

Alliqua, Inc.  
Form 10-K  
March 24, 2014

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON D.C. 20549**

**FORM 10-K**

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

For the fiscal year ended: **December 31, 2013**

**OR**

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

COMMISSION FILE NUMBER: **001-36278**

**Alliqua, Inc.**

(Exact name of Registrant as specified in its charter)

**Florida**

(State or other jurisdiction of incorporation)

**58-2349413**

(I.R.S. Employer Identification Number)

**2150 Cabot Blvd. West**

**Langhorne, PA**

(Address of principal executive office)

**19047**

(Zip Code)

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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 ☒

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was

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required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) . Yes ☐ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

(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 ☒

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 28, 2013 was \$18,146,801. (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 March 20, 2014 was 12,501,525 shares.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Proxy Statement for the 2014 Annual Meeting of Shareholders, which is to be filed with the Securities and Exchange Commission no later than April 30, 2014 are incorporated by reference into Part III of this report.

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**ALLIQUA, INC.**

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## PART I

### ITEM 1. BUSINESS

#### Forward-Looking Statements

This 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,” “believe,” “e” 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:

- the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- inadequate capital;
- 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;
- loss or retirement of key executives;
- 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;
- 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 “Part I Item 1A. Risk Factors” in this Report. 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 Florida corporation that was originally formed in 1997 under the name Zeta Corporation. On April 17, 2003, we changed our name to Hepalife Technologies, Inc. and, on December 20, 2010, we changed our name to Alliqua, Inc. We operate through the following wholly-owned subsidiaries: AquaMed Technologies, Inc. (“AquaMed Technologies”), Alliqua Biomedical, Inc. (“Alliqua Biomedical”) and HepaLife Biosystems, Inc. (“HepaLife”).

Our principal executive offices are located at 2150 Cabot Boulevard West, Langhorne, Pennsylvania 19047. Our telephone number is 215-702-8550 and our website is located at <http://www.alliqua.com>.

## **Description of Business**

### ***Products and Services***

We are a provider of advanced wound care solutions. Through our hydrogel technology platform and licensed and proprietary products, we seek to create superior outcomes for patients, providers, and partners. Our core businesses include advanced wound care and contract manufacturing. We leverage our proprietary hydrogel and licensed technology to add value to our own products and those of our partners.

We have historically served as a contract manufacturer, supplying our gels to third parties who incorporate them into their own products. In July 2012, we began to market two proprietary products, SilverSeal® (“SilverSeal”), a hydrogel wound dressing with silver coated fibers, and Hydress® (“Hydress”), an over-the-counter hydrogel wound dressing. We supply these gels primarily to the wound care segment of the healthcare industry.

Our SilverSeal and Hydress dressings are each currently available in two sizes. They are used to provide and maintain a moist wound environment. The benefits of these products include reduced scarring and pain, greater speed of healing and increased absorption of exudate (fluid that filters from the circulatory system into lesions or areas of inflammation). 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, our SilverSeal dressing was shown to have a lower incidence of incision complications, including infection, and a greater 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 incision complications such as superficial or deep infections or wound rupture, along the surgical suture. Of the nine incision 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. Length of post-surgical scarring was also reduced to a greater extent in patients using SilverSeal compared to those with a standard petroleum-based dressing. Additional studies may be necessary to further investigate those potentially favorable results.

In September 2013, we entered into a long-term agreement with Sorbion GmbH & Co. KG (“Sorbion”) to distribute the sorbion sachet S, sorbion sana and new products with hydrokinetic fibers as primary dressings. We have the exclusive rights to sell these products throughout all of the Americas. In September 2013, we also entered into an agreement with Carolon Company (“Carolon”) pursuant to which we purchased the distribution rights to the sorbion sachet and sana products from Carolon.

Intended for wound bed preparation, sorbion sachet S (a comprehensive approach to removing barriers to healing and stimulating the healing process), is indicated as a primary dressing for moderately to highly exudating wounds such as surgical wounds, venous leg ulcers and diabetic ulcers. It assists in the removal of slough (dead skin tissue) and toxins, locks in bacteria and reduces odor. 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 and granulation (the formation of 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.

In connection with our 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 believe that we are one of only two known manufacturers of high performance gels in the world. 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***

On November 14, 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 collagen-based decellularized and dehydrated topical wound covering produced from human amniotic membrane for the management of non-infected partial- and full-thickness wounds. The license agreement permits us to develop and commercialize ECM and Biovance in the United States. The development and application of the intellectual property covered under the license agreement will be managed by a joint steering committee, composed of members of us and CCT. Following the commencement of commercial sales of the licensed products, we will 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 November 14, 2013, we also entered into a supply agreement with CCT, pursuant to which CCT will supply us with the entire requirement of Biovance for distribution and sale in the United States. We expect to commence selling the Biovance product in April 2014. The Supply Agreement also provides that we and CCT will enter into a supply agreement for ECMs, on substantially the same terms as the Supply Agreement, prior to the anticipated date on which all regulatory approvals or clearances are acquired for the commercial sale of ECMs.

Biovance is a wound healing product made from decellularized and dehydrated human amniotic membrane. It is commercially available under Section 361 of the Public Health Service Act, which allows “minimally manipulated” human cells, tissues, and cellular and tissue-based products (HCT/Ps) to be marketed in the United States (U.S.) without pre-market FDA approval (also called a ‘361 product). Biovance is derived from the placenta of a normal, full-term pregnancy, therefore it is natural human tissue that contains collagen, fibronectin, and other proteins and nutrients that are essential to promote wound healing. Additionally, no cells are contained in the finished product (Biovance is decellularized), which is different from other placenta-based wound care products, and these features can reduce irritation and inflammation that can hamper more rapid and complete wound closure. The extracellular matrix composition of Biovance forms a collagen scaffold within the wound bed, which serves as a platform to attract the body’s own cells and growth factors required for proper wound closure. Biovance is intended for use as a biological tissue graft for the repair of non-infected damaged tissue. It is intended for application to open traumatic wounds, complex wounds such as burns, open surgical wounds, Moh’s procedure (microscopically controlled surgery for skin cancer), and chronic wounds such as diabetic ulcers, venous and arterial ulcers, pressure, and other ulcers. Biovance may also be used for wounds with exposed tendon, muscle, bone or other vital structures.

While Biovance is made from amniotic membrane, products that will come from CCT's ECM platform are derived from whole placenta, which we believe will enable greater supply, greater ease of manufacture, a lower cost of goods, and most importantly, the ability to manufacture various product "forms", which can be more versatile versus tissue-based (or '361) products. We expect to obtain approval of the ECM product line using the 510(k) medical device regulatory route in 2014, with the first of such wound care solutions entering the market in 2015. Under the 510(k) process, CCT will file with the FDA data demonstrating safety and efficacy of ECM, as well its similarity to devices already on the market. CCT's proprietary manufacturing process for its ECM-based products results in a paste-like raw material that can be finished into sheets with various shapes, sizes, and thicknesses, a powder, or a flowable matrix configuration. These product forms can be clinically useful given the different types of wounds and different wound conditions (larger, deeper, and/or tunneling wounds). This next-generation line of placenta-based products is intended to address a broad range of wound types and topical wound conditions such as partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled wounds, surgical wounds, trauma and draining wounds.

ECM products are rich in collagen and elastin, and while they do not contain all of the components of amniotic membrane (little to no fibronectin or laminin), they still provide the scaffold and key nutrients to attract the body's growth factors for proper wound healing.

Key attributes anticipated for the ECM products include:

- they can be used off the shelf, with little to no preparation;
- no special storage is required;
- there is potential for large sheets (coverage of large wounds);
- no specific product orientation is required for graft placement;
- no removal required, integrates into the wound; and
- they facilitate high quality healing, appropriate pigmentation and hair growth and limit burn injury progression and scarring.

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, that it will be easier to sell a more comprehensive suite of wound care products, and that acquiring a product with established sales channels would 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 of our existing products through both improvements and the expansion of customer options (e.g. improvements to our liner and additional offerings in different sizes and shapes). Because our products are already approved by the U.S. Food and Drug Administration, 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.

### ***Drug Delivery and HepaMate***

Our strategy is to primarily focus on building a portfolio of wound care products. We are, therefore, evaluating strategic alternatives for our drug delivery and HepaMate technologies.

We believe our hydrogels can be utilized as delivery mechanisms for both prescription and over-the-counter medications to be delivered through the skin into the blood stream, known as transdermal delivery, or to be delivered between the layers of the skin, known as intradermal delivery. Active ingredients can also be added to our gels for use in wound and burn dressings and to provide for the topical application of non-prescription drugs.

We have begun to develop a transdermal lidocaine patch to treat pain associated with past herpetic neuralgia, or PHN, a complication of shingles in which pain lasts after the shingles rash and blisters have disappeared. In 2013 we commissioned a preclinical study that concluded that our investigational lidocaine transdermal patch compares favorably to the Lidoderm® (Lidocaine patch 5%) patch that is currently on the market. The overall results indicate that our patch is able to deliver in the pig a slightly higher amount of lidocaine than Lidoderm and to reach maximum delivery within a comparable period. No skin irritation occurred with either the Alliqua transdermal patch or Lidoderm patch. The study concludes that further development could result in the creation of a commercial lidocaine patch that could be a generic version of the Lidoderm patch or provide better drug delivery resulting in a 505 (b)(2) approval by the U.S. Food and Drug Administration.

The primary objective of the study was to conduct a comparative pharmacokinetic (PK) analysis of lidocaine in our transdermal patch compared to Lidoderm in the pig. The non-GLP (good laboratory practices, a system of quality management controls) in vivo crossover study was designed to evaluate the delivery of lidocaine over 24 hours in our patch and Lidoderm with regard to feasible length of application.

The study found that our patch offers a higher peak plasma concentration (C<sub>max</sub>) of lidocaine than Lidoderm (4.96±1.16 ng/mL versus 3.03±1.92 ng/mL) and higher mean total area under the curve (AUC<sub>total</sub>) than the competing product 66.5 ng/mL-h versus 48.9 ng/mL-h)). The mean period of peak concentration (T<sub>max</sub>) was 8.7 hours for our patch versus 10.7 hours for Lidoderm.

In addition, our patch was easier and cleaner to remove from the skin after application, with minimal or no patch impression (outline) remaining. The presence of adhesive in Lidoderm seemed to have a "peel-off effect" on the skin (similar to an adhesive bandage); in contrast, our hydrogel patch has self-adhering characteristics and is easily removed from the skin at the end of a patch application without residual skin markings.

Our HepaMate technology focuses on the development of a cell-based bioartificial liver system. Our strategy has evolved to become a provider of advanced wound care products. We do not intend to further develop this technology nor do we intend to allocate any new capital to this technology. In 2013 we engaged an investment bank to find a strategic partner for the technology; however this process has been unsuccessful.

### ***Industry and Markets***

According to a study by the medical market research firm Kalorama Information ("Wound Care Markets 2012") the global market for wound care management products, which had revenues of approximately \$16 billion in 2011, is expected to grow to \$23 billion by 2016, which is a compound annual growth rate of 9.5% for 2011 to 2016. Growth in the worldwide 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. New emerging markets in countries such as China, Brazil, and India are also a major driving force behind the expected growth in the global wound care market.

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

**Diabetic Ulcers.** According to the National Diabetes Clearinghouse ("National Diabetes Fact Sheet, 2011" available at [www.cdc.gov](http://www.cdc.gov)) there are over 25.8 million diabetics in the U.S., or more than 8.3% of the U.S. population. Almost 11 million people over the age of 65 are diabetic, which equates to almost 27% 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](http://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: 2013 Fact Sheet,” available at [www.ameriburn.org/resources\\_factsheet.php](http://www.ameriburn.org/resources_factsheet.php)), an estimated 450,000 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. In 2013, we restructured our senior management team with the goal of maximizing the potential for success in achieving our sales and marketing goals. In addition to appointing a new chief executive officer and chief financial officer, we have also hired a number of senior sales and marketing executives. We believe these individuals have significant experience in our industry, selling products similar to ours. In addition, we have hired several other professionals with industry marketing experience. We expect to continue to attend trade shows and seek other avenues to market our products.

During 2013, we also established an independent network of agents to sell our wound care products as well as an extensive network of distributors to supply our products. To enhance our sales efforts, we intend to hire approximately 20 direct sales agents in 2014, who have a background in the wound care industry.

We have also retained certain consultants and an outside sales organization to educate medical professionals about the benefits of these dressings. These individuals will visit physician offices, hospitals, home health care facilities, nursing homes and medical facilities to perform in-service presentations in order to educate medical personnel about the attributes of our products. We have also assembled a Medical Advisory Board to help us target improvements and new applications for our products and assist in our marketing efforts.

Below is a discussion of our anticipated marketing efforts:

**Advanced Wound Care Dressings.** We have begun to market our own branded line of advanced wound care hydrogel products, and more recently the product portfolio of our partner, Sorbion. In 2014, we intend to start the marketing of the biologics portfolio licensed from CCT. These marketing efforts include, but are not limited to: an independent selling organization; hiring of direct sales agents, conferences and educational events. We believe that the markets for our wound healing products will continue to expand due to the growing recognition by professionals and consumers of these technologies.

**Contract Manufacturing.** We sell our hydrogel technologies on a contract manufacturing basis for use in a variety of other applications, including medical devices and cosmetics. We have identified and targeted manufacturers of high quality medical devices (such as monitoring electrodes and devices and defibrillator pads) as a core segment of our future revenue streams. In addition, hydrogel patches and hydrogel products have been used by some of the

leading cosmetic companies in the U.S. These products include over-the-counter skin care preparation and other products for cosmetic use. On a regular basis, we receive product inquiries from cosmetic companies looking for hydrogel solutions. We believe that our products will be considered as replacements for existing adhesive and gels due to the quality and increased acceptance of our products in the marketplace.

## ***Customers***

During 2013 and 2012 our sales were comprised primarily of contract manufacturing sales. We are dependent on a small number of customers that account for the vast majority of our contract manufacturing revenue. For the fiscal year ended December 31, 2013, two major customers accounted for approximately 67% of our revenue, with each customer individually accounting for 51% and 16%, respectively. These customers accounted for approximately 76% of our revenue for the fiscal year ended December 31, 2012, with each customer individually accounting for 60% and 16%, respectively. These customers are both medical device manufacturers. We expect that as revenues from the sales of our proprietary wound dressings increase, this customer concentration will continue to abate in 2014.

## ***Hydrogel Technology and Manufacturing***

Hydrogels are manufactured by introducing a hydrophilic polymer, which is a polymer that has a tendency to mix with or dissolve in water, into water to create a feed mix. 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, are 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 Hydrogel Technologies***

*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 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 estimated to be in excess of \$7 million. 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.

Using our RDI Accelerator, we both cross-link materials for own products and perform contract irradiation services related to modifying certain materials for third parties. These third party contract activities account for less than 10% of our revenue. Products processed using these irradiation services include catheter tubing, sheet material and gemstones. These services are performed on an hourly basis, require minimal labor, and typically do not require us to supply any materials.

### ***Competition***

We believe that our proprietary competitive manufacturing advantages, along with the high barrier to entry, including the substantial cost of acquiring an electron beam as compared to other cross-linking devices, the cost and extended time required for installing this beam, and current minimal level of competition for high performance gels, affords us the opportunity to be a leader in the applications that require tight tolerances and/or incorporate active ingredients.

Our main competitor in the high performance gel industry is Covidien plc. We believe that we are able to compete effectively with Covidien plc, primarily due to our proprietary manufacturing methods. In addition, our smaller size, as compared to Covidien plc, allows us to provide greater individualized service to our customers and make decisions as a company more quickly and efficiently. However, we believe that, due to its size, Covidien plc may have significant advantages over us. Covidien plc has its own distribution networks for its products, including its hydrogel products, which, we believe, gives it an advantage over us in reaching potential customers. In addition, Covidien plc is vertically-integrated, which may allow it to maximize efficiencies that we cannot achieve with our third-party shippers and distributors. Finally, because of its significantly greater resources, Covidien plc may be able to focus on research and development of hydrogel technology more than we are able to. In general, we believe that Covidien plc has, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do.

