation

The following table summarizes stock-based compensation expense:

	Year Ended December 31,	
	2015	2014
Options	$5,942,058	$7,815,411
Warrants	-	210,160
Restricted stock units	-	180,715
Restricted stock	2,691,729	2,523,760
Total stock-based compensation	$8,633,787	$10,730,046

For the year ended December 31, 2015, $364,000 of stock-based compensation expense is included in cost of revenues and $8.3 million is included in selling, general and administrative expenses in the consolidated statements of operations. For the year ended December 31, 2014, $200,000 of stock-based compensation expense is included in cost of revenues and $10.5 million is included in selling, general and administrative expenses in the consolidated statements of operations.

Restricted Stock

The following table summarizes the restricted stock issued as compensation during the years ended December 31, 2015 and 2014:

Issuance Date	Grantee Type	Shares Issued	Vesting Term	Grant Date Value
01/06/14	Officer	369,395	[1]	$2,582,072
01/17/14	Consultant	1,107	Immediate	10,007
01/27/14	Consultant	13,000	Immediate	118,300
03/06/14	Employee	8,300	[2]	74,700
03/09/14	Consultant	1,108	Immediate	10,005
03/21/14	Consultant	1,136	Immediate	10,008
04/02/14	Consultant	1,219	Immediate	10,008
05/29/14	Consultant	1,000	Immediate	7,000
06/16/14	Consultant	1,525	Immediate	10,004
06/18/14	Consultant	1,558	Immediate	10,002
07/01/14	Consultant	1,743	Immediate	10,005

	2014- Restricted Stock - Total	401,091		$2,852,111
02/06/15	Officers	600,000	[3]	$3,738,000
06/15/15	Officer	120,000	[4]	630,000
	2015 - Restricted Stock - Total	720,000		$4,368,000

[1] Vests in equal quarterly installments, with one-eighth vesting on January 6, 2014 and the remaining vesting on the first day of each calendar quarter thereafter.

[2] 2,425 shares vest on both March 6, 2014 and April 1, 2014. 1,725 shares vest on each of April 1, 2015 and April 1, 2016.

[3] Vests in three equal annual installments, with one-third vesting on each of February 6, 2016, February 6, 2017 and February 6, 2018.

[4] Vests in four equal installments, with one-fourth vesting on the date of grant and one-fourth vesting on each of June 15, 2016, June 15, 2017 and June 15, 2018.

On March 14, 2014, in connection with the resignation of the chief executive officer of a wholly-owned subsidiary of the Company, the Company accelerated the vesting of 17,688 RSUs that, prior to the modification, contained performance conditions which, for accounting purposes, were deemed improbable of being achieved. As a result, the Company recorded stock-based compensation expense of $157,000 during year ended December 31, 2014, which represented the modification date value of the modified RSUs.

As of December 31, 2015, there was $2.0 million of unrecognized stock-based compensation expense related to restricted stock which will be amortized over a weighted average period of 1.6 years.

A summary of restricted stock award activity during the years ended December 31, 2015 and 2014 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value	Total Grant Date Fair Value
Non-vested, December 31, 2014	35,376	$ 2.19	$77,387
Granted	401,091	$ 7.11	2,852,111
Vested	(248,318)	$ 6.47	(1,607,402)
Forfeited	-	$ -	-
Non-vested, December 31, 2014	188,149	$ 7.03	$1,322,096
Granted	720,000	$ 6.07	4,368,000
Vested	(216,424)	$ 6.76	(1,464,071)
Forfeited	-	-	-
Non-vested, December 31, 2015	691,725	$ 6.11	$4,226,025

Warrants

See Common Stock Issuances above for details of warrants issued in connection with equity offerings. See Note 9 - Debt – Senior Secured Term Loan Facility for details associated with a warrant issued in connection with debt.

On April 11, 2014, the Company entered into a letter agreement with certain of the holders of warrants to purchase shares of the Company's common stock that were granted pursuant to that certain securities purchase agreement, dated November 18, 2013, by and among the Company and the investors signatory thereto. The Company received approximately $5.3 million from the exercising holders upon the exercise of the warrants, and the Company issued a total of 930,313 shares of common stock to the exercising holders pursuant to the terms of the warrants. In connection with the holders exercising their warrants pursuant to the letter agreement, the Company paid $265,000 in placement agent fees and $2,500 of professional fees for the escrow agent, both of which were deducted from gross proceeds. The warrants, which were exercised at a price of $5.69 per share, had an aggregate intrinsic value of $1.5 million.