In the general hydrogel market, there are other companies producing hydrogel products that are larger than us, with greater knowledge and resources than we have. We believe that we are competitive on the basis of our low cost and high quality, as well as the other factors described above. There are manufacturers in Asia who offer low-cost solutions like ours, however we believe that the quality of their product is inferior to ours. For new market entrants, we believe that the barrier to entry is both timely and costly, and it could take two years or more to successfully complete the build-out necessary to produce high performance hydrogel like ours.

In addition, while we believe that our hydrogel products have many applications, there are limitations on our hydrogel products. For example, our hydrogels are not designed to remain moist for extended periods of time once removed from their packaging; therefore, our hydrogels may not be appropriate for products that require a gel to remain moist. Furthermore, our hydrogels may not be cost-efficient replacements for adhesives that are not used as method of drug delivery because regular adhesives are less expensive than our hydrogels.

There are several established silver-based wound dressings and other products which are already in the marketplace that compete with SilverSeal. These include Acticoat (sold by Smith & Nephew), SeaSorb (sold by Coloplast), and Actisorb (sold by Systagenix). We believe that our low cost of sales will enable us to capture market share from our competitors. However, our ability to establish sales in a market with many larger manufacturers may be difficult. We continue to recruit proven 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.

The sorbion products compete in the exudate management area of advanced wound care. The competitors in this space are the foam and alginate based products as well as the “superabsorbent” category of products. The market leaders in the foam and alginate categories are Smith and Nephew and Molnlycke. These companies have large market shares with their products making it difficult to compete. In the superabsorbent area, Medline and DermaSciences compete most directly with sorbion products. The proprietary sorbion (Hydration Response Technology), offers significantly better absorption and retention properties than the foam and traditional alginates providing differentiation against these competitors. With regard to the “superabsorbent” dressings, sorbion has demonstrated higher absorption capacity in studies, as well as retention of bacteria and harmful wound drainage components that the others have not matched. Medline with their large distribution capability and low price strategy makes them a challenging competitor. We will rely on product differentiation and data to compete.

Leading competitors in the tissue based wound care area that will compete with our Biovance and ECM products include companies such as Smith and Nephew, MiMedx Group, LLC, Organogenesis and Osiris. This market is estimated to be \$600 million and growing at approximately 10% (“MedMarket Diligence, March 2013”). As the tissue based market expands, we believe that our partnership with Celgene Cellular Therapeutics for placenta derived treatments will help the market grow overall. We also believe that human derived tissue based products such as ours can compete favorably versus animal derived products. Additionally, many competitors in this space do not offer a range of wound care solutions to the clinician for when the tissue based products are not needed or to prepare the wound for the graft products. Smith and Nephew has this advantage and we intend to be able to do this as well with our suite of advanced wound care technologies.

***Sources and Availability of Raw Materials; Principal Suppliers***

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 our hydrogels. We believe that, due to the size and scale of production of our suppliers, there should be adequate supply of these raw materials from our manufacturers. Although we have not experienced significant production delays attributable to supply changes, we believe that developing alternative sources of supply for the polymers used to make our current hydrogels would be difficult over a short period of time. 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.

***Patents, Proprietary Rights and Trademarks***

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 on trade secret protection for our confidential and proprietary information.

Our subsidiary, Alliqua Biomedical, Inc., has an exclusive worldwide license to use Noble Fiber Technologies, LLC's silver coated fibers marketed under the trademarks X-Static® and SilverSeal® in Alliqua Biomedical, Inc.'s manufacture, sale, use and distribution of Hydrogel Wound Dressing identified in 510(k) K040019 and Hydrocolloid Wound Dressing identified in 510(k) K033900. 510(k) is a premarket notification form that device manufacturers are required to file in order to notify the U.S. Food and Drug Administration of their intent to market a medical device at least 90 days in advance. We have an exclusive license until July 2021 with the ability to renew for another 10 years.

Our subsidiary, HepaLife Biosystems, Inc. has an exclusive license agreement with the U.S. Department of Agriculture, Agricultural Research Service for existing and future patents related to the PICM-19 hepatocyte cell lines. Under this license agreement, we are responsible for annual license maintenance fees commencing in 2010 for the term of the license, which is until the expiration of the last to expire licensed patents unless terminated earlier. The license agreement also requires certain milestone payments, if and when milestones are reached, as well as royalties on net sales of resulting licensed products, if any.

We are party to a long-term agreement with Sorbion GmbH & Co. KG ("Sorbion") to distribute the Sorbion sachet S, Sorbion sana and new products with hydrokinetic fibers as primary wound dressings. We have the exclusive rights to sell these Sorbion products throughout all of the Americas.

The initial term of the Sorbion agreement ends on December 31, 2018, unless sooner terminated pursuant to the termination rights under the agreement, and will be extended for additional year terms until December 31, 2023, so long as we and Sorbion agree in September as to the minimum annual purchase amount for the calendar year that ends four years from the calendar year of such September, such that, for example, in September 2014, we and Sorbion must agree to the minimum annual purchase amount for the 2018 calendar year so that the Sorbion agreement is extended until December 31, 2019. We may terminate the agreement upon six months prior written notice to Sorbion. Sorbion may terminate the agreement for good cause, which shall include our application for insolvency proceedings, a change of control of us that may disrupt our relationship with Sorbion, our failure to cure a material breach of the agreement within 60 days or our challenge of Sorbion's intellectual property.

In order to maintain our exclusivity, we must purchase the following minimum amounts, in Euros, under the Sorbion agreement for the indicated calendar year:

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Calendar Year	Minimum Annual Purchase Amount
2014	500,000 Euros
2015	1,000,000 Euros
2016	2,500,000 Euros
2017	4,000,000 Euros

Since we must purchase the minimum amounts in Euros, the equivalent U.S dollar expenditure will be subject to fluctuations in foreign currency. The minimum annual purchase amounts in US. Dollars for each calendar year in the period from 2014-2017, based on the exchange rate as of December 31, 2013, are \$689,000, \$1,378,000, \$3,444,000, and \$5,510,000, respectively.

We may cure a failure to purchase products in amounts that meet or exceed the minimum annual purchase amount for a calendar year by paying Sorbion in cash an amount equal to the minimum annual purchase amount for such calendar year less the amount we paid to Sorbion for the products purchased for such calendar year. If we do not cure such failure for a calendar year, Sorbion may terminate our exclusivity and grant us non-exclusive rights. If we do not cure such failure for two calendar years, Sorbion may terminate the agreement. We will not be required to meet the minimal annual purchase amount if Sorbion fails to supply us with products in accordance with the Sorbion agreement. Sorbion may also terminate our exclusivity if we do not cure a material breach of the agreement within 30 days.

Pursuant to the Sorbion agreement, we have the right to use the trademarks related to the products for sale of the products in the applicable territory.

We are also party to a license, marketing and development agreement with CCT, pursuant to which we hold an exclusive, royalty-bearing license in CCT's intellectual property related to certain placental based products, including ECM 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 will be managed by a joint steering committee, composed of members of us and CCT. Following the commencement of commercial sales of the licensed products, we will 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 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 in the second year of the license agreement, and by either CCT or us in the third year of the license agreement and beyond, if we fail 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.

### ***Government Regulation***

***Product Regulation.*** Under the Federal Food, Drug and Cosmetic Act, medical devices are classified by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration, hydrogels are

generally classified as Class I exempt devices and the majority of the hydrogel products that we manufacture are thereby exempt from the U.S. Food and Drug Administration filing of any regulatory submissions and/or pre-market notification requirements. To the extent that any U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 we are developing will be classified as either Class I or Class II medical devices. Class I medical devices are subject to the U.S. Food and Drug Administration's general controls, which include compliance with the applicable portions of the U.S. Food and Drug Administration'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 U.S. Food and Drug Administration's general controls and may also be subject to other special controls as deemed necessary by the U.S. Food and Drug Administration to ensure the safety and effectiveness of the device. Most Class II devices require pre-market clearance by the U.S. Food and Drug Administration through the 510(k) pre-market notification process. When a 510(k) is required, the manufacturer must submit to the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration is required to clear a 510(k) within 90 days of submission of the application. As a practical matter, clearance often takes longer.

The U.S. Food and Drug Administration 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 U.S. Food and Drug Administration's refusal to grant future pre-market clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution.

If there are any modifications to an approved drug, 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 U.S. Food and Drug Administration, and in many cases, approval for such changes must be submitted to the U.S. Food and Drug Administration. Additionally, the U.S. Food and Drug Administration 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. 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. The U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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.

*Regulation of Human Cells, Tissues, and Cellular and Tissue-based Products.* The U.S. Food and Drug Administration regulates the manufacture of human cells, tissues, and cellular and tissue-based products ("HCT/Ps") under the authority of section 361 of the Public Health Service Act ("PHS Act") and exercises this authority pursuant to the regulations set forth in Part 1271 in Title 21 of the Code of Federal Regulations. An HCT/P that meets the Part 1271 criteria for regulation solely under section 361 of the PHS Act and the regulations in Part 1271 is called a "361 HCT/P," and may be marketed without the premarket approval or clearance of the U.S. Food and Drug Administration. To be a 361 HCT/P, the product must meet all four of the following criteria: (1) it is minimally manipulated, (2) it is intended for homologous use as determined by labeling, advertising, or other indications of the manufacturer's objective intent, (3) its manufacture does not involve combination with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, (4) it does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function, or if so, it is intended for autologous use, allogeneic use in close relatives, or for reproductive use. 21 C.F.R. § 1271.10(a). For structural tissue, the U.S. Food and Drug Administration defines "minimal manipulation" as "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement." 21 C.F.R. § 1271.3(f)(1). The U.S. Food and Drug Administration permits manufacturers to proceed to market based upon a self-determination that a product qualifies as a 361 HCT/P. As a wound covering product made from decellularized and dehydrated human amniotic membrane, we believe that Biovance meets the regulatory requirements to be marketed in the United States as a 361 HCT/P without being subject to any premarket review requirements.

*New Drug Application ("NDA").* We have no current plans to file an NDA, however, it should be noted that FDA approval is required before any "new drug" may be marketed, including new formulations, strengths, dosage forms, and generic versions, of previously approved drugs. Generally, the following two types of applications are used to obtain FDA approval of a "new drug." For a drug product containing an active ingredient not previously approved by the FDA, a prospective manufacturer must submit a complete application containing the results of clinical studies supporting the drug product's safety and efficacy. A shorter form of an NDA under the FDA's 505(b)(2) regulatory pathway is also required for a drug with a previously approved active ingredient if the drug will be modified in some way, e.g., used to treat an indication for which the drug was not previously approved or if the dosage form, strength or method of delivery is changed. The process required by the FDA before a pharmaceutical product may be approved

for marketing in the U.S. generally involves the steps listed below, which could take from approximately three to more than ten years to complete.

Laboratory and clinical tests;

Submission of an Investigational New Drug (“IND”) application, which must become effective before clinical studies may begin;

Adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed product for its intended use;

Submission of an NDA containing the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its intended use, as well as extensive data addressing such matters such as manufacturing and quality assurance;

Scale-up to commercial manufacturing; and

FDA approval of an NDA.

As noted above, the submission of an NDA is no guarantee that the FDA will find it complete and accept it for filing. The FDA reviews all NDAs submitted before it accepts them for filing. It may refuse to file the application and instead request additional information, in which case, the application is delayed and must be resubmitted with the supplemental information. After the application is deemed filed by the FDA, FDA staff will review an NDA to determine, among other things, whether a product is safe and efficacious for its intended use.

If, after reviewing the NDA, the FDA determines that the application cannot be approved in its current form, the FDA sends the NDA applicant a Complete Response Letter identifying all outstanding deficiencies that preclude final approval. The FDA then halts its review until the applicant resubmits the NDA with new information designed to address the deficiencies. An applicant receiving a Complete Response Letter may resubmit the application with data and information addressing the FDA’s concerns or requirements, withdraw the application without prejudice to a subsequent submission of a related application or request a hearing on whether there are grounds for denying approval of the application. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, among other limits, which could restrict the commercial value of the product. In addition, the FDA may require an applicant to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug’s safety and effectiveness after NDA approval, and may require complex and costly surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market. The agency may also impose requirements that the NDA holder conduct new studies, make labeling changes, implement Risk Evaluation and Mitigation Strategies, and take other corrective measures.



*Quality Assurance Requirements.* The U.S. Food and Drug Administration enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs and medical devices conform with current good manufacturing practices. The current good manufacturing practices regulations the U.S. Food and Drug Administration 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 good manufacturing practices 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. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The U.S. Food and Drug Administration conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the drugs subject to new drug applications or NDAs and abbreviated new drug applications, or ANDAs. If the U.S. Food and Drug Administration concludes that the facilities to be used do not or did not meet current good manufacturing practices, good laboratory practices or good clinical practices requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients, or APIs, used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing current good manufacturing practices inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on our business, results of operations, financial condition and cash flows.

The U.S. Food and Drug Administration also conducts periodic inspections of drug and device facilities to assess their current good manufacturing practices status. If the U.S. Food and Drug Administration were to find serious current good manufacturing practices non-compliance during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations, financial condition and cash flows. In respect to domestic establishments, the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 with the U.S. Food and Drug Administration and we intend to register as a drug facility with the U.S. Food and Drug Administration when we are required to do so.

*Reimbursement Legislation.* Reimbursement legislation, such as Medicaid, Medicare, and other programs, governs reimbursement levels. All pharmaceutical manufacturers rebate to individual states a percentage of their revenues arising from Medicaid-reimbursed drug sales. Generic drug manufacturers currently rebate an applicable percentage of the calculated average manufacturer price marketed under abbreviated new drug applications. We believe that the federal and state governments may continue to enact measures in the future aimed at reducing the cost of drugs and devices to the public. We cannot predict the nature of such measures or their impact on our profitability.



In early 2012, we received from the Pricing, Data, Analysis, and Coding contractor for the Centers for Medicare and Medicaid Services, or CMS, the Healthcare Common Procedural Coding System, or HCPCS, codes, for use when billing for our silver based antimicrobial hydrogel 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.

We have applied to CMS for permanent outpatient reimbursement for our Biovance product that we intend to launch in 2014. This approval, if received, would be effective in 2015. We intend to apply for temporary outpatient reimbursement for Biovance, which approval, if received, would be effective in the second half of 2014.

*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.

### ***Research and Development Costs***

For the fiscal years ended December 31, 2013 and 2012, we incurred research and development costs totaling \$63,204 and \$233,819, respectively. We bear our own research and development costs and do not directly pass along our research and development costs to our customers; however, we build our research and development costs into the pricing structure of our products.

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 March 21, 2014, we had 39 full-time employees. Of these employees, 29 are involved with finance, sales, marketing, and administration and 10 are involved with manufacturing, research and development, 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. To the best of our knowledge, none of our employees, officers or directors is bound by restrictive covenants from prior employers that would preclude them from providing services to us, except as described under "Item 3. Legal Proceedings." We currently plan to retain and utilize the services of outside consultants for additional research, testing, regulatory, accounting, 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.*

## **Risk Relating to Our Company**

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

We have yet to establish any history of profitable operations. We have incurred annual net losses of \$21,976,882 and \$4,905,335, respectively, during the fiscal years ended December 31, 2013 and 2012. As of December 31, 2013, we had an accumulated deficit of \$44,597,279. We expect to incur additional operating losses for the foreseeable future. Although we expect sales and order backlogs to increase in 2014 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, pre-launch marketing costs, the purchasing of inventory, and the billing and collection of revenue, we expect to record an increase in net operating cash outflows from operations for the first half of 2014 as compared to the last half of 2013. 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 our competition, regulatory approval of our new products, technological change, and dependence on key personnel.

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 depend on key personnel.***

We believe that our success will depend, in part, upon our ability to retain the skilled personnel we have recently added 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 personnel. Our inability to hire qualified personnel, the loss of services of our key personnel, or the loss of services of executive officers or key employees that 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.

### ***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 develop further 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.***

Our contract manufacturing business has generated most of our revenue and much of this revenue to date is generated from a limited number of clients, who account for a substantial percentage of our total revenues. For the year ended December 31, 2013, two major customers accounted for approximately 67% of revenue, with each customer individually accounting for 51% and 16%, respectively. For the year ended December 31, 2012, two major customers accounted for approximately 76% of our revenue, with each customer individually accounting for 60% and 16%, respectively. 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 licensing fees and royalties and litigation costs and the results of such litigation.

***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, 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.

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 payors;
- 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 U.S. Food and Drug Administration 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.

***We are dependent on our contract manufacturing business for all revenues.***

At this point in time, we do not generate significant revenue from the sale of our products. As a result, our business, operating results and financial condition are largely dependent upon the business, operating results and financial condition of our contract manufacturing business. Any decline in revenue or business prospects of our contract manufacturing will have a significant negative affect on us and our business.

***We are subject to governmental regulations.***

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. As a manufacturer of medical products, we are generally subject to regulation by the U.S. Food and Drug Administration and the Federal Trade Commission, among other state and federal governmental authorities in the U.S., with respect to the manufacturing, marketing, labeling, record keeping, claims and advertising of our products. 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.

The submission of a new drug application, or NDA, or an abbreviated new drug application, or ANDA, to the U.S. Food and Drug Administration with supporting clinical safety and efficacy data, does not guarantee that the U.S. Food and Drug Administration will grant approval to market the product. Meeting the U.S. Food and Drug Administration's regulatory requirements to obtain approval to market a product typically takes many years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product, and the application process is subject to uncertainty. The NDA approval process for a new product varies in time, generally requiring a minimum of 10 months, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly.

NDA approvals, if granted, may not include all uses (known as indications) for which a company may seek to market a product. The U.S. Food and Drug Administration also requires companies to undertake post-approval surveillance regarding their drug products and to report adverse events.

With respect to medical devices, such as those that we manufacture, before a new medical device, or a new use of, or claim for, an existing product can be marketed, it must first receive either premarket clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act or premarket approval from the U.S. Food and Drug Administration, unless an exemption applies. In the 510(k) clearance process, the U.S. Food and Drug Administration 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 premarket 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.

The U.S. Food and Drug Administration also regulates the manufacture of human cells, tissues, and cellular and tissue-based products (“HCT/Ps”) under the authority of section 361 of the Public Health Service Act (“PHS Act”) and exercises this authority pursuant to the regulations set forth in Part 1271 in Title 21 of the Code of Federal Regulations. 361 HCT/P products that meet the Part 1271 criteria may be marketed without the premarket approval or clearance of the U.S. Food and Drug Administration. The U.S. Food and Drug Administration permits manufacturers to proceed to market based upon a self-determination that a product qualifies as a 361 HCT/P. As a wound covering product made from decellularized and dehydrated human amniotic membrane, we believe that Biovance meets the regulatory requirements to be marketed in the United States as a 361 HCT/P without being subject to any premarket review requirements.

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 U.S. Food and Drug Administration 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.

Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current U.S. Food and Drug Administration standards of review for approving new pharmaceutical and medical device products are sometimes more stringent than those that were applied in the past. For example, the U.S. Food and Drug Administration 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. Further, some new or evolving review standards or conditions for approval or clearance were not applied to many established products currently on the market, including certain opioid products. As a result, the U.S. Food and Drug Administration does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the U.S. Food and Drug Administration has recently expressed an intention to develop such databases for certain of these products, including many opioids.

In addition, on September 27, 2007, through passage of the Food and Drug Administration Amendments Act of 2007, Congress passed legislation authorizing the U.S. Food and Drug Administration to require companies to undertake additional post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the U.S. Food and Drug Administration to require companies to formulate risk evaluation and mitigation strategies to ensure a drug's benefits outweigh its risks.

The U.S. Food and Drug Administration regulates the facilities, processes and procedures used to manufacture and market pharmaceutical and medical products in the U.S. Manufacturing facilities must be registered with the U.S. Food and Drug Administration and all products made in such facilities must be manufactured in accordance with "current good manufacturing practices," or cGMP, regulations enforced by the U.S. Food and Drug Administration. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The U.S. Food and Drug Administration periodically inspects our manufacturing facilities and those of our subcontractors and procedures to assure compliance. The U.S. Food and Drug Administration 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 U.S. Food and Drug Administration to curtail or cease operations, or otherwise becomes inoperable, or a third party contract manufacturing facility faces manufacturing problems, obtaining the required U.S. Food and Drug Administration 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 cannot determine what effect changes in regulations or legal interpretations by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration could have an adverse effect on the sales of these products. The U.S. Food and Drug Administration has authority to require a risk evaluation and mitigation strategy under the Food and Drug Administration Amendments Act of 2007 when necessary to address whether the benefits of these products continue to outweigh the risks. In addition, on September 27, 2007, Congress re-authorized requirements for testing drug products in children, which may increase the time and cost necessary for new drug development. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the U.S. Food and Drug Administration 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.

***If we fail to comply with continuing federal and state regulations, 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 experiences 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 U.S. Food and Drug Administration. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 drugs, with significant potential penalties and restrictions for promotion of drugs 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 are dependent on proprietary know-how.***

Our competitors may develop or market technologies that are more effective or more commercially attractive than ours. 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.

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.

***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 claims that the relevant law has been violated. 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, 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.

Anti-kickback laws and regulations prohibit 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 Medicare, Medicaid or other government-sponsored healthcare programs. We may engage additional physicians on a consulting basis. While these agreements with physicians will be structured with the intention of complying with all applicable laws, including the federal ban on physician self referrals, commonly known as the “Stark Law,” state anti-referral laws and other applicable anti-kickback laws, 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, or prohibit us from accepting referrals from these physicians. 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 applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of our physician advisors. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally funded healthcare programs, including Medicare and Medicaid, for non-compliance.



The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory or enforcement authorities 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 regulatory or enforcement review of us, regardless of the outcome, would 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.

***We could receive claims and demands by former employers of our employees and personnel alleging actual or potential violations of restrictive covenants, such as non-competition agreements, which if material and successfully prosecuted against us, could materially and adversely affect our business, financial condition and results of operations.***

From time to time, we may recruit and hire employees or other key personnel who are subject to restrictive covenants, such as non-competition agreements, with their former employers, of which we may not be aware at the time of hire, or which we may believe to be inapplicable. We are currently in the process of hiring several new management employees and sales personnel to expand our sales and marketing efforts for our wound care products, some of whose former employers sell products similar to ours or operate within the wound care industry. As a result, we have in the past and may in the future receive claims and demands from former employers related to alleged violations of restrictive covenants, such as non-competition agreements.

For example, a former employer recently filed suit against us, our subsidiary and three of our new employees, requesting injunctive relief for allegations involving breach of contract, tortious interference with employment agreements, unfair competition and common law conspiracy. The complaint is seeking, among other things, to enjoin us from continuing to employ the three individuals in positions related to sales of wound care products within certain geographic areas. We intend to vigorously defend these claims against us to the fullest extent permitted by the law and believe them to be wholly without merit. Although the ultimate outcome of these matters cannot be accurately predicted due to the inherent uncertainty of litigation, in the opinion of management, based upon current information, these matters are not expected to have a material adverse effect on our business, financial condition or results of operations. See “Item 3. Legal Proceedings.”

Even if we are successful on the merits, any pending or future lawsuits, claims or proceedings could be time-consuming and expensive to defend or settle and could result in the diversion of significant management time and operational resources, which could materially and adversely affect us. In addition, it is possible that an unfavorable resolution of one or more proceedings could in the future materially and adversely affect our financial position, results of operations or cash flows.

***We are uncertain regarding the success of our clinical trials for our products in development.***

Some of our products, including licensed products, in development may require clinical trials to determine their safety and efficacy for U.S. marketing approval by regulatory bodies, including the U.S. Food and Drug Administration. There can be no assurance that we or the partners to our agreements will be able to successfully complete the U.S. regulatory approval process for products in development. In addition, there can be no assurance that we or they will not encounter additional problems that will cause us or them to delay, suspend or terminate our clinical trials. In addition, we cannot make any assurance that clinical trials will be deemed sufficient in size and scope to satisfy regulatory approval requirements, or, if completed, will ultimately demonstrate these products to be safe and efficacious.

***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 payors 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 payors. 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.

***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 U.S. Food and Drug Administration-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 U.S. Food and Drug Administration 510(k) clearance or, possibly, a premarket approval. The U.S. Food and Drug Administration requires every manufacturer to make its own determination as to whether a modification requires a new 510(k) clearance or premarket approval, but the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration clearance or approval and, in appropriate circumstances, determine that new clearance or approval is unnecessary. Regulations in other countries in which we market or sell, or propose to market or sell, our products may also require that we make judgments about changes to our products and whether or not those changes are such that regulatory approval or clearance should be obtained. In the U.S. and elsewhere, 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.

***Changes in reimbursement levels by governmental or other third-party payors for procedures using our products may cause our revenues to decline***

We believe that our products will be purchased principally by hospitals or physicians, which typically bill various third-party payors, such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of our future customers to obtain appropriate reimbursement for products and services from third-party payors is critical to the success of medical product companies because it affects which products customers purchase and the prices they are willing to pay. Implementation of healthcare reforms in the U.S. may limit, reduce or eliminate reimbursement for our products and adversely affect both our pricing flexibility and the demand for our products. Even when we develop a promising new product, we may find limited demand for the product unless reimbursement approval is obtained from private and governmental third party payors.

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

- controls on government-funded reimbursement for healthcare services and price controls on medical products and services providers;
- challenges to the pricing of medical procedures or limits or prohibitions on reimbursement for specific devices and therapies through other means; and
- the introduction of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person.

We are unable to predict whether 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. in a manner that significantly reduces reimbursement for procedures using our products or denies coverage for these procedures, or adverse decisions relating to our products by administrators of these systems in coverage or reimbursement issues, would have an adverse impact on the acceptance of our products and the prices which our customers are willing to pay for them.

***We are reliant upon two manufacturers for key ingredients of the manufacture of our hydrogels.***

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. Although we have not experienced significant production delays attributable to supply changes, we believe that developing an alternative sources of supply for the polymers used to make our current hydrogels would be difficult over a short period of time. 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, which would have a material and adverse effect on our business, results of operations and financial condition.

**Risks Related to the Common Stock**

***Our stock price may be volatile, which could result in substantial losses for investors.***

## Edgar Filing: Alliqua, Inc. - Form 10-K

The market price of our common stock is likely 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;
- 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;
- operating results that fall below expectations;
- loss of any strategic relationship;

industry developments;

economic 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.

***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. We currently have very limited research coverage by securities and industry analysts and 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 downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts 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.

***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.

***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.

***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 do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investment in our common stock will only occur if our stock price appreciates.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

Our corporate headquarters are located at 2150 Cabot Boulevard West, Langhorne, Pennsylvania, where we lease approximately 16,500 square feet of office and manufacturing space. We believe that our facility is well maintained and is 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. Except as set forth below, 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.

On February 27, 2014, ConvaTec Inc. filed suit in the Court of Common Pleas of Philadelphia against us, our subsidiary, Alliqua Biomedical, Inc. and three individual defendants (each a former employee of ConvaTec Inc.), requesting injunctive relief for allegations involving breach of contract, tortious interference with employment agreements, unfair competition and common law conspiracy. The complaint alleges, among other things, that (i) the individual defendants breached certain restrictive covenants in their respective employment agreements with ConvaTec Inc. by engaging in employment with us within one year of their employment termination and using and disclosing confidential and proprietary business information in their employment with us, (ii) we tortuously interfered with such employment agreements by inducing the individual defendants to accept employment with us and to recruit other employees of ConvaTec Inc. to resign and accept employment with us and (iii) we solicited, recruited and hired employees of ConvaTec Inc. for the purpose of utilizing their knowledge of confidential and proprietary information related to the wound care industry in order to unfairly compete with ConvaTec Inc. ConvaTec Inc. is seeking, among other things, to enjoin us from continuing to employ a sales manager who is one former employee of ConvaTec, Inc. in a position related to wound care products and two sales representatives who are former ConvaTec employees in positions related to sales of wound care products in certain geographic areas.

We intend to fully dispute the allegations of ConvaTec Inc. and the relief sought to the fullest extent permitted by the law and believe them to be wholly without merit.

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 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. All quotations are adjusted for the 1-for-43.75 reverse stock split of our common stock that occurred November 18, 2013.

	High	Low
2013		
Fourth Quarter	\$ 8.44	\$ 2.63
Third Quarter	\$ 3.94	\$ 3.06
Second Quarter	\$ 3.94	\$ 2.63
First Quarter	\$ 4.38	\$ 1.75
2012		
Fourth Quarter	\$ 3.94	\$ 1.75
Third Quarter	\$ 2.19	\$ 1.31
Second Quarter	\$ 3.50	\$ 2.19
First Quarter	\$ 3.94	\$ 1.75

### ***Holders of Record***

As of March 20, 2014, there were approximately 170 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.

## **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. Through our hydrogel technology platform and licensed and proprietary products, we seek to create superior outcomes for patients, providers, and partners. Our core businesses include advanced wound care and contract manufacturing. We leverage our proprietary hydrogel and licensed technology to add value to our own products and those of our partners.

We effected a 1-for-43.75 reverse stock split of our outstanding common stock on November 18, 2013. The accompanying consolidated financial statements and accompanying notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented. The shares of common stock retained a par value of \$0.001 per share. Accordingly, stockholders' equity reflects the reverse stock split by reclassifying from common stock to additional paid-in capital an amount equal to the par value of the decreased shares resulting from the reverse stock split.

### **Results of Operations**

#### *Year Ended December 31, 2013 Compared to the Year Ended December 31, 2012*

**Overview.** For the years ended December 31, 2013 and 2012, we had a net loss of \$21,976,882 and \$4,905,335, respectively, which was inclusive of non-cash items, including the impairment charge of \$8,100,000 of our in-process research and development recognized in the year ended December 31, 2013. Additionally, we recognized approximately \$5,513,861 and \$1,975,115 of stock-based compensation in the years ended December 31, 2013 and 2012, respectively.

**Revenues, net.** For the year ended December 31, 2013 revenues increased by \$569,071, or 46%, to \$1,797,745 from \$1,228,674 for the year ended December 31, 2012. The increase was primarily due to greater sales volume from our largest two customers during 2013 for the manufacturing of hydrogel products, as well as an increase in the sales of our proprietary products. The components of revenue are as follows:

	For the Years Ended December 31,	
	2013	2012
Revenues		
Contract manufacturing	\$ 1,618,670	\$ 1,221,145
Products	179,075	7,529
Total revenue, net	\$ 1,797,745	\$ 1,228,674

**Gross loss.** Our gross loss was \$299,288 for the year ended December 31, 2013 compared to \$608,495 for the year ended December 31, 2012. The improved results for the year ended December 31, 2013, as compared to 2012, was

due to the higher volume of sales with sustained fixed overhead expenses. The components of cost of revenues are as follows:

	For the Years Ended December 31,	
	2013	2012
Cost of revenues		
Compensation and benefits	\$ 496,660	\$ 442,558
Depreciation and amortization	668,961	644,304
Materials	459,721	386,084
Equipment, production and other expenses	471,691	364,223
Total cost of revenues	\$ 2,097,033	\$ 1,837,169

**Selling, general and administrative expenses.** The following table highlights selling, general and administrative expenses by type for the years ended December 31, 2013 versus 2012:

	For the Years Ended December 31,	
	2013	2012
Selling, general and administrative expenses		
Stock-based compensation	\$ 5,513,861	\$ 1,975,115
Compensation and benefits	3,069,209	842,433
Marketing	298,860	139,024
Royalty fees	200,000	50,000
Other expenses	2,588,068	1,047,801
Total selling, general and administrative expenses	\$ 11,669,998	\$ 4,054,373

Selling, general and administrative expense increased \$7,615,625 to \$11,669,998 for the year ended December 31, 2013, as compared to \$4,054,373 for the year ended December 31, 2012.