During the year ended December 31, 2014, away from exercised warrants discussed above, the Company issued an aggregate of 258,295 shares of common stock to several holders of warrants who elected to exercise warrants to purchase an aggregate of 400,137 shares of common stock (353,137 shares on a "cashless" basis under the terms of the warrants and 47,000 shares for cash proceeds of $199,000). The warrants had exercise prices of $4.24 per share (241,060 gross shares), $3.02 per share (65,362 gross shares) and $2.19 per share (93,715 gross shares). Excluding the value of the warrants discussed in the paragraph above, the aggregate intrinsic value of the warrants exercised was $2.0 million.

During the year ended December 31, 2015, the Company issued an aggregate of 8,970 shares of common stock to several holders of warrants who elected to exercise warrants to purchase an aggregate of 15,999 shares of common stock (inclusive of a warrant to purchase 9,142 shares of common stock that was classified as a derivative liability) at an exercise price of $2.19 per share on a "cashless" basis under the terms of the warrants. The aggregate intrinsic value of the warrants exercised was $45,000. See Note 15 – Fair Value Measurement for additional details regarding the exercise of the warrant accounted for as a derivative liability.

There were no compensatory warrants issued during the years ended December 31, 2015 and 2014.

As of December 31, 2015, there was no unrecognized stock-based compensation expense related to compensatory warrants.

A summary of the warrant activity during the years ended December 31, 2015 and 2014 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Intrinsic Value
Outstanding, December 31, 2013	3,822,557	$ 5.12		
Issued	427,858	10.50		
Exercised	(1,330,450)	5.03		
Cancelled	(244,844)	7.88		
Outstanding, December 31, 2014	2,675,121	$ 5.76		
Issued	750,000	5.51		
Exercised	(15,999)	2.19		
Cancelled	(36,572)	7.88		
Outstanding, December 31, 2015	3,372,550	$ 5.70	3.1	$ -
Exercisable, December 31, 2015	3,372,550	$ 5.70	3.1	$ -

The following table presents information related to warrants at December 31, 2015:

Warrants Outstanding			Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Average Remaining Life in Years	Exercisable Number of Warrants	
$ 2.19	92,573	1.8	92,573	
3.02	74,286	1.1	74,286	
3.50	2,286	1.3	2,286	
4.24	780,191	2.4	780,191	
4.38	188,444	2.8	188,444	
4.81	8,889	2.8	8,889	

5.51	750,000	4.4	750,000
5.69	1,040,880	2.9	1,040,880
8.75	7,143	0.2	7,143
10.50	427,858	3.3	427,858
	3,372,550	3.1	3,372,550

As of December 31, 2015 and 2014, warrants to purchase an aggregate of 816,287 and 75,429 shares of common stock at a weighted average exercise price of $5.24 and $2.19 per share were deemed to be a derivative liability, respectively. See Note 15 – Fair Value Measurement.

Stock Options

Options - 2014 Grants

During 2014, ten-year options to purchase an aggregate of 1,273,520 shares of common stock at exercise prices ranging from $3.89 to $9.05 (with a weighted average exercise price of $7.00 per share) with an aggregate grant date value of $7.1 million were granted to directors, employees and consultants. Of the above, options to purchase an aggregate of 736,500, 268,000 and 269,020 shares of common stock were granted pursuant to the 2011 Plan, 2014 Plan and not pursuant to a plan, respectively. Most of the 2014 grants vest over three years on the anniversaries of the grant date. In general, the grant date value is being amortized over the vesting term.

Details of the grants with the more significant grant date values are as follows:

(1) On January 6, 2014, a ten-year option to purchase 91,520 shares of common stock with a grant date value of $506,000 was granted to an employee of the Company. The option is scheduled to vest and become exercisable at $6.99 per share as follows: (i) 22,800 shares vested immediately on the date of grant (ii) 22,880 shares on each of the next three anniversaries of the date of grant.

(2) On March 6, 2014, a ten-year option to purchase 70,000 shares of common stock at an exercise price of $9.00 per share was granted to three employees of the Company (options to purchase 210,000 shares of common stock in the aggregate). The options had an aggregate grant date value of $1.5 million. Each option is scheduled to vest and become exercisable as follows: (i) 23,333 or 23,334 shares on each of the next three anniversaries of the date of grant.

Options – 2015 Grants

During 2015, ten-year options to purchase an aggregate of 1,905,000 shares of common stock at exercise prices ranging from $2.38 to $6.23 with an aggregate grant date value of $8.0 million were granted to employees and directors. Options to purchase an aggregate of 1,818,000 and 87,000 shares of common stock were granted pursuant to the 2014 Plan and 2011 Plan, respectively. The options vest as follows: (i) options to purchase 4,500 shares vested immediately, (ii) options to purchase 90,000 shares vest one-twelfth monthly over one year, and (iii) options to purchase 1,810,500 shares vest ratably over three years on the anniversaries of the grant date. The grant date value is being amortized over the vesting term. Details of the grants with the more significant grant date values are as follows:

(1)

On February 6, 2015, ten-year options to purchase an aggregate of 745,000 shares of common stock with a grant date value of $3.6 million were granted to employees and an executive of the Company. The options are scheduled to vest and become exercisable at $6.23 per share ratably over three years on the anniversaries of the date of grant.

(2) On May 29, 2015, ten-year options to purchase an aggregate of 455,000 shares of common stock with a grant date value of $1.8 million were granted to employees and a director of the Company. The options are scheduled to vest and become exercisable at $4.95 per share as follows: (i) options to purchase an aggregate of 440,000 shares of common stock vest ratably over three years on the anniversaries of the date of grant and (ii) an option to purchase 15,000 shares of common stock vests ratably over the next year on the monthly anniversary of the date of grant.

(3) On August 3, 2015, ten-year options to purchase an aggregate of 270,000 shares of common stock with a grant date value of $1.0 million were granted to employees of the Company. The options are scheduled to vest and become exercisable at $5.08 per share ratably over three years on the anniversaries of the date of grant.

Options – Summary Data

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following weighted average assumptions:

	Year Ended December 31,			
	2015		2014	
Risk free interest rate	1.19% - 2.11	%	1.39% - 2.38	%
Expected term (years)	5.00-6.50		5.00 - 10.00	
Expected volatility	93.70% - 98.25	%	100.56% - 102.63	%
Expected dividends	0.00	%	0.00	%

The risk-free interest rate is based on rates of treasury securities with the same expected term as the options. The Company uses the "simplified method" to calculate the expected term of employee and director stock-based options. The expected term used for consultants is the contractual life. The Company is utilizing an expected volatility figure based on a review of the Company's historical volatility, over a period of time, equivalent to the expected life of the instrument being valued. The expected dividend yield is based upon the fact that the Company has not historically paid dividends, and does not expect to pay dividends in the near future.

Option forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate will be adjusted periodically based on the extent to which actual option forfeitures differ, or are expected to differ, from the previous estimate, when it is material. The Company estimated forfeitures related to options at annual rates ranging from 0% to 5% for options outstanding at December 31, 2015 and 2014.

The weighted average estimated fair value of the options granted during the years ended December 31, 2015 and 2014 was $4.18 and $5.60 per share, respectively.

During the year ended December 31, 2014, the Company issued an aggregate of 306,403 shares of common stock to several holders of options who elected to exercise options to purchase an aggregate of 333,876 shares of common stock (57,143 shares on a "cashless" basis under the terms of the options and 276,733 shares for cash proceeds of $1.4 million). The options had exercise prices of $4.38 per share (252,217 gross shares), $5.47 per share (11,428 gross shares), $6.34 per share (22,857 gross shares) and $6.56 per share (47,374 gross shares). The aggregate intrinsic value of the options exercised was $943,000 for the year ended December 31, 2014.

During the year ended December 31, 2015, the Company issued an aggregate of 75,919 shares of common stock to several holders of options who elected to exercise options to purchase an aggregate of 75,919 shares of common stock for cash proceeds of $332,000. The options had an exercise price of $4.38 per share. The aggregate intrinsic value of the options exercised was $86,000 for the year ended December 31, 2015.

As of December 31, 2015, there was $5.4 million of unrecognized stock-based compensation expense related to stock options which will be amortized over a weighted average period of 1.6 years.