Stock-based compensation increased by \$3,538,746 to \$5,513,861 for the year ended December 31, 2013, as compared to \$1,975,115 for the year ended December 31, 2012. Compensation and benefits increased \$2,226,776 to \$3,069,209 for the year ended December 31, 2013, as compared to \$842,433 for the year ended December 31, 2012. The increase in both stock-based compensation and compensation and benefits was due to the hiring of a new chief executive officer and chief financial officer, and various senior sales and marketing executives and professionals during the year ended December 31, 2013.

Marketing increased by \$159,836 to \$298,860 for the year ended December 31, 2013, as compared to \$139,024 for the year ended December 31, 2012. The increase was primarily due to increased efforts to market our proprietary and licensed products.

Other selling, general and administrative expenses increased by \$1,540,267 to \$2,588,068 for the year ended December 31, 2013, as compared to \$1,047,801 for the year ended December 31, 2012. Other general and administrative expense include legal, accounting, consulting, investor relation fees, and other costs administrative in nature. These increases were due to our increased business development, sales, and investor relation activities in the year ended December 31, 2013.

**Research and Development.** We recorded \$63,204 in research and development expenses for the year ended December 31, 2013, as compared to \$233,819 for the year ended December 31, 2012. The decrease in research and development expenses was due principally to a reduction in expenses associated with the development of our transdermal pain patch.

**Impairment of In-Process Research and Development.** We recorded an impairment charge of \$8,100,000 for the year ended December 31, 2013 to the in-process research and development of our HepaMate technology. Our strategy has evolved to become a provider of advanced wound care products. We do not intend to further develop this technology nor do we intend to allocate any new capital to this technology. In 2013 we engaged an investment bank to find a strategic partner for the technology; however this process has been unsuccessful. See Note 7 Intangible Assets for further discussion.

**Change in Value of Warrant Liability.** The change in value of our warrant liability for the year ended December 31, 2013 was \$1,833,498 compared to \$0 for the year ended December 31, 2012. The loss recorded resulted from an increase in the fair value of our warrant liability attributable to the increase in the fair value of our common stock during the year ended December 31, 2013.

## Liquidity and Capital Resources

### *Year Ended December 31, 2013 Compared to the Year Ended December 31, 2012*

At December 31, 2013, we had cash and cash equivalents totaling \$12,100,544 compared to \$260,357 at December 31, 2012. The increase was largely attributable to net financing proceeds of \$16,727,293 offset by cash used in operating activities of \$4,769,039 during the year ended December 31, 2013.

Net cash flow used in operating activities was \$4,769,039 and \$1,966,093 for the years ended December 31, 2013 and 2012, respectively. The increase was primarily attributable to an increase in net loss excluding impairment of in-process research and development, stock compensation and other non-cash items of \$5,736,827 offset by an increase in accrued expenses and other liabilities compared to the prior year.

Cash flow generated from financing activities was \$16,727,293 for the year ended December 31, 2013, compared to cash flow generated from financing activities of \$2,052,525 for the year ended December 31, 2012.

At December 31, 2013, current assets totaled \$12,847,234 and current liabilities totaled \$3,353,464, as compared to current assets of \$882,196 and current liabilities of \$1,532,497 at December 31, 2012. As a result, we had working capital of \$9,493,770 at December 31, 2013 compared to a working capital deficit of \$650,301 at December 31, 2012.

Our cash requirements have historically been for 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**

We have revamped our strategy to focus on being a provider of wound care solutions as well as continuing to be a contract manufacturer. The use of proceeds from our 2013 financings will largely be used to support the sales and marketing of our wound care solutions.

In 2013, we restructured our senior management team with the goal of maximizing the potential for success in achieving our sales and marketing goals. In addition to appointing a new chief executive officer and chief financial officer, we have also hired a number of senior sales and marketing executives and professionals. We expect to continue to attend trade shows and seek other avenues to market our products. In January 2014, we hired a chief medical officer.

During 2013, we also established an independent network of agents to sell our wound care products as well as an extensive channel reach through a network of distributors. To enhance our sales efforts, we intend to hire approximately 20 direct sales agents in 2014. We expect to increase our number of employees from 21 at December 31, 2013 to approximately 45 by March 31, 2014.

We continue to focus our efforts on expanding our product offerings. We are seeking complementary products to our hydrogels in an effort to expand our offerings. In addition, we are seeking ways to modify products' size, shape or thickness in order to appeal to a broader marketplace.

In September 2013, we entered into a distributor agreement with 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 U.S., Canada and Latin America, subject to certain exceptions.

In September 2013, we entered into an agreement with Carolon pursuant to which, among other things, Carolon transferred certain assets related to sorbion sachet and sana products to us, including its saleable inventory, customer information, sales and training materials, customer orders and certain sales force members.

In November 2013, we entered into agreements with CCT, pursuant to which we received the right to develop and market the advanced wound care products Biovance and ECM. Under these agreements, CCT will also supply us with our entire requirements of Biovance for distribution and sale in the U.S.

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, pre-launch marketing costs, the purchasing of inventory, and the billing and collection of revenue, we expect to record an increase in our net cash outflows from operations for the first half of 2014 as compared to the last half of 2013.

We believe that our cash on hand and our cash generated from operations will be sufficient to fund our business for the next 12 months. However, our future results of operations involve significant risks and uncertainties. Factors that could affect the 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 competition, regulatory approval of our new products, technological change, and dependence on key personnel.

In order to complete our future growth strategy, we will require additional equity and/or debt financing. If we are unable to raise additional capital or we encounter circumstances that place unforeseen constraints on our 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 terms favorable to us.

#### **Off Balance Sheet Arrangements**

As of December 31, 2013, 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 and Estimates**

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: in-process research and development, long-lived assets and goodwill. We base our estimates and assumptions on historical experience, known or expected trends and various other assumptions that we believe to be reasonable. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates, which may cause our future results to be significantly affected.

We believe that the following critical accounting policies comprise the more significant estimates and assumptions used in the preparation of our consolidated financial statements.

### **Acquired In-Process Research and Development**

In-process research and development (“IPR&D”) represents the fair value assigned to incomplete research projects that we acquire through business combinations which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Once an IPR&D project has been completed, the useful life of the IPR&D asset is determined and amortized accordingly. If the IPR&D asset is abandoned, the remaining carrying value will be written off. Our in-process research and development technology represents HepaMate<sup>®</sup> patented biotech technologies that currently have no commercial use. HepaMate<sup>®</sup> is an extracorporeal (outside the body), temporary liver support system designed to provide ‘whole’ liver function to patients with acute or severe liver failure. During the fourth quarter of 2013, we believed there were impairment triggering events and circumstances which warranted an evaluation of certain indefinite-lived intangible assets. As a result of our assessment, we recognized impairment of our IPR&D of \$8,100,000.

### **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, 2013 and 2012.

### **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 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 its 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.

## **Recent Accounting Pronouncements**

There are no accounting standards that have been issued but not yet adopted that we believe will have a material impact on our consolidated financial position or results of operations.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY 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, 2013, 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, 2013.

### ***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, 2013. 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* (1992). Based on its assessment and those criteria, management has concluded that we

maintained effective internal control over financial reporting as of December 31, 2013.

***Changes in Internal Control over Financial Reporting.***

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2013 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 OFFIERS AND CORPORATE GOVERNANCE**

Information with respect to this item will be set forth in our definitive Proxy Statement for the 2014 Annual Meeting of Shareholders, which is to be filed with the Securities and Exchange Commission no later than April 30, 2014, (our "Proxy Statement"), and which is incorporated herein by reference.

We have adopted a code of corporate governance and ethics that applies to all our directors and employees, including the principal executive officer, principal financial officer, principal accounting officer and controller. The full text of our Amended and Restated Code of Corporate Governance and Ethics is published on the Investors section of our website at [www.alliqua.com](http://www.alliqua.com). We intend to disclose any future amendments to certain provisions of the Amended and Restated Code of Corporate Governance and Ethics, or waivers of such provisions granted to executive officers and directors, on this website within four business days following the date of any such amendment or waiver.

### **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 RELATIONSHIP 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 Statement Schedules:

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2013 and 2012	F-3
Consolidated Statements of Operations for the years ended December 31, 2013 and 2012	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013 and 2012	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2013 and 2012	F-6
Notes to Consolidated Financial Statements	F-7

(2)

Financial Statement Schedules:

None

(3)

Exhibits:

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

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## 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, INC.

By: /s/ DAVID JOHNSON

David Johnson

President and Chief Executive Officer

Date: March 24, 2014

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)	March 24, 2014
/s/ BRIAN M. POSNER Brian M. Posner	Chief Financial Officer, Treasurer and Secretary (principal financial and accounting officer)	March 24, 2014
/s/JEROME ZELDIS Jerome Zeldis, M.D., Ph.D.	Chairman of the Board of Directors	March 24, 2014
/s/ JOSEPH LEONE Joseph Leone	Director	March 24, 2014
/s/ PERRY KARSEN Perry Karsen	Director	March 24, 2014
/s/ KENNETH PEARSEN Kenneth Pearsen	Director	March 24, 2014
/s/ JEFFREY SKLAR Jeffrey Sklar	Director	March 24, 2014

## Index to Exhibits

Exhibit No.	Description
3.1	Composite Articles of Incorporation of Alliqua, Inc., incorporated by reference to Exhibit 3.1 to the Form 10-K/A filed May 16, 2013.
3.2	Articles of Amendment to Articles of Incorporation of Alliqua, Inc., incorporated by reference to Exhibit 3.1 to the Form 8-K filed September 27, 2013.
3.3	Certificate of Designation of the Relative Rights and Preferences of the Series A Convertible Preferred Stock, incorporated by reference to Exhibit 3.1 to the Form 8-K filed October 28, 2013.
3.4	Articles of Amendment to the Articles of Incorporation, incorporated by reference to Exhibit 3.1 to the Form 8-K filed November 19, 2013.
3.5	Amended and Revised Bylaws, incorporated by reference to Exhibit 3.2 to the Form 8-K filed June 10, 2010.
4.1	Form of Series E Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 to the Form 8-K filed May 17, 2010.
4.2	Form of Series F Stock Purchase Warrant, incorporated by reference to Exhibit 4.2 to the Form 8-K filed May 17, 2010.
4.3	Investor Warrant Issued March 2, 2011, incorporated by reference to Exhibit 10.2 to the Form 8-K filed March 3, 2011.
4.4	Placement Agent Warrant Issued March 2, 2011, incorporated by reference to Exhibit 10.3 to the Form 8-K filed March 3, 2011.
4.5	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.
4.6	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.
4.7	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.
4.8	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.
4.9	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.
4.10	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.

- 4.11 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.



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- 4.12\* Warrant issued to Celgene Corporation on November 18, 2013.
- 4.13\* Form of Warrant used in connection with November 18, 2013 private placement.
- 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 Securities Purchase Agreement, dated as of March 2, 2011, by and between the Company and the purchasers identified therein, incorporated by reference to Exhibit 10.1 to the Form 8-K filed March 3, 2011.
- 10.8 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.
- 10.9 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.
- 10.10+ Alliqua, Inc. 2011 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.1 to the Form 8-K filed December 20, 2011.
- 10.11 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.
- 10.12+ Executive Employment Agreement, dated as of May 16, 2012, by and between the Company and Richard Rosenblum, incorporated by reference to Exhibit 10.1 to the Form 8-K filed May 17, 2012.
- 10.13+ Executive Employment Agreement, dated as of May 31, 2012, by and between the Company and David Stefansky, incorporated by reference to Exhibit 10.1 to the Form 8-K filed June 5, 2012.
- 10.14 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.
- 10.15+

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Executive Employment Agreement, dated September 28, 2012, by and between Alliqua, Inc. and James Sapirstein, incorporated by reference to Exhibit 10.1 to the Form 8-K filed October 3, 2012.

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- 10.16 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.
- 10.17+ Nonqualified Stock Option Agreement, dated as of November 8, 2012, by and between the Company and James Sapirstein, incorporated by reference to Exhibit 10.21 to the Form 10-K/A filed May 16, 2013.
- 10.18+ Restricted Stock Unit Award, dated as of November 8, 2012, by and between the Company and James Sapirstein, incorporated by reference to Exhibit 10.22 to the Form 10-K/A filed May 16, 2013.
- 10.19+ Nonqualified Stock Option Agreement, dated as of November 27, 2012, by and between the Company and Jerome Zeldis, incorporated by reference to Exhibit 10.23 to the Form 10-K/A filed May 16, 2013.
- 10.20+ Nonqualified Stock Option Agreement, dated as of November 27, 2012, by and between the Company and Joseph Leone, incorporated by reference to Exhibit 10.24 to the Form 10-K/A filed May 16, 2013.
- 10.21+ Nonqualified Stock Option Agreement, dated as of November 27, 2012, by and between the Company and Ken Londoner, incorporated by reference to Exhibit 10.25 to the Form 10-K/A filed May 16, 2013.
- 10.22+ Nonqualified Stock Option Agreement, dated as of November 27, 2012, by and between the Company and Jeffrey Sklar, incorporated by reference to Exhibit 10.26 to the Form 10-K/A filed May 16, 2013.
- 10.23+ Nonqualified Stock Option Agreement, dated as of November 27, 2012, by and between the Company and Steven Berger, incorporated by reference to Exhibit 10.27 to the Form 10-K/A filed May 16, 2013.
- 10.24+ Nonqualified Stock Option Agreement, dated as of November 27, 2012, by and between the Company and Jerome Zeldis, incorporated by reference to Exhibit 10.28 to the Form 10-K/A filed May 16, 2013.
- 10.25+ Nonqualified Stock Option Agreement, dated as of November 27, 2012, by and between the Company and Kenneth Pearsen, incorporated by reference to Exhibit 10.29 to the Form 10-K/A filed May 16, 2013.
- 10.26+ Nonqualified Stock Option Agreement, dated as of November 29, 2012, by and between the Company and David Johnson, incorporated by reference to Exhibit 10.30 to the Form 10-K/A filed May 16, 2013.
- 10.27+ First Amendment to the Alliqua, Inc. 2011 Long-Term Incentive Plan, incorporated by reference to Exhibit 10.1 to the Form 8-K filed December 20, 2012.
- 10.28+ 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.
- 10.29+ 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.
- 10.30+ 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.
- 10.31+ First Amendment to Executive Employment Agreement, dated as of February 4, 2013, between Alliqua, Inc. and James Sapirstein, incorporated by reference to Exhibit 10.2 to the Form 8-K filed February 7,

2013.

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- 10.32+ 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.
- 10.33 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.
- 10.34 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.
- 10.35+ Separation and General Release Agreement, dated as of June 28, 2013, by and between Alliqua, Inc. and Richard Rosenblum, incorporated by reference to Exhibit 10.1 to the Form 8-K filed July 5, 2013.
- 10.36+ Consulting Agreement, dated as of June 28, 2013, by and between Alliqua, Inc. and Richard Rosenblum, incorporated by reference to Exhibit 10.2 to the Form 8-K filed July 5, 2013.
- 10.37 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.
- 10.38+ 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.
- 10.39+ 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.
- 10.40+ Transition Agreement and Release, dated September 3, 2013, between Steven Berger and Alliqua, Inc., incorporated by reference to Exhibit 10.3 to the Form 8-K filed September 9, 2013.
- 10.41+ Nonqualified Stock Option Agreement, dated September 3, 2013, between Steven Berger and Alliqua, Inc., incorporated by reference to Exhibit 10.4 to the Form 8-K filed September 9, 2013.
- 10.42^ 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.
- 10.43 Agreement, dated September 23, 2013, by and between Carolon Company and Alliqua Biomedical, Inc., incorporated by reference to Exhibit 10.6 to the Form 10-Q filed November 12, 2013.
- 10.44 Securities Purchase Agreement, dated as of October 22, 2013, by and between Alliqua, Inc. and Crossover Healthcare Fund, LLC, incorporated by reference to Exhibit 10.2 to the Form 8-K filed October 28, 2013.
- 10.45 Amendment to Securities Purchase Agreement, dated as of November 6, 2013, by and between Alliqua, Inc. and Crossover Healthcare Fund, LLC, incorporated by reference to Exhibit 10.1 to the Form 8-K filed November 12, 2013.
- 10.46+ Separation and General Release Agreement, dated as of November 11, 2013, by and between Alliqua, Inc. and David Stefansky, incorporated by reference to Exhibit 10.7 to the Form 10-Q filed November

12, 2013.