A summary of the stock option activity during the years ended December 31, 2015 and 2014 is presented below:

				Intrinsic Value

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	
Outstanding, December 31, 2013	4,985,586	$ 6.47		
Granted	1,273,520	7.00		
Exercised	(333,876)	4.86		
Forfeited	(1,107,570)	7.19		
Outstanding, December 31, 2014	4,817,660	$ 6.56		
Granted	1,905,000	5.38		
Exercised	(75,919)	4.38		
Forfeited	(416,192)	5.96		
Outstanding, December 31, 2015	6,230,549	$ 6.26	7.4	$ -
Exerciseable, December 31, 2015	3,296,198	$ 6.09	6.2	$ -

The following table presents information related to stock options at December 31, 2015:

	Options Outstanding		Options Exercisable		
Range of Exercise Price	Weighted Average Exercise Price	Outstanding Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Exercisable Number of Options
$3.28-$3.99	$3.35	512,971	$ 3.36	7.4	407,304
$4.00-$4.99	4.58	1,488,505	4.41	3.8	894,502
$5.00-$5.99	5.28	676,760	5.44	5.9	228,687
$6.00-$6.99	6.59	2,212,796	6.77	7.6	1,045,141
$7.00-$7.99	7.75	31,000	7.75	8.3	10,333
$8.00-$8.99	8.74	780,065	8.74	6.7	540,174
$9.00-$9.99	9.00	264,833	9.00	6.8	113,828
$10.00-$26.69	10.96	263,619	11.01	7.2	56,229
		6,230,549		6.2	3,296,198

12. Income Taxes

The Company files corporate income tax returns in U.S. federal, state and local jurisdictions, including Pennsylvania, and has tax returns subject to examination by tax authorities generally beginning in the year ended December 31, 2012 and through December 31, 2015. However, to the extent the Company utilizes the net operating loss (“NOL”) carryforwards in the future, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities of the future period tax return in which the attribute is utilized.

The income tax (benefit) expense consists of the following:

	For The Years Ended December 31,	
	2015	2014
Federal:		
Current	$-	$-
Deferred	(1,509,375)	10,000
State and local:		
Current	3,480	-
Deferred	(211,808)	4,000
Income tax (benefit) expense	$(1,717,703)	$14,000

F-27

For the years ended December 31, 2015 and 2014, the expected tax (benefit) expense based on the statutory rate reconciled with the actual (benefit) expense is as follows:

	For The Years Ended December 31,	
	2015	2014
U.S. federal statutory rate	34.0 %	34.0 %
State tax rate, net of federal benefit	4.8 %	4.2 %
Permanent differences		
- Change in fair value of warrant liability	2.6 %	(0.1)%
- Change in fair value of contingent	1.8 %	0.0 %
-Acquisition Costs	(2.2)%	0.0 %
- Other	(0.6)%	(1.6)%
Adjustments to deferred taxes	(2.4)%	(13.8)%
Change in valuation allowance	(31.8)%	(22.8)%
Income tax (benefit) expense	6.2 %	(0.1)%

As of December 31, 2015 and 2014, the Company’s deferred tax assets consisted of the effects of temporary differences attributable to the following:

	As of December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	$35,283,725	$18,844,000
Stock-based compensation	7,713,496	5,028,000
Accruals	496,396	579,000
Other	252,595	244,000
Total deferred tax assets	43,746,212	24,695,000
Valuation allowance	(32,976,841)	(24,081,000)
Deferred tax assets, net of valuation allowance	$10,769,371	$614,000
Deferred tax liabilities:		
Property and equipment	(409,193)	(515,000)
Intangible assets	(10,360,178)	(99,000)
Goodwill	(1,468,066)	(67,000)
Total deferred tax liabilities	(12,237,437)	(681,000)
Net deferred tax liabilities	$(1,468,066)	$(67,000)

For the years ended December 31, 2015 and 2014, the Company had approximately $92,990,000 and $50,043,000 of federal NOL carryovers, respectively, which substantially begin to expire in 2020 and through 2035. The company also has state NOL carryovers in multiple jurisdictions, including most materially in Pennsylvania, $22,876,000 and $11,648,000, and in Florida, $9,812,000 and $7,850,000, as of December 31, 2015 and December 31, 2014, respectively. The net operating loss carryovers may be subject to annual limitations under Internal Revenue Code Section 382, and similar state provisions, should there be a greater than 50% ownership change as determined under the applicable income tax regulations. The amount of the limitation would be determined based on the value of the company immediately prior to the ownership change and subsequent ownership changes could further impact the amount of the annual limitation. An ownership change pursuant to Section 382 may have occurred in the past or could happen in the future, such that the NOLs available for utilization could be significantly limited. The Company will perform a Section 382 analysis in the future. On May 29, 2015, the Company acquired Celleration, Inc. (see Note 3 - Acquisitions) and the company has performed a Section 382 study for Celleration, Inc. The amount of federal NOL carryforwards as of December 31, 2015 disclosed above do not include $47,945,000 of Celleration, Inc. NOL carryforwards that are expected to expire unutilized pursuant to the Section 382 study. The Celleration, Inc. state NOL carryforwards have also been reduced accordingly. On May 5, 2014, the Company acquired the equity interests of Choice (see Note 3 – Acquisitions) and the Company believes the Choice NOL carryforwards as of that date are subject to Section 382 limitations. The amount of federal NOL carryforwards as of December 31, 2015 and December 31, 2014 disclosed above do not include $2,498,000 of Choice NOL carryforwards that the Company has estimated will expire unutilized pursuant to this limitation.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of the deferred tax assets is dependent upon the future generation of taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. The deferred tax liabilities related to goodwill and to a tradename cannot be used in this determination since both assets are considered to be assets with an indefinite life for financial reporting purposes. After consideration of all the evidence, both positive and negative, management has recorded a full valuation allowance against net deferred tax assets at December 31, 2015 and December 31, 2014 because management has determined that it is more likely than not that these deferred tax assets will not be realized. The valuation allowance increased by $8,895,000 and $6,474,000 during the years ended December 31, 2015 and December 31, 2014, respectively, primarily related to increases in NOL carryforwards. The increase during the year ended December 31, 2015 was net of the release of valuation allowances of $1,735,000 million resulting from the acquisition of Celleration in May 2015 for which the Company recorded an income tax benefit.

13. Related Party

In November 2015, the Company entered into a manufacturing supply agreement with a company where a Company director is a member of the Board of Directors. No payments were made to this vendor in the year ended December 31, 2015.

The Company has entered into several agreements with CCT, a wholly-owned subsidiary of Celgene Corporation, as described in Note 10 – Commitments and Contingencies. Celgene is an affiliate of the Company. Two executives of Celgene are on the Company's board of directors. On May 6, 2015, the Company amended its exclusive licensing agreement with CCT, which granted the Company the right to develop and market CCT's connective tissue matrix product ("CTM").

On May 4, 2015, the Company entered into a securities purchase agreement with Celgene, pursuant to which the Company issued 659,340 shares of common stock at $4.55 per share.

On April 14, 2014, the Company entered into a securities purchase agreement with Celgene, pursuant to which the Company issued (i) 714,286 shares of common stock at $7.00 per share and (ii) five year warrants to purchase 142,857 shares of common stock at an exercise price of $10.50 per share, in exchange for aggregate consideration of approximately $5,000,000.

On January 6, 2014, the Company entered into an option cancellation and release agreement with two former directors, pursuant to which each of the parties agreed to cancel options previously granted to purchase 278,096 shares

of common stock of the Company at exercise prices ranging from $6.34 to $9.19. In exchange for the cancellation of the options, the Company granted each individual 194,667 shares of common stock of the Company pursuant to the 2011 Plan. The incremental expense for the exchange was $99,000 and is included in stock-based compensation in the year ended December 31, 2014.

14. Concentration of Risk

Revenue for the years ended December 31, 2015 and 2014, and accounts receivable as of December 31, 2015 from the Company's largest customer, a contract manufacturing customer, was as follows:

	2015		2014	
Customer	% of Total Revenue	Accounts Receivable	% of Total Revenue	Accounts Receivable
A	10 %	9 %	23 %	9 %

15. Fair Value Measurement

Fair value is defined as the price that would be received upon selling an asset or the price paid to transfer a liability on the measurement date. It focuses on the exit price in the principal or most advantageous market for the asset or liability in an orderly transaction between willing market participants. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair values are as follows:

Level 1: Observable prices in active markets for identical assets and liabilities.

Level 2: Observable inputs other than quoted prices in active markets for identical assets and liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities.

During the year ended December 31, 2014, warrant liabilities to purchase an aggregate of 82,971 shares of common stock were exercised. These warrants had an aggregate exercise date fair value of $673,000 which was credited to equity. The Company recorded a loss on the change in fair value of these warrants of $202,000 during the year ended December 31, 2014. The Company recomputed the fair value of these warrants using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 102.63%, risk-free rate of 1.19%-1.22%, expected term of 3.78-3.81 years, and expected dividends of 0.00%.