10.47+ Consulting Agreement, dated as of November 11, 2013, by and between Alliqua, Inc. and David Stefansky, incorporated by reference to Exhibit 10.8 to the Form 10-Q filed November 12, 2013.

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10.48*^^	License, Marketing and Development Agreement, dated as of November 14, 2013, by and between Anthrogenesis Corporation, d/b/a CCT, and Alliqua, Inc.
10.49*^^	Supply Agreement, dated as of November 14, 2013, by and between Anthrogenesis Corporation and Alliqua, Inc.
10.50*	Stock Purchase Agreement, dated as of November 14, 2013, by and between Celgene Corporation and Alliqua, Inc.
10.51*	Securities Purchase Agreement, dated as of November 18, 2013, by and among Alliqua, Inc. and certain purchasers set forth therein.
10.52	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.
10.53	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.
10.54+	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.
10.55+	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.
10.62*+	Form of Restricted Stock Award Agreement under the 2011 Long-Term Incentive Plan.
10.63*+	Form of Restricted Stock Award Agreement for 2013 Executive Bonuses under the 2011 Long-Term Incentive Plan.
21.1	List of Subsidiaries, incorporated by reference to Exhibit 21.1 to the Form 10-K/A filed May 16, 2013.
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, 2013, 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.

\*\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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

^^ Certain portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission under a confidential treatment request pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

+ Management contract or compensatory plan or arrangement.



**ALLIQUA INC. AND SUBSIDIARIES**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of the  
Board of Directors and Stockholders  
of Alliqua, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Alliqua, Inc. and Subsidiaries (the “Company”) as of December 31, 2013 and 2012, 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 financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our 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 financial position of Alliqua, Inc. and Subsidiaries, as of December 31, 2013 and 2012, and the results of its consolidated operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum LLP

Marcum LLP  
New York, NY  
March 24, 2014

**ALLIQUA, INC. AND SUBSIDIARIES**  
**Consolidated Balance Sheets**

	December 31, 2013	December 31, 2012
<b>ASSETS:</b>		
Current Assets:		
Cash and cash equivalents	\$ 12,100,544	\$ 260,357
Accounts receivable	156,831	108,866
Inventory	501,469	319,326
Prepaid expenses and other current assets	88,390	193,647
Total current assets	12,847,234	882,196
Improvements and equipment, net	1,745,248	1,915,179
Intangible assets, net	2,258,477	10,329,167
Goodwill	425,969	425,969
Other assets	174,640	174,640
Total assets	\$ 17,451,568	\$ 13,727,151
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 746,609	\$ 572,635
Accrued expenses	1,267,899	249,728
Payable for distribution rights	333,333	-
Deferred revenue	39,000	39,000
Warrant liability	933,465	605,737
Deferred lease incentive liability - current	8,337	-
Other current liabilities	24,821	65,397
Total current liabilities	3,353,464	1,532,497
Deferred lease incentive liability	92,408	-
Deferred tax obligation	53,000	44,000
Total liabilities	3,498,872	1,576,497
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; 11,484,191 and 5,924,627 shares issued and outstanding as of December 31, 2013 and December 31, 2012, respectively	11,484	5,925
Additional paid-in capital	58,538,491	34,785,126
Subscription receivable	-	(20,000)
Accumulated deficit	(44,597,279)	(22,620,397)
Total stockholders' equity	13,952,696	12,150,654
Total liabilities and stockholders' equity	\$ 17,451,568	\$ 13,727,151

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

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**Alliqua, Inc. and Subsidiaries**  
**Consolidated Statements of Operations**

	Year Ended December 31, 2013	2012
Revenue, net of returns, allowances and discounts	\$ 1,797,745	\$ 1,228,674
Cost of revenues	2,097,033	1,837,169
Gross loss	(299,288)	(608,495)
Operating expenses		
Selling, general and administrative, (inclusive of stock-based compensation)	11,669,998	4,054,373
compensation of \$5,513,861 and \$1,975,115 for the years ended December 31, 2013 and 2012 - see Note 10)		
Research and product development	63,204	233,819
Impairment of in-process research and development	8,100,000	-
Total operating expenses	19,833,202	4,288,192
Loss from operations	(20,132,490)	(4,896,687)
Other income (expense)		
Interest expense	(4,807)	(3,353)
Other income	-	4,888
Interest income	2,913	817
Change in value of warrant liability	(1,833,498)	-
Total other (expense) income	(1,835,392)	2,352
Income tax provision	9,000	11,000
Net loss	(21,976,882)	(4,905,335)
Deemed dividend to preferred stockholders	(462,006)	-
Net loss attributable to common stockholders	\$ (22,438,888)	\$ (4,905,335)
Basic and diluted net loss per common share	\$ (3.14)	\$ (0.91)
Weighted average shares used in computing basic and diluted net loss per common share	7,140,613	5,383,995

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

**ALLIQUA, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Stockholders' Equity**

	Redeemable Series A Convertible Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit	Total Stockhold Equity
Balance, December 31, 2011	-	\$ -	4,778,831	\$ 4,779	\$ 31,344,369	\$ -	\$ (17,715,062)	\$ 13,634,0
Issuance of common stock for cash, net of issuance costs of \$87,475 and warrant liabilities of \$605,737	-	-	987,429	988	1,465,800	(20,000)	-	1,446,78
Issuance of common stock for services	-	-	57,143	57	249,943	-	-	250,000
Issuance of common stock to related party for services	-	-	101,224	101	299,899	-	-	300,000
Stock-based compensation	-	-	-	-	1,425,115	-	-	1,425,11
Net loss	-	-	-	-	-	-	(4,905,335)	(4,905,3
Balance, December 31, 2012	-	\$ -	5,924,627	\$ 5,925	\$ 34,785,126	\$ (20,000)	\$ (22,620,397)	\$ 12,150,6
Issuance of common stock for cash, net of issuance costs of \$680,132	-	-	4,599,334	4,599	15,772,694	-	-	15,777,2
Issuance of preferred stock for cash, net of cash issuance costs of \$70,000,	250,000	516,191	-	-	413,809	-	-	413,809

warrant  
issuance costs  
of \$43,906 and  
\$369,903  
discount  
attributable to  
warrant and  
beneficial  
conversion  
feature

Preferred stock  
contingent  
beneficial  
conversion  
feature  
triggered due  
to price reset  
provision

Accretion of  
discount as  
deemed  
dividend on  
preferred stock

Conversion of  
preferred stock  
into common  
stock

Issuance of  
common stock  
for services

Issuance of  
common stock  
to related party  
for services

Exercise of  
warrants

Extinguishment  
of warrant  
liability

Receipt of  
subscription  
receivable

-	(89,379)	-	-	89,379	-	-	89,379
-	462,006	-	-	(462,006)	-	-	(462,006)
(250,000)	(888,818)	279,505	280	888,538	-	-	888,818
-	-	26,264	26	87,353	-	-	87,379
-	-	372,330	372	1,221,336	-	-	1,221,700
-	-	261,030	261	(261)	-	-	-
-	-	-	-	1,505,770	-	-	1,505,770
-	-	-	-	-	20,000	-	20,000

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Stock-based compensation, net 14,299 of shares withheld for employee taxes	-	-	21,101	21	4,204,753	-	-	4,204,753
Fair value of rent provided by related party	-	-	-	-	32,000	-	-	32,000
Net Loss	-	-	-	-	-	-	(21,976,882)	(21,976,882)
Balance, December 31, 2013	-	\$ -	11,484,191	\$ 11,484	\$ 58,538,491	\$ -	\$ (44,597,279)	\$ 13,952,692

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



**ALLIQUA, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Cash Flows**

	Years Ended December 31,	
	2013	2012
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (21,976,882)	\$ (4,905,335)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	674,225	647,818
Amortization of deferred lease incentive	(695)	-
Deferred income taxes	9,000	11,000
Provision for inventory obsolescence	58,930	17,650
Loss on disposal of property and equipment	19,236	-
Stock-based compensation expense	4,204,774	1,425,115
Impairment of in process research and development	8,100,000	-
Stock issued for services rendered	87,379	250,000
Stock issued for services rendered by related parties	1,221,708	300,000
Change in value of warrant liability	1,833,498	-
Fair value of rent provided by related party	32,000	-
Changes in operating assets and liabilities:		
Accounts receivable	(47,965)	(41,093)
Inventory	(241,073)	(106,686)
Prepaid expenses and other current assets	105,257	(133,311)
Accounts payable	173,974	320,883
Accrued expenses and other current liabilities	977,595	208,866
Deferred revenue	-	39,000
<b>Net Cash Used in Operating Activities</b>	<b>(4,769,039)</b>	<b>(1,966,093)</b>
<b>Cash Flows From Investing Activities</b>		
Purchase of distribution rights	(66,667)	-
Purchase of property and equipment	(51,400)	(86,186)
<b>Net Cash Used by Investing Activities</b>	<b>(118,067)</b>	<b>(86,186)</b>
<b>Cash Flows From Financing Activities</b>		
Net proceeds from issuance of common stock	15,797,293	2,002,525
Net proceeds from issuance of preferred stock	930,000	-
Net proceeds from issuance of notes payable	-	50,000
<b>Net Cash Provided by Financing Activities</b>	<b>16,727,293</b>	<b>2,052,525</b>
<b>Net Increase in Cash and Cash Equivalents</b>	<b>11,840,187</b>	<b>246</b>
<b>Cash and Cash Equivalents - Beginning of year</b>	<b>260,357</b>	<b>260,111</b>
<b>Cash and Cash Equivalents - End of year</b>	<b>\$ 12,100,544</b>	<b>\$ 260,357</b>
<b>Supplemental Disclosure of Cash Flows Information</b>		
Cash paid during the period for:		
Interest	\$ 4,808	\$ 3,353
Non-cash investing and financing activities		
Cashless warrant exercise	\$ 1,505,770	\$ -

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Leasehold improvements provided by landlord	\$ 101,440	\$ -
Conversion of note payable to equity	\$ -	\$ 50,000
Warrant issued to placement agent in connection with preferred stock	\$ 43,906	\$ -
Warrant and beneficial conversion feature issued to investor as discount in connection with preferred stock	\$ 369,903	\$ -
Preferred stock contingent beneficial conversion feature triggered due to price reset provision	\$ 89,379	\$ -
Deemed dividend on preferred stock	\$ 462,006	\$ -
Conversion of preferred stock into common stock	\$ 888,818	\$ -

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

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**ALLIQUA, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Description of Business and Basis of Presentation**

Alliqua, Inc. (the “Company”) is a provider of advanced wound care solutions. The Company’s primary business strategy is to create superior outcomes for patients, providers, and partners through its hydrogel technology platform and licensed and proprietary products. Core businesses include advanced wound care and contract manufacturing. The Company seeks to leverage its proprietary hydrogel and licensed technology platform to add value to its own products and those of its partners.

***Principles of Consolidation***

The accompanying consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiaries, AquaMed Technologies, Inc., HepaLife Biosystems, Inc. and Alliqua Biomedical, 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.

***Reverse Stock Split***

The Company effected a 1-for-43.75 reverse stock split of its outstanding common stock on November 18, 2013. The accompanying consolidated financial statements and accompanying notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented. The shares of common stock retained a par value of \$0.001 per share. Accordingly, stockholders’ equity reflects the reverse stock split by reclassifying from common stock to additional paid-in capital an amount equal to the par value of the decreased shares resulting from the reverse stock split.

**2. Liquidity**

The Company has experienced negative operating cash flows since inception and has funded its operations primarily from sales of common stock and other securities. The Company’s cash requirements have historically been for product development, clinical trials, marketing and sales activities, finance and administrative costs, capital expenditures and overall working capital.

During the year ended December 31, 2013, the Company sold 4,599,334 shares of common stock for total net proceeds of \$15,797,293, and 250,000 shares of preferred stock for total net proceeds of \$930,000 as detailed in Note 10 Stockholders’ Equity. The Company has revamped strategies to focus on being a provider of wound care solutions as well as continue to be a contract manufacturer. The use of proceeds of the 2013 financings will largely be used to support the sales and marketing of wound care solutions.

In 2013, the Company restructured its senior management team with the goal of maximizing the potential for success in achieving sales and marketing goals. In addition to appointing a new chief executive officer and chief financial officer, the Company has also hired a number of senior sales and marketing executives and professionals. The Company expects to continue to attend trade shows and seek other avenues to market its products. During 2013, the Company also established an independent network of agents to sell wound care products as well as an extensive

channel reach through a network of distributors.

The implementation of the growth strategy will continue to result in an increase in the Company's 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, pre-launch marketing costs, the purchasing of inventory, and the billing and collection of revenue, the Company expects to record an increase in net operating cash outflows from operations for the first half of 2014 as compared to the last half of 2013.

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Based on the factors above, the Company believes that cash on hand and cash generated from operations will be sufficient to fund the business for the next 12 months. However, future results of operations involve significant risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, potential demand for the Company's products, risks from its competition, regulatory approval of new products, technological change, and dependence on key personnel.

In order to complete the Company's future growth strategy additional equity and/or debt financing will be required. If unable to raise additional capital or if the Company encounters circumstances that place unforeseen constraints on capital resources, it 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. The Company would have to curtail business development activities and suspend the pursuit of the Company's business plan. There can be no assurance that the Company will be successful in improving revenues, reducing expenses and/or securing additional capital in sufficient amounts and on favorable terms.

### **3. 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, account receivable reserves, inventory reserves, deferred taxes and related valuation allowances, and the fair values of long lived assets, intangibles and goodwill. 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, 2013 and 2012 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.

#### ***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. At December 31, 2013 and 2012, the Company had reserves for obsolete inventory of \$76,580 and \$17,650, respectively.

***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.

***Acquired In-Process Research and Development***

In-process research and development (“IPR&D”) represents the fair value assigned to incomplete research projects that the Company acquires through business combinations which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. The Company tests IPR&D for impairment at least annually or more frequently if impairment indicators exist.

### ***Goodwill and Other Intangible Assets***

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. Goodwill of \$425,969 was assigned during the acquisition of Hydrogel Design Systems by AquaMed Technologies, Inc. in 2009. 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. In 2013, 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 assessments, the Company concluded that a positive assertion can be made from the qualitative assessment that it is not more likely than not that the fair value of the reporting unit is less than its carrying amount. 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 as of December 31, 2013.

### ***Impairment of Long-Lived Assets Subject to Amortization***

The Company amortizes intangible assets with finite lives over their estimated useful lives and reviews them for impairment annually or whenever an impairment exists. 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, 2013, 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, 2012.

### ***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. Deposits received on product orders are recorded as deferred revenue until revenues are earned when the products are shipped to customers. For irradiation services, the Company records revenue based upon an hourly service charge as services are provided.

### ***Research and Development***

Research and development expenses represent costs incurred to develop technology. Research and development expenses are charged to operations as they are incurred, including internal costs, costs paid to sponsoring organizations, and contract services for any third party laboratory work. Research and development expenses are tracked by project. As of December 31, 2013 and 2012 research and development costs totaled \$63,204 and \$233,819, respectively.

### ***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, 2013 and 2012 were \$298,859 and \$139,024, respectively.

### ***Shipping and Handling***

Shipping and handling costs are paid for by the Company. Shipping and handling costs amounted to approximately \$23,523 and \$14,635 as of December 31, 2013 and 2012, respectively, and are included in selling, general and administrative expenses.