On December 31, 2014, the Company recomputed the fair value of its remaining warrant liability of warrants to purchase an aggregate of 75,429 shares of common stock as $304,000 using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 98.25%, risk-free rate of 1.10%, expected term of 2.86 years, and expected dividends of 0.00%. The Company recorded a gain on the change in fair value of these warrant liabilities of $159,000 during the year ended December 31, 2014.

During the year ended December 31, 2015, a warrant to purchase an aggregate of 9,142 shares of common stock which had been accounted for as a derivative liability was exercised. These warrants had an aggregate exercise date fair value of $31,000 which was credited to equity. The Company recorded a gain on the change in fair value of these warrants of $4,000 during the year ended December 31, 2015. The Company recomputed the fair value of these warrants using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 98.25%, risk-free rate of 0.96%, expected term of 2.52 years, and expected dividends of 0.00%.

During the year ended December 31, 2015, in connection with the Credit Agreement, a five-year warrant to purchase 750,000 shares of common stock at an exercise price of $5.5138 per share was issued to Perceptive. See Note 9 – Debt for details associated with the warrant. The issuance date fair value of $2.7 million was computed using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 98.25%, risk-free rate of 1.49%, expected term of 5.00 years, and expected dividends of 0.00%.

On December 31, 2015, the Company recomputed the fair value of its warrant liability of outstanding warrants to purchase an aggregate of 816,287 shares of common stock as $861,000 using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 89.95%, risk-free rate of 1.06-1.54%, expected term of 1.86-4.41 years, and expected dividends of 0.00%. The Company recorded a gain on the change in fair value of these warrant liabilities of $2.1 million during the year ended December 31, 2015.

The following table sets forth a summary of the changes in the fair value of Level 3 warrant liabilities that are measured at fair value on a recurring basis:

	December 31,	
	2015	2014
Warrant Liabilities		
Beginning balance as of January 1,	$304,223	$933,465
Change in fair value of warrant liability	(2,094,784)	43,390
Value of warrants issued	2,682,710	-
Value of warrants exercised	(31,498)	(672,632)
Ending balance as of December 31,	$860,651	$304,223

	December 31,	
	2015	2014
Contingent Consideration		
Beginning balance as of January 1,	$2,931,598	$-
Initial fair value of contingent consideration	15,570,000	2,700,000
Change in fair value of contingent consideration	(1,473,700)	231,598
Ending balance as of December 31,	$17,027,898	$2,931,598

Assets and liabilities measured at fair value on a recurring or nonrecurring basis are as follows:

	December 31, 2015		
	Level 1	Level 2	Level 3
Liabilities:			
Warrant liabilities	$-	$ -	$860,651
Contingent consideration	-	-	17,027,898
Total liabilities	$-	$ -	$17,888,549

	December 31, 2014		
	Level 1	Level 2	Level 3
Liabilities:			
Warrant liabilities	$-	$ -	$304,223
Contingent consideration	-	-	2,931,598
Total liabilities	$-	$ -	$3,235,821

Warrants that contain exercise reset provisions and contingent consideration liabilities are Level 3 derivative liabilities measured at fair value on a recurring basis using pricing models for which at least one significant assumption is unobservable as defined in ASC 820. The fair value of contingent consideration liabilities that are classified as Level 3 were estimated using a discounted cash flow technique with significant inputs that are not observable in the market and thus represents a Level 3 fair value measurement as defined in ASC 820. The significant inputs in the Level 3 measurement not supported by market activity include the probability assessments of expected future cash flows related to the acquisitions, appropriately discounted considering the uncertainties associated with the obligation, and as calculated in accordance with the terms of the acquisition agreements. The development and determination of the unobservable inputs for Level 3 fair value measurements and the fair value calculations are the responsibility of the Company’s Chief Financial Officer and are approved by the Chief Executive Officer.

16. Defined Contribution Plan

The Company maintains the Alliqua, Inc. 401(k) Profit Sharing Plan and Trust ("Plan") in accordance with the provisions of Section 401(k) of the Internal Revenue Code ("Code"). The Plan covers substantially all full-time employees of the Company. Participants may contribute up to 100% of their total compensation to the Plan, not to exceed the limit as defined in the Code. Under this plan, the Company matches 50% of the employee's contributions up to 6% of the employee's annual compensation, as defined by the plan. Employees are eligible for the match after a six-month waiting period and the Company match vests immediately. The Company's contribution to the plan was $75,000 for the year ended December 31, 2015. The Company did not provide a Company match prior to 2015, therefore, no expenses were recorded during the years ended December 31, 2014.