### ***Income Taxes***

The Company accounts for income taxes pursuant to the asset and liability method which requires deferred tax assets and liabilities to be recognized 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. 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, 2013 and 2012. As of December 31, 2013 and December 31, 2012, no liability for unrecognized tax benefits was required to be reported. The Company files tax returns in U.S. federal, state and local jurisdictions, including Pennsylvania, and has tax returns subject to examination by tax authorities beginning in the year ended December 31, 2010. 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 on November 8, 2012. 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, 2013 and 2012. 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 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 warrants, stock options and non-vested restricted stock units ("RSUs"), 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 units are as follows:

	December 31, 2013	2012
Stock Options	4,985,586	2,333,822
Warrants	3,822,557	1,004,208
Non-Vested Restricted Stock Units	35,376	70,753
Total	8,843,519	3,408,783

**4. Inventory**

Inventory consists of the following:

December 31, 2013	2012
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Raw materials	\$	174,176	\$	209,820
Work in process		57,030		25,119
Finished goods		346,843		102,037
Less: Inventory reserve		(76,580)		(17,650)
Total	\$	501,469	\$	319,326

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## 5. Improvements and Equipment, net

Improvements and equipment consist of the following:

	Useful Life (Years)	December 31, 2013	2012
Machinery and equipment	10	\$ 2,869,453	\$ 2,869,453
Office furniture and equipment	10	44,844	40,124
Leasehold improvements	(A)	228,021	108,139
		3,142,318	3,017,716
Less: Accumulated depreciation and amortization		(1,397,070)	(1,102,537)
Improvements and equipment, net		\$ 1,745,248	\$ 1,915,179

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

Depreciation and amortization expense was \$303,535 and \$297,818 for the years ended December 31, 2013 and 2012, respectively.

## 6. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2013	2012
Salaries, benefits and incentive compensation	\$ 1,036,771	\$ 230,281
Professional fees	83,317	11,736
Inventory	127,786	-
Other	20,025	7,711
Total accrued expenses	\$ 1,267,899	\$ 249,728

## 7. Intangible Assets

### *Intangible Assets*

During the fourth quarter of 2013 the Company tested the in-process research and development, also referred to as the Company's HepaMate artificial liver technology acquired as part of the 2010 merger with AquaMed, for impairment. Prior to the impairment analysis, the value of the IPR&D remained at the fair value assigned at acquisition of \$8,100,000. At acquisition, the project had not reached technological feasibility. The Company has not allocated any resources to the HepaMate technology since the merger other than the fees associated with the maintenance of patents and intellectual property related to the technology. No plans have been made to renew the clinical trials. The Company currently estimates a significant expense over a 5 year period is needed to complete the remainder of the clinical trial process.

The strategy of the Company has evolved to become a provider of advanced wound care products through the sale of its proprietary products and technologies acquired through in-licensing and acquisition. The Company does not intend to further develop the HepaMate technology. In 2013 the Company engaged an investment bank to find a strategic partner for the HepaMate technology however this process has been unsuccessful. Given the change in management as discussed and the refocus of efforts, management does not intend to allocate any new capital towards the

development activities of this technology. Management has also considered the marketability and valuation considerations of the technology and has concluded the fair value of the technology to have limited commercial recoverability. As a result of these evaluations, the Company recognized an impairment of IPR&D of \$8,100,000 during the year ended December 31, 2013. The evaluation of amounts recoverable in connection with intangible assets is a process that requires considerable exercise of judgment. Had different estimates and assumptions been used in this process, the measured impairments may have been different. The Company will continue to pursue strategies to optimize the value of the HepaMate technology.

The Company reviewed its other intangible definite-lived assets and did not identify any other impairment as of December 31, 2013.

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The gross carrying amount and accumulated amortization of intangible assets as of December 31, 2013 and 2012 are as follows:

December 31, 2013					
	Useful Life (Years)	Gross Amount	Accumulated Amortization	Impairment	Net Carrying Amount
In process research and development		\$ 8,100,000	\$ -	\$ (8,100,000)	\$ -
Technology	10	3,000,000	(1,475,000)	-	1,525,000
Customer relationships	12	600,000	(245,834)	-	354,166
Distribution rights	5.27	400,000	(20,689)	-	379,311
		\$ 12,100,000	\$ (1,741,523)	\$ (8,100,000)	\$ 2,258,477

December 31, 2012					
	Useful Life (Years)	Gross Amount	Accumulated Amortization	Impairment	Net Carrying Amount
In process research and development		\$ 8,100,000	\$ -	\$ -	\$ 8,100,000
Technology	10	3,000,000	(1,175,000)	-	1,825,000
Customer relationships	12	600,000	(195,833)	-	404,167
		\$ 11,700,000	\$ (1,370,833)	\$ -	\$ 10,329,167

Amortization expense attributable to intangible assets for the years ended December 31, 2013 and 2012 was \$370,690 and \$350,000, respectively.

Amortization expense in each of the five years and thereafter subsequent to December 31, 2013 related to the Company's intangible assets is expected to be as follows:

	Expected Amortization Expense
2014	\$ 426,190
2015	426,190
2016	426,190
2017	426,190
2018	424,548
Thereafter	129,169
Total	\$ 2,258,477

**8. Operating Leases**

The Company has an obligation for its corporate offices and commercial manufacturing facility located at 2150 Cabot Boulevard West, Langhorne, Pennsylvania. On July 24, 2013 the Company extended its lease for its operating facilities in Langhorne, PA for an additional period of 10 years commencing on February 1, 2016 and continuing through and including January 31, 2026. Under the extended lease, the landlord agreed to make certain improvements to the facility. For tenant improvements funded by the landlord, the Company recorded a deferred lease incentive liability in accrued and other long-term liabilities on the consolidated balance sheet and amortizes the deferred liability as a reduction to rent expense on the consolidated statement of operations over the term of the lease. At December 31, 2013, the deferred lease incentive liability was \$100,745.

Total rent expense was \$204,930 and \$191,597 for the years ended December 31, 2013 and 2012, respectively.



Future minimum lease payments, excluding expense reimbursements, under noncancelable operating leases in each of the five years and thereafter subsequent to December 31, 2013 are as follows:

2014	\$ 204,689
2015	206,250
2016	207,309
2017	207,405
2018	207,405
Thereafter	1,469,119
Total	\$ 2,502,177

The Company previously had an agreement for shared corporate office space located at 850 3rd Avenue, New York, NY. This agreement was modified in January 2012, such that, the Company issued a related party 45,714 shares of common stock as consideration for an extension of the lease agreement until December 31, 2012 and, effective as of December 31, 2011, the elimination of the requirement to make any further cash payments. At the date of issuance, the common stock was valued at \$100,000 and the associated expense was amortized over the term of the lease. The Company did not have any right to extend the terms of the lease agreement past December 31, 2012. As the Company was in the process of moving its corporate headquarters to its Langhorne, PA facility, it was authorized to occupy this space through June 30, 2013 at no additional cost. As such, the Company recognized the fair value of the rent of \$32,000 in the year ended December 31, 2013. Total rent expense for this space amounted to \$86,000 for the year ended December 31, 2012.

## 9. Commitments and Contingencies

### *Employment Agreements for Former Employees*

On May 16, 2012, the Company entered into a three year executive employee agreement with its former president and former Board member retroactive to January 1, 2012. The agreement provided for an annual salary of \$200,000 in 2012, \$225,000 in 2013 and \$250,000 in 2014, payable in a combination of cash and shares of common stock. An option to purchase 125,714 shares of common stock, at an exercise price of \$8.75 per share, was granted and was scheduled to vest one third each year on the first, second and third anniversary of the date of grant and had a term of ten years. In addition, stock options to purchase 68,571 shares of common stock previously awarded were accelerated to vest and became exercisable on the date of execution of the employment agreement. On November 27, 2012, the executive resigned from his position as president, but remained a member of the Board. On June 28, 2013, the Company entered into a separation and general release agreement with this executive, pursuant to which the employment agreement was terminated effective as of December 31, 2012; non-competition and non-solicitation obligations under the employment agreement remain. All unvested options were immediately vested in full. The Company also entered into a consulting agreement on June 28, 2013, retroactively effective to January 1, 2013, pursuant to which, this former executive will provide consulting services in exchange for (i) a one-time grant of 186,165 shares of common stock, and (ii) monthly payments of \$2,500 from June 2013 through June 2014. The value of the shares issued were \$570,130 and are included in stock-based compensation. See Note 10 Stockholders' Equity.

On May 31, 2012, the Company entered into a three year executive employee agreement with its former executive chairman and a current Board member retroactive to January 1, 2012. The agreement provided for an annual salary of \$200,000 in 2012, \$225,000 in 2013 and \$250,000 in 2014, payable in a combination of cash and shares of common stock. An option to purchase 125,714 shares of common stock, at an exercise price of \$8.75 per share, was granted and scheduled to vest one third each year on the first, second and third anniversary of the date of grant and had a term of ten years. In addition, stock options to purchase 68,571 shares of common stock previously awarded were accelerated to vest and became exercisable on the date of execution of the employment agreement. On November 27,

2012, the executive resigned from his position as executive chairman, but remained a member of the Board. On November 11, 2013, the Company entered into a separation and general release agreement with this executive, pursuant to which the employment agreement was terminated effective as of December 31, 2012; non-competition and non-solicitation obligations under the employment agreement remain. All unvested options were immediately vested in full. The Company also entered into a consulting agreement on November 11, 2013, retroactively effective to January 1, 2013 pursuant to which, this former executive will provide consulting services in exchange for (i) a one-time grant of 186,165 shares of common stock, and (ii) monthly payments of \$2,500 from June 2013 through March 2014. The value of the shares issued were \$651,578 and are included in stock-based compensation. See Note 10 Stockholders' Equity.

Concurrently with the appointment of a new chief financial officer, the former chief financial officer, who also served as secretary and treasurer of the Company, resigned. He remained with the Company through the end of 2013 as vice president of operations to assist with the transition, in accordance with a Transition Agreement and Release dated September 3, 2013. The Company granted an award of nonqualified stock options to purchase 114,286 shares of common stock at an exercise price of \$4.38, which vested immediately upon the execution of a release on such date. The options have a term of three years. In addition, options held under the following grants shall remain outstanding and exercisable: (i) incentive stock option granted December 9, 2010 with respect to 22,857 shares of the Company's common stock granted pursuant to the HepaLife Technologies, Inc. 2001 Incentive Stock Option Plan; (ii) nonqualified stock option agreement dated May 22, 2012 with respect to 22,857 shares of the Company's common stock granted pursuant to the Alliqua, Inc. 2011 Long-Term Incentive Plan (the "2011 Plan"); and (iii) nonqualified stock option granted November 27, 2012 with respect to 11,429 shares of the Company's common stock granted pursuant to the 2011 Plan. The Company has also agreed to pay him a monthly stipend of \$600 per month during 2014.

### ***Consulting Agreements***

The Company currently has various consulting agreements for management consulting, marketing, public relations, investor relations and research and development. Some agreements are based on fixed fee arrangements and others on specified hourly rates. The total fees included in operating expenses were \$1,963,114 and \$292,305 for years ended December 31, 2013 and 2012, respectively. Included in this expense is stock-based compensation of \$1,309,087 and \$550,000 for the years ended December 31, 2013 and 2012, respectively.

### ***Cooperative and License Agreements***

On November 20, 2007, the Company exercised its license right under the CRADA by entering into an exclusive license agreement with the USDA, ARS for existing and future patents related to the PICM-19 hepatocyte cell lines. Under this license agreement, the Company is responsible for annual license maintenance fees commencing in 2010 for the term of the license, which is until the expiration of the last to expire licensed patents unless terminated earlier. The license agreement also requires certain milestone payments, if and when milestones are reached, as well as royalties on net sales of resulting licensed products, if any.

On July 15, 2011, the Company, through its Alliqua Biomedical subsidiary, entered into a license agreement with Noble Fiber Technologies, LLC, whereby Alliqua 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. An upfront license fee of \$100,000 was expensed in 2011 as a selling, general and administrative expense. 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: 2013 - \$200,000, 2014 - \$400,000; 2015 - \$500,000; and 2016 - \$600,000. Total royalties charged to selling, general and administrative expense for the years ended December 31, 2013 and 2012 were \$200,000 and 50,000, respectively. The remaining \$192,987 royalty due for the year ended December 31, 2013, is included in accounts payable.

### ***Sorbion Distributor Agreement***

On September 23, 2013, Alliqua Biomedical 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 U.S. of America, Canada and Latin America, subject to certain exceptions.

The initial term of the agreement ends on December 31, 2018 and will be extended for additional year terms until December 31, 2023, so long as the Company and Sorbion agree in September as to the minimum annual purchase amount for the calendar year that ends four years from the calendar year of such September.

In order to maintain its exclusivity, the Company must purchase the following minimum amounts, in Euros, of the products for the indicated calendar year:

Calendar Year	Minimum Annual Purchase Amount
2014	500,000 Euros
2015	1,000,000 Euros
2016	2,500,000 Euros
2017	4,000,000 Euros

Since the Company must purchase the minimum amounts in Euros, the equivalent U.S. dollar expenditure will be subject to fluctuations in foreign currency exchange rates.

The minimum annual purchase amounts in US. Dollars for each calendar year in the period from 2014-2017, based on the exchange rate as of December 31, 2013, are \$689,000, \$1,378,000, \$3,444,000, and \$5,510,000, respectively.

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 Sorbion in cash an amount equal to the minimum annual purchase amount for such calendar year less the amount the Company paid to Sorbion 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, Sorbion 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, Sorbion may terminate the agreement. The Company will not be required to meet the minimal annual purchase amount if Sorbion fails to supply the Company with the products in accordance with the agreement. Sorbion 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 will sell the products under their respective trademarked names and at prices determined by the Company. Sorbion may determine in its sole discretion the prices of the products sold to the Company, which are subject to change beginning January 1, 2015. The Company will be eligible for certain discounts with respect to the purchase and shipping of the products if its orders of the products are above certain amounts.

#### ***Carolon Distribution Rights Agreement***

In September 2013, the Company entered into an agreement with Carolon Company (“Carolon”) pursuant to which, the Company purchased the distribution rights to the sorbion sachet and sana products from Carolon. The Company is committed to pay Carolon (i) an aggregate payment of \$400,000 in 12 equal monthly payments beginning November 2013, and (ii) if the Company sells at least \$600,000 of Sorbion sachet products in the 2014 calendar year, \$50,000 in January 2015. This transaction was recorded as the purchase of distribution rights and was recorded as an intangible asset, subject to amortization over the remaining useful life of sixty-three months, and a corresponding liability of \$400,000. In consideration of this agreement, an upfront fee of \$50,000 for sales and training materials, was expensed in the year ended December 31, 2013 as a selling, general and administrative expense. As of December 31, 2013, the balance of distribution rights payable was \$333,333.

#### ***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, pursuant to which CCT granted the Company an exclusive, royalty-bearing license in its intellectual property of certain placental based products, including ECMs, an extracellularmatrix derived from the human placenta, and Biovance, CCT’s proprietary wound coverings produced from decellularized, dehydrated humanamniotic membrane, to develop and commercialize ECMs and Biovance in the United States. Following the commencement of commercial sales of the licensed products, the Company will 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 November 2013, the Company also entered into a Supply Agreement (the “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 Supply Agreement also provides that the Company and CCT will enter into a supply agreement for ECMs, on substantially the same terms as the Supply Agreement, prior to the anticipated date on which all regulatory approvals or clearances are acquired for the commercial sale of ECMs. The 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 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.

In connection with the License and Supply Agreements, the Company entered into a Stock Purchase Agreement with Celgene Corporation in which the Company sold an aggregate of 1,672,474 shares of the Company's common stock, and a five year warrant to purchase 836,237 shares of common stock at an exercise price of \$5.69 per share, in exchange for aggregate consideration of \$6,000,000. See Note 10 Stockholders' Equity.

### ***Litigation, Claims and Assessments***

The Company is subject to periodic lawsuits, investigations and claims that arise in the ordinary course of business.

On February 27, 2014, ConvaTec Inc. filed suit against the Company and three of its current employees (each a former employee of ConvaTec Inc.), requesting injunctive relief for allegations involving breach of contract, tortious interference with employment agreements, unfair competition and common law conspiracy. ConvaTec Inc. is seeking, among other things, to enjoin the Company from continuing to employ a sales manager who is a former employee of ConvaTec, Inc. in a position related to wound care products and two sales representatives in positions related to wound care products in certain geographic areas.

The Company intends to fully dispute the allegations of ConvaTec Inc. and the relief sought to the fullest extent permitted by the law and believes them to be wholly without merit. The Company does not believe that the results of this suit will have a material adverse impact on its financial position, results of operations or cash flows.

## **10. 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.

On October 22, 2013, as amended on November 6, 2013, the Company issued 250,000 shares of Series A Convertible Preferred Stock (the "Preferred Stock") and a five-year warrant to purchase 126,984 shares of common stock at an exercise price of \$4.38 per share (the "Investor Warrant") to an accredited investor in exchange for \$1,000,000. The stated value of the Preferred Stock was \$4.00 per share and it accrued dividends at the rate of 6% per annum. Each share of Preferred Stock was convertible by the investor at any time into common stock at an initial conversion price of \$3.94 per share. In connection with the closing of the sale of the Preferred Stock and Investor Warrant, the Company paid \$70,000 in cash fees to the Company's placement agent (the "Placement Agent") and issued a five-year warrant to purchase 8,889 shares of common stock at an exercise price of \$4.38 per share and a five-year warrant to purchase 8,889 shares of common stock at an exercise price of \$4.81 per share to the Placement Agent.

On November 18, 2013, the Company closed on a private placement of equity securities (see below for additional details) which, pursuant to the terms of the Preferred Stock, triggered (i) an adjustment of the Preferred Stock conversion price to \$3.59 per share of Common Stock; and (ii) mandatory conversion of the Preferred Stock into 279,505 shares of common stock (the "Conversion Shares"), which represents the \$1,000,000 principal amount, plus a 6% dividend of \$2,724, divided by the \$3.59 adjusted conversion price.

The Preferred Stock was initially classified as mezzanine (or temporary) equity on the balance sheet, because the Company was obligated to redeem the Preferred Stock on October 21, 2015 if the holders did not elect to convert the Preferred Stock into common stock prior to that date. The Preferred Stock was eventually recorded net of a \$573,188 discount, which was comprised of a \$113,906 issuance cost discount and a \$459,282 discount associated with the issuance of related equity instruments. The \$113,906 issuance cost discount represented \$70,000 of cash and the \$43,906 value of the warrants issued to the Placement Agent. The \$459,282 equity instrument discount was comprised of the \$240,507 relative fair value of the Investor Warrant, the \$129,396 value of the initial beneficial conversion feature and the \$89,379 value of the contingent beneficial conversion feature. The aggregate beneficial conversion feature represented the difference between the \$978,268 commitment date value of the Conversion Shares (279,505 shares times the \$3.50 closing price of the Company's common stock on October 22, 2013) and the \$759,493 accounting conversion price of the Conversion Shares (\$1,000,000 proceeds less the \$240,507 relative fair value of the Investor Warrant). The Warrants were valued using the Black-Scholes option pricing model using the following

assumptions: October 22, 2013 closing common stock price of \$3.50 per share, an expected term equal to the five-year contractual term; volatility of 99.44%; a 0% annual rate of quarterly dividends and a 1.3% risk-free interest rate. On the conversion date, the full \$459,282 equity instrument discount was recognized as a deemed dividend and the remaining carrying value of the Preferred Stock was reclassified to permanent equity.

The Investor Warrant will be automatically exercised on the date that the closing price of the common stock equals or exceeds 2.5 times the then-applicable exercise price for a period of sixty consecutive trading days; provided, that, at such time, the Company has an effective registration statement for the resale of the shares of common stock issuable upon exercise of the Investor Warrant (the "Warrant Shares") or the Warrant Shares may be offered for sale to the public without any volume restrictions. The Investor Warrant is exercisable at any time on a cashless basis.

### ***Authorized Common Stock***

Effective September 25, 2013, the authorized shares of the Company's common stock was increased from 11,428,571 shares to 45,714,286 shares, with a \$0.001 par value per share.



**Common Stock and Warrant Offerings**

The following table summarizes the common stock and warrant offerings during the years ended December 31, 2013 and 2012:

Issuance Date	Gross Proceeds	Issuance Costs	Common Stock (Shares)	Five-Year Warrants		Exercise Price
				Investor Warrants (Shares)	Placement Agent Warrants (Shares)	
02/16/12	\$ 1,050,000	\$ 62,975	480,000	240,000	25,360	\$ 3.02
08/14/12 [1]	265,000	-	121,143	60,571	-	\$ 2.19
09/28/12 [2]	25,000	-	11,429	5,714	-	\$ 2.19
10/11/12 [2]	5,000	-	2,286	1,143	-	\$ 2.19
11/08/12 [3]	815,000	[4] 24,500	372,572	372,572	[5] 8,000	[5] \$ 2.19
2012 Total	2,160,000	87,475	987,430	680,000	33,360	
02/22/13	380,500	-	107,372	107,372	-	\$ 4.24
04/11/13	236,000	37,100	66,596	66,596	6,660	\$ 4.24
04/22/13	576,000	55,100	162,540	162,540	13,150	\$ 4.24
05/31/13	288,000	31,300	81,270	81,270	8,127	\$ 4.24
06/28/13	1,976,925	62,632	557,862	557,862	17,674	\$ 4.24
11/14/13	6,000,000	[6] -	1,672,474	836,237	-	\$ 5.69
11/18/13	7,000,000	494,000	1,951,220	975,610	136,490	\$ 5.69
2013 Total	16,457,425	680,132	4,599,334	2,787,487	182,101	
Total	\$ 18,617,425	\$ 767,607	5,586,764	3,467,487	215,461	

Includes 86,857 shares of common stock and five-year warrants to purchase 43,429 shares of common stock at an exercise price of \$2.19 per share issued to certain officers and members of the Board of Directors in exchange for gross proceeds of \$190,000.

[2] Issued to a member of the Board of Directors.

Includes 89,143 shares of common stock and five-year warrants to purchase 89,143 shares of common stock at an exercise price of \$2.19 per share issued to certain members of the Board of Directors for gross proceeds of \$195,000.

[4] Includes \$50,000 represented by the conversion of debt.

[5] See Note 15 Fair Value Measurement for details regarding the fair value of the warrant liability recorded in connection with these issued warrants.

[6] See Note 9 Commitment and Contingencies for details regarding the Celgene License, Marketing, and Development Agreement and Supply Agreement.

The securities purchase agreements the Company entered into in 2012 contain a variety of contractual provisions, which include certain affirmative and negative covenants made by the Company. The Company's covenants principally consist of a requirement to reserve sufficient authorized shares to issue upon the exercise of the related warrants, and, subject to certain exceptions, in the event the Company subsequently issues or sells common shares at a price lower than the purchase price per share which was offered to the investors, each investor will be entitled to additional shares such that the total purchase price paid by such investor, when divided by the number of shares held by such investor (including additional shares) equals the lower price.

In connection with the securities purchase agreements entered into on February 16, 2012 and November 8, 2012, pursuant to which Palladium Capital Advisors, LLC served as the placement agent, the Company is required to (i) upon its failure to provide for the timely delivery of shares upon the exercise of the warrants, pay liquidated damages consisting of a cash payment of \$10 per trading day (increasing to \$20 per trading day on the fifth trading day) for each \$1,000 of warrant shares until such certificates are delivered, (ii) upon its failure to maintain timely required filings with the SEC, pay liquidated damages consisting of a cash payment of one percent (1.0%) of the aggregate subscription amount of such purchasers' securities on the day of the failure to maintain timely filings with the SEC and on every thirtieth (30th) day thereafter, until the required documents are filed with the SEC or such filing is no longer required for the purchaser to transfer the underlying shares pursuant to Rule 144, and (iii) upon its failure to provide for the timely delivery of unlegended shares, upon the satisfaction of certain conditions, pay in cash to the investor (in addition to any other remedies available to or elected by the investor) the amount, if any, by which (A) such investor's total purchase price (including any brokerage commissions) for the common stock the investor was required to purchase to cover a sale order exceeds (B) the aggregate purchase price of the common shares or warrant shares delivered to the Company for reissuance as unlegended shares.

The securities purchase agreement for each of the above 2013 financings contain customary representations, warranties and covenants. In addition, the securities purchase agreement for 2013 transactions prior to November 2013 contain a “full ratchet” anti-dilution adjustment provision, pursuant to which, in the event that the Company sells or issues shares of common stock or common stock equivalents at a price (the “Base Price”) lower than \$3.54 per share, the Company will be required to issue to each investor, for no additional consideration, a certain number of shares of common stock such that the purchase price paid by such investor under the securities purchase agreement for the number of shares originally held, when divided by the aggregate number of shares originally held and any additional shares issued to such investor, will equal the Base Price. This investor right will terminate for an investor at any time following the nine month anniversary of the final closing under such investor’s securities purchase agreement, if (i) the closing sales price of the common stock for thirty (30) consecutive trading days is at least 200% of the per share purchase price, (ii) the product of (A) the volume weighted average price of the common stock on its principal market and (B) its corresponding daily trading volume, each as reported by Bloomberg L.P., equals or exceeds \$50,000 for such thirty (30) consecutive trading days and (iii) the investor shares that were acquired by investors who are not our affiliates were eligible for unrestricted sale pursuant to Rule 144 under the Securities Act of 1933, as amended on the Company’s principal market from the six month anniversary of the final closing under the securities purchase agreement through at least the nine month anniversary of such final closing. Each warrant is exercisable immediately for cash. In addition, in the event that there is no effective registration statement registering, or no current prospectus available for, the resale of the shares of common stock issuable upon exercise of a warrant at any time following the one year anniversary of the issuance date of such warrant, such warrant may also be exercised by way of a cashless exercise. The warrants also contain customary provisions that protect their holders against dilution by adjustment of the purchase price in certain events such as stock dividends, stock splits and other similar events.

### ***Stock-Based Compensation***

The following table summarizes stock-based compensation expense, which is reflected as selling, general and administrative expenses in the consolidated statements of operations:

	For The Years Ended December 31,	
	2013	2012
Options	\$ 3,948,025	\$ 1,421,338
Warrants	172,913	3,777
Restricted Stock Units	83,836	-
Restricted Stock	1,309,087	550,000
Total Stock-Based Compensation	\$ 5,513,861	\$ 1,975,115

**Restricted Stock**

The following table summarizes the restricted stock issued as compensation during the years ended December 31, 2013 and 2012:

Issuance Date	Grantee Type	Shares Issued	Vesting Term	Grant Date Value	
01/11/12	Vendor	45,714	Immediate	\$ 100,000	[1]
06/30/12	Officer	22,857	Immediate	100,000	
06/30/12	Officer	32,653	Immediate	100,000	
08/15/12	Consultant	2,286	Immediate	10,000	
09/20/12	Consultant	2,286	Immediate	10,000	
11/14/12	Consultant	4,571	Immediate	20,000	
11/14/12	Consultant	45,714	Immediate	200,000	
11/30/12	Consultant	2,286	Immediate	10,000	
	Restricted Stock - Total	158,367		550,000	
11/08/12	Officer	70,753	[2]	154,773	
	Restricted Stock Units - Total	70,753		154,773	
	2012 - Total	229,120		704,773	
05/24/13	Consultant	2,286	Immediate	7,000	
06/28/13	Fmr. Officer	186,165	Immediate	570,130	
07/01/13	Consultant	16,429	Immediate	50,312	
10/15/13	Consultant	3,265	Immediate	10,000	
11/11/13	Fmr. Officer	186,165	Immediate	651,578	
11/14/13	Consultant	2,875	Immediate	10,063	
12/12/13	Employee	21,614	One year	150,001	[3]
12/24/13	Consultant	1,409	Immediate	10,004	
	Restricted Stock - Total	420,208		1,459,088	
	2013 - Total	420,208		\$ 1,459,088	

[1] See Note 13 Related Party Transactions for additional details.

[2] Vests over three years and is subject to the Company's achievement of certain market capitalization targets. During the fourth quarter of 2013, 35,377 shares vested as a performance condition was met.

[3] Shares forfeited during 2013. The Company did not record any stock-based compensation expense during 2013 related to the issuance.

As of December 31, 2013, there was \$23,646 of unrecognized stock-based compensation expense related to RSUs which will be amortized over a weighted average period of 1.8 years, provided the performance condition remains probable of being achieved. Separately, as of December 31, 2013, there was \$38,693 of unrecognized stock-based compensation expense related to RSUs with performance conditions that are currently improbable of being achieved.

**Warrants**

See Note 10 Stockholders' Equity - Preferred Stock, Common Stock and Warrant Offerings for details of warrants issued to investors and placement agents in connection with equity offerings.

On April 10, 2012, the Company entered into an agreement for investment banking services. The agreement had a term of twelve months. As compensation for services, the Company agreed to pay a cash fee of \$6,500 per month and a five-year warrant to purchase 1,143 shares of common stock at an exercise price \$3.50 per share was to be issued monthly. During 2012, the Company issued warrants to purchase an aggregate of 2,286 shares of common stock with an aggregate grant date value of \$3,777. The grant date value was recognized immediately. A warrant to purchase an additional 1,143 shares of common stock was waived by the receiving party due to non-performance. The agreement was terminated in July of 2012.

On July 11, 2013, the Company issued to a consultant a five-year warrant to purchase 6,857 shares of common stock at an exercise price of \$4.38 per share, which will vest and become exercisable in 12 equal monthly installments over the first year from the date of issuance. The aggregate grant date value was \$14,640.

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Between October 28 and November 12, 2013, the Company issued to various consultants five-year warrants to purchase an aggregate of 68,571 shares of common stock at exercise prices ranging from \$4.38 to \$5.69 per share. The warrants vest in twelve equal monthly installments from the date of issuance. The aggregate grant date value was \$168,255.

In applying the Black-Scholes option pricing model to compensatory warrants issued, the Company used the following weighted average assumptions:

	For The Year Ended December 31,			
	2013		2012	
Risk free interest rate	1.27	%	0.74	%
Expected term (years)	5.00		5.00	
Expected volatility	99.59	%	98.49	%
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 warrants. The expected term used for warrants 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.

The weighted average estimated fair value per share of the compensatory warrants issued during the year ended December 31, 2013 and 2012 was \$2.42 and \$1.65, respectively.

During the year ended December 31, 2013, the Company issued an aggregate of 261,030 shares of common stock to several holders of warrants who elected to exercise warrants to purchase an aggregate of 371,429 shares of common stock on a "cashless" basis under the terms of the warrants. The warrants had exercise prices of \$3.02 per share (125,714 gross shares) and \$2.19 per share (245,715 gross shares). The aggregate intrinsic value of the warrants exercised was \$2,167,657 for the year ended December 31, 2013.

As of December 31, 2013, there was \$255,537 of unrecognized stock-based compensation expense related to compensatory warrants that are subject to non-employee mark-to-market adjustments and will be amortized over a weighted average period of 0.9 years.

A summary of the warrant activity, including common stock purchase warrants, during the years ended December 31, 2013 and 2012 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, December 31, 2011	310,107	\$ 10.94		
Issued	715,647	2.63		
Anti-Dilutive Adjustment	539	51.19		
Exercised	-	-		
Forfeited	(22,085)	51.19		
Outstanding, December 31, 2012	1,004,208	\$ 3.94		
Issued	3,189,778	5.15		

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Exercised	(371,429)		1.01			
Forfeited	-		-			
Outstanding, December 31, 2013	3,822,557	\$	5.12	4.4	\$	8,369,579
Exercisable, December 31, 2013	3,756,558	\$	5.12	4.4	\$	8,207,235

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The following table presents information related to warrants at December 31, 2013:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$ 2.19	202,286	3.8	202,286
3.02	139,648	3.1	139,648
3.50	2,286	3.3	2,286
4.24	1,021,251	4.4	1,021,251
4.38	188,444	4.8	143,112
4.81	8,889	4.8	8,889
5.69	1,971,194	4.9	1,950,527
7.00	140,708	1.4	140,708
8.75	147,851	1.4	147,851
	3,822,557	4.4	3,756,558

As of December 31, 2013, five-year warrants to purchase an aggregate of 152,000 shares of common stock at an exercise price of \$2.19 per share were deemed to be a derivative liability. See Note 15 Fair Value Measurement.

## 11. Stock Options

### *Options - 2011 Plan*

The Company maintains an active stock option plan (the “2011 Plan”) that provides for option grants 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, 2013, 681,053 shares were reserved for outstanding options and 1,147,518 shares were available for future option issuances. As of December 31, 2013, an inactive stock option plan had 352,191 shares reserved for outstanding options (no shares were available for future option issuances), while there were 3,952,342 shares reserved for non-plan outstanding options.

### *Options - 2012 Grants*

During 2012, options to purchase an aggregate of 1,979,576 shares of common stock at exercise prices ranging from \$4.38 to \$8.75 with an aggregate grant date value of \$3,056,383 were granted to directors, employees and consultants. Most of the 2012 grants had five or ten year terms and vested between immediately or within three years. 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:

- On May 17, 2012, a ten-year option to purchase 530,286 shares of common stock with an aggregate grant date value of \$914,080 was granted to a director. The options were scheduled to vest and become exercisable as follows: (i) options to purchase 79,543 shares of common stock at \$4.38 per share vested immediately on the date of grant; and (ii) the remainder were to vest and become exercisable at \$4.38 or \$6.56 per share based on various performance measures that were never met or were cancelled based on mutual agreement.
- On November 27, 2012, a ten-year option to purchase 457,143 shares of common stock with an aggregate grant date value of \$695,000 was granted to a director. The options were scheduled to vest and become exercisable as



follows: (i) options to purchase 57,143 shares of common stock at \$8.75 per share vested immediately on the date of grant; (ii) options to purchase 57,143 shares of common stock at \$8.75 per share vest on each of the one-, two-, and three-year anniversaries of the date of grant; (iii) options to purchase 57,143 shares of common stock at \$8.75 per share vested on November 14, 2013 upon meeting a performance condition and (iv) the remainder were to vest based on various performance measures that were never met or were cancelled based on mutual agreement.

- (3) On November 5, 2012, a ten-year option to purchase 212,261 shares of common stock with an aggregate grant date value of \$318,833 was granted to an officer of the Company. The options are scheduled to vest and become exercisable at \$4.38 per share on each of the one- (70,754 shares), two- (70,754 shares), and three-year (70,753 shares) anniversaries of the date of grant.

On November 29, 2012, a ten-year option to purchase 177,600 shares of common stock with an aggregate grant date value of \$292,670 was granted to a director of the Company. The options are scheduled to vest and become  
(4) exercisable as follows: (i) options to purchase 59,200 shares at \$4.38 per share vested immediately; and (ii) options to purchase 59,200 shares of common stock vest on each of the one- (at \$6.56 per share) and two- (at \$8.75 per share) year anniversaries of the date of grant.

#### *Options - 2013 Grants*

During 2013, options to purchase an aggregate of 3,319,421 shares of common stock at exercise prices ranging from \$3.28 to \$10.94 (most between \$4.38 and \$8.75) with an aggregate grant date value of \$9,375,010 were granted to directors, employees and consultants. Most of the 2013 grants had five or ten year terms and vested between immediately or within three years. 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:

On December 20, 2013, a ten-year option to purchase 730,535 shares of common stock with an aggregate grant date value of \$3,826,039 was granted to an officer of the Company. The options are scheduled to vest and  
(1) become exercisable at \$6.82 per share as follows: (i) 81,171 shares on January 1, 2014 and (ii) 81,170 or 81,171 shares on each of the next eight succeeding quarterly anniversaries of the first vesting date.

On July 22, 2013, a 9.5-year option to purchase 622,170 shares of common stock with an aggregate grant date value of \$1,556,984 was granted to a director. The options were scheduled to vest and become exercisable as follows: (i) options to purchase 207,290 shares of common stock at \$6.56 per share are currently deemed probable of vesting upon the meeting of certain performance criteria; (ii) options to purchase 207,290 shares of common stock at \$8.75 per share are currently deemed probable of vesting upon the meeting of certain performance  
(2) criteria; (iii) options to purchase 207,290 shares of common stock at \$10.94 per share are also currently deemed probable of vesting upon the meeting of certain performance criteria. In conjunction with this grant, certain outstanding options with as yet unmet 2013 performance conditions held by this director were cancelled, as follows: (a) options to purchase 106,057 shares of common stock at \$6.56 per share; (b) options to purchase 114,286 shares of common stock at \$8.75 per share; and (c) options to purchase 57,142 shares of common stock at \$8.75 per share.

On February 4, 2013, a ten-year immediately vested option to purchase 279,227 shares of common stock at an  
(3) exercise price of \$3.18 per share with an aggregate grant date value of \$684,107 was granted to an officer of the Company.

On May 10, 2013, a ten-year option to purchase 274,275 shares of common stock with an aggregate grant date value of \$476,794 was granted to an officer of the Company. The options were scheduled to vest and become exercisable (the exercise price for one-fifth of each tranche is \$4.38, \$5.47, \$6.56, \$8.75 and \$10.94 per share) as  
(4) follows: (i) options to purchase 54,855 shares of common stock vested immediately on the date of grant; (ii) options to purchase 54,855 shares of common stock vest on each of the one-, two-, three-, and four-year anniversaries of the date of grant.

On September 3, 2013, a ten-year option to purchase 185,142 shares of common stock with an aggregate grant date value of \$384,210 was granted to an officer of the Company. The options are scheduled to vest and become  
(5) exercisable as follows: (i) options to purchase 61,714 shares at \$4.38 per share vested immediately; and (ii) options to purchase 61,714 shares of common stock vest on each of the one- (at \$6.56 per share) and two- (at \$8.75 per share) year anniversaries of the date of grant.

(6)

On November 14, 2013, a five-year option to purchase 160,000 shares of common stock with an aggregate grant date value of \$371,992 was granted to a consultant of the Company. The options are scheduled to vest and become exercisable as follows: (i) options to purchase 80,000 shares at \$5.69 per share vested immediately; and (ii) options to purchase 80,000 shares at \$6.56 per share vest on the six month anniversary of the date of grant.

(7) On November 14, 2013, a ten-year option to purchase 117,125 shares of common stock with an aggregate grant date value of \$310,482 was granted to an officer of the Company. The options are scheduled to vest and become exercisable at \$3.50 per share as follows: (i) options to purchase 32,549 shares on March 28, 2014 (ii) options to purchase 41,116 shares on June 28, 2014; and (iii) options to purchase 43,460 shares on September 30, 2014.

(8) On May 10, 2013, a ten-year option to purchase 171,432 shares of common stock with an aggregate grant date value of \$292,406 was granted to an employee of the Company. The options were scheduled to vest and become exercisable (the exercise price for one-fourth of each tranche is \$4.38, \$5.47, \$6.56 and \$8.75 per share) as follows: (i) options to purchase 57,144 shares of common stock vested immediately on the date of grant and (ii) options to purchase 57,144 shares of common stock vest on each of the one- and two-year 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:

	For The Years Ended December 31,			
	2013		2012	
Risk free interest rate	1.40	%	0.75	%
Expected term (years)	5.55		5.49	
Expected volatility	99.78	%	97.87	%
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.

The weighted average estimated fair value per share of the options granted during the year ended December 31, 2013 and 2012 was \$2.80 and \$1.54, respectively.

During the year ended December 31, 2013, the Company recognized a credit of \$411,614 relating to options containing performance conditions, of which, \$386,119 related to previously recognized expense for options where the performance was not rendered by the required date and have been forfeited, and \$25,495 related to the expense previously recognized for options which were originally deemed probable of being achieved that are now deemed improbable of being achieved. As of December 31, 2013, there was \$6,609,208 of unrecognized stock-based compensation expense related to stock options which will be amortized over a weighted average period of 1.6 years, of which \$536,764 is subject to non-employee mark-to-market adjustments. Separately, as of December 31, 2013, there was \$137,332 of unrecognized stock-based compensation expense related to stock options with performance conditions that are currently improbable of being achieved.

A summary of the stock option activity during the years ended December 31, 2013 and 2012 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, December 31, 2011	431,314	\$ 7.00		
Granted	1,979,576	6.13		
Exercised	-	-		
Forfeited	(77,068)	4.81		
Outstanding, December 31, 2012	2,333,822	\$ 6.56		
Granted	3,319,421	6.37		
Exercised	-	-		
Forfeited	(667,657)	6.96		
Outstanding, December 31, 2013	4,985,586	\$ 6.47	8.2	\$ 6,574,508

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Exercisable, December 31, 2013	2,381,469	\$	5.87	6.9	\$	4,241,527
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The following table presents information related to stock options at December 31, 2013:

Options Outstanding		Outstanding Number of Options	Options Exercisable	
Price	Exercise		Weighted Average Remaining Life In Years	Exercisable Number of Options
\$	3.28	279,227	9.1	279,227
	3.50	117,125	-	-
	3.94	7,619	9.9	7,619
	4.38	1,233,854	6.4	853,325
	5.47	120,569	9.4	30,971
	5.69	114,286	4.9	114,286
	5.91	17,142	7.0	17,142
	6.34	280,342	5.9	280,342
	6.56	657,634	5.0	205,599
	6.82	780,535	10.0	12,500
	8.75	999,349	8.7	453,828
	9.19	114,285	4.9	114,285
	10.94	262,245	9.4	10,971
	11.38	1,145	4.7	1,145
	26.69	229	4.4	229
		4,985,586	6.9	2,381,469

## 12.

## Income Taxes

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

	For The Years Ended December 31,	
	2013	2012
Federal:		
Current	\$ -	\$ -
Deferred	(6,528,000)	(1,648,000)
State and local:		
Current	-	-
Deferred	(1,140,000)	(139,000)
	(7,668,000)	(1,787,000)
Change in valuation allowance	7,677,000	1,798,000
Income tax provision (benefit)	\$ 9,000	\$ 11,000

The expected tax expense (benefit) based on the statutory rate reconciled with the actual expense (benefit) is as follows:

	For The Years Ended December 31,			
	2013	2012		
US federal statutory rate	(34.0)	(34.0)	%	%

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State tax rate, net of federal benefit	(5.9)	%	(5.9)	%
Permanent differences				
- Exercised warrant liability	3.3	%	0.0	%
- Other	1.7	%	3.4	%
Change in valuation allowance	34.9	%	36.7	%
Income tax provision (benefit)	0.0	%	0.2	%

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Deferred tax assets consisted of the effects of temporary differences attributable to the following:

	As of December 31, 2013	2012
Deferred tax assets:		
Net operating loss carryforwards	\$ 10,703,000	\$ 7,940,000
Stock-based compensation	2,825,000	1,469,000
Intangible assets	4,059,000	870,000
Accruals	326,000	-
Other	230,000	196,000
Total deferred tax assets	18,143,000	10,475,000
Valuation allowance	(17,607,000)	(9,930,000)
Deferred tax assets, net of valuation allowance	536,000	545,000
Deferred tax liabilities:		
Property and equipment	(536,000)	(545,000)
Goodwill	(53,000)	(44,000)
Total deferred tax liabilities	(589,000)	(589,000)
Net deferred tax liabilities	\$ (53,000)	\$ (44,000)

For the years ended December 31, 2013 and 2012, the Company had approximately \$27,408,000 and \$20,468,000 of federal and state net operating loss carryovers ("NOLs"), respectively, which begin to expire in 2018. The net operating loss carryovers may be subject to annual limitations under Internal Revenue Code Section 382 should there be a greater than 50% ownership change as determined under the regulations. The Company conducted a preliminary Section 382 analysis and has determined that no ownership changes have occurred wherein the annual limitations will inhibit the Company from ultimately realizing the benefit of NOL's if the Company generates sufficient taxable income.

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 taxing strategies in making this assessment. The deferred tax liability related to goodwill cannot be used in this determination since goodwill is considered to be an asset with an indefinite life for financial reporting purposes. Therefore, the deferred tax liability related to goodwill cannot be considered when determining the ultimate realization of deferred tax assets. Based upon this assessment, management has established a full valuation allowance for the amount of the deferred tax assets which cannot be supported through the production of future taxable income generated through the reversal of the deferred tax liability related to the depreciation of the property and equipment, since it is more likely than not that these deferred tax assets will not be realized.

### 13.

### Related Party

On January 11, 2012, the Company issued 45,714 shares of common stock to a related party in satisfaction of its obligation for office space and services.

On February 15, 2013, a subscription receivable of \$20,000 was received from a director in connection with a private placement.



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On February 22, 2013, the Company issued to four directors and an affiliate of a director, in the aggregate, (i) 76,190 shares of common stock and (ii) five year warrants to purchase, in the aggregate, up to 76,190 shares of common stock at an exercise price of \$4.24 per share, in exchange for aggregate consideration of \$270,000.

On June 28, 2013, the Company issued to five directors, in the aggregate, (i) 231,393 shares of common stock and (ii) five year warrants to purchase, in the aggregate, up to 231,393 shares of common stock at an exercise price of \$4.24 per share, in exchange for aggregate consideration of \$820,000.

#### 14. Concentration of Risk

Revenues and accounts receivable from our largest customers for the years ended December 31 were as follows:

Customer	2013		2012	
	% of Total Revenue	Accounts Receivable	% of Total Revenue	Accounts Receivable
A	51	% 51	% 60	% 38
B	16	% 0	% 16	% 39

Principal components used in manufacturing are purchased from the following sources: Berry Plastics, Dow Chemical and BASF. The total material purchases from these sources were \$203,239 and \$124,552 for the years ended December 31, 2013 and 2012, respectively.

#### 15. Fair Value Measurement

On December 31, 2012, the Company recomputed the fair value of its warrant liability as \$605,737 using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 97.26%, risk-free rate of 0.65%, expected term of 5.00 years, and expected dividends of 0.00%. The change in fair value of these warrant liabilities for the year ended December 31, 2012 was de minimis.

On December 2, 2013, warrants to purchase an aggregate of 228,572 shares of common stock were exercised. These warrant liabilities had an aggregate exercise date fair value of \$1,505,770 which was credited to equity. The Company recorded a loss on the change in fair value of these warrant liabilities of \$1,141,964 during the year ended December 31, 2013. The Company recomputed the fair value of these warrant liabilities using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 99.44%, risk-free rate of 1.01%, expected term of 3.94 years, and expected dividends of 0.00%.

On December 31, 2013, the Company recomputed the fair value of its warrant liability as \$933,465 using the Binomial option pricing model (Level 3 inputs) using the following assumptions: expected volatility of 102.63%, risk-free rate of 1.27%, expected term of 3.86 years, and expected dividends of 0.00%. The Company recorded a loss on the change in fair value of these warrant liabilities of \$691,534 during the year ended December 31, 2013.

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, 2013	2012
Beginning balance as of January 1,	\$ 605,737	\$ -
Aggregate value of warrants issued	-	605,737
Change in fair value of warrant liability	1,833,498	-
Value of warrants exercised	(1,505,770)	-
Ending balance as of December 31,	\$ 933,465	\$ 605,737

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

Level	Level	Level
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	1	2	3
December 31, 2012			
Recurring:			
Warrant liabilities	N/A	N/A	\$ 605,737
December 31, 2013			
Recurring:			
Warrant liabilities	N/A	N/A	\$ 933,465

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Warrants that contain exercise reset provisions 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. 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 AquaMed Technologies, 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. The Company does not currently provide any Company match, therefore no expenses were recorded in 2013 and 2012.

#### **17. Subsequent Events**

On January 6, 2014 the Company entered into an option cancellation and release agreement with two 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 director 194,667 shares of common stock of the Company pursuant to 2011 Plan.

On January 6, 2014, the Company granted a restricted stock award of 369,395 shares of common stock to the Company's president and chief executive officer, pursuant to the Company's 2011 Long-Term Incentive Plan. The restricted stock vests, subject to certain terms and conditions included in the restricted stock agreement, in eight quarterly installments, with one-eighth vesting on January 6, 2014 and the first day of each calendar quarter, thereafter.

On March 14, 2014 the chief executive officer of a wholly-owned subsidiary of the Company resigned. In connection with his resignation, the executive entered into a General Release and Severance Agreement with the Company, pursuant to which, the Company will provide the executive with the following: (a) a lump sum payment in the amount of \$210,000; (b) severance payments, in an amount equal to his base salary for a period of six months from the date of resignation; (c) continued health insurance coverage for a period of six months; and (d) the full and immediate vesting of all outstanding stock options and restricted stock unit awards granted to the executive with such stock options remaining exercisable for a period of two years following the date of resignation.