

BIOLIFE SOLUTIONS INC
Form 10-K
March 15, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

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

For the year ended December 31, 2016

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

For the transition period from to

Commission File Number 001-36362

BioLife Solutions, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE **94-3076866**
(State or other jurisdiction of (IRS Employer
incorporation or organization) Identification No.)

3303 MONTE VILLA PARKWAY, SUITE 310, BOTHELL, WASHINGTON, 98021
(Address of registrant's principal executive offices, Zip Code)

(425) 402-1400
(Telephone number, including area code)

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

COMMON STOCK, \$0.001 PAR VALUE

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (S232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post said files). Yes ☒ No ☐

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

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

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

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

As of the registrant's most recently completed second fiscal quarter, the aggregate market value of common equity held by non-affiliates was \$10,043,170.

As of March 7, 2017, 13,000,386 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Shareholders to be held in 2017, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

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PART I

ITEM 1. BUSINESS

References in this Form 10-K to “BioLife”, the “Company,” “we,” “us” or “our” refer to BioLife Solutions, Inc. The information in this Annual Report on Form 10-K contains certain forward-looking statements, including statements related to our products, customers, regulatory approvals, markets for our products, future financial and operational performance, capital requirements, intellectual property, suppliers, joint venture partners, controlling shareholders and trends in our business that involve risks and uncertainties. Our actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as those discussed elsewhere in this Annual Report on Form 10-K.

Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Report

We were incorporated in Delaware in 1987 under the name Trans Time Medical Products, Inc. In 2002, the Company, then known as Cryomedical Sciences, Inc., and engaged in manufacturing and marketing cryosurgical products, completed a merger with our wholly-owned subsidiary, BioLife Solutions, Inc., which was engaged as a developer and marketer of biopreservation media products for cells and tissues. Following the merger, we changed our name to BioLife Solutions, Inc.

For a summary of recent developments, see “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Business Overview

We develop, manufacture and market a portfolio of biopreservation tools for cells, tissues, and organs, including proprietary clinical grade cell and tissue hypothermic storage and cryopreservation freeze media.

Our products are used in basic and applied research on, and commercialization of, new biologic based therapies by maintaining the health and function of biologic source material and finished products during manufacturing, distribution, and patient delivery.

Our product offerings include:

- Patented hypothermic storage and cryopreservation freeze media products for cells, tissues, and organs
- Generic blood stem cell freezing and cell thawing media products
- Custom product formulation and custom packaging services
- Contract aseptic manufacturing formulation, fill, and finish services of liquid media products
- Cold chain logistics services incorporating precision thermal packaging products and cloud-hosted web applications

Our proprietary, clinical grade HypoThermosol ® FRS and CryoStor ® biopreservation media products are marketed to the regenerative medicine, biobanking, drug discovery markets including hospital-based stem cell transplant centers, pharmaceutical companies, cord blood and adult stem cell banks, hair transplant centers, and suppliers of cells to the drug discovery, toxicology testing and diagnostic markets, including private and public cell therapy companies. All of our biopreservation media products are serum-free and protein-free, fully defined, and are manufactured under current Good Manufacturing Practices (cGMP) using United States Pharmacopia (USP)/Multicompidual or the highest available grade components.

Our patented biopreservation media products are formulated to reduce preservation-induced, delayed-onset cell damage and death. Our platform enabling technology provides our customers significant shelf life extension of biologic source material and final cell products, and also greatly improves post-preservation cell and tissue viability and function. Our products have been incorporated in over 250 regenerative medicine applications, including chimeric antigen receptor (CAR) and other T cell receptor (TCR) types.

On December 31, 2016, we restructured our biologistex CCM, LLC joint venture (“biologistex” prior to December 31, 2016 or “SAVSU” December 31, 2016 and thereafter) with Savsu Technologies, LLC (“STLLC”), whereby we contributed certain assets, including our outstanding loan owed by biologistex, and STLLC contributed certain assets, including all cold chain management intellectual property, into SAVSU. Prior to the restructuring, we owned a 52% ownership interest in biologistex. As a result for consideration given by both parties, we own a 45% interest in SAVSU, which is subsequently reduced to 25% on December 31, 2018. Although we intend to continue to provide certain sales and marketing services to SAVSU, we do not consider these activities, or the potential economic impact thereafter to be a material part of our business in 2017 and beyond.

See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” for additional details.

Products and Services Overview

Biopreservation Media

Stability (shelf life) and functional recovery are crucial aspects of academic research and clinical practice in the biopreservation of biologic-based source material, intermediate derivatives, and isolated/derived/expanded cellular products. Limited stability is especially critical in the regenerative medicine field, where harvested cells and tissues, if not maintained appropriately at normothermic body temperature (98.6°F/37°C), or stored in a hypothermic state in an effective preservation medium, will lose viability over time. Chilling (hypothermia) is used to reduce metabolism and delay degradation of harvested cells, tissues, and organs. However, subjecting biologic material to hypothermic environments induces damaging molecular stress and structural changes. Although cooling successfully reduces metabolism (i.e., lowers demand for energy), various levels of cellular damage and death occur when using suboptimal methods. Traditional preservation media range from simple "balanced salt" (electrolyte) formulations to complex mixtures of electrolytes, energy substrates such as sugars, osmotic buffering agents and antibiotics. The limited stability which results from the use of these traditional biopreservation media formulations is a significant shortcoming that our optimized products address with great success.

Our scientific research activities over the last 20+ years enabled a detailed understanding of the molecular basis for the hypothermic and cryogenic (low-temperature induced) damage/destruction of cells through apoptosis and necrosis. This research led directly to the development of our HypoThermosol® FRS and CryoStor® technologies. Our patented preservation media products are specifically formulated to:

- Minimize cell and tissue swelling
- Reduce free radical levels upon formation
- Maintain appropriate low temperature ionic balances
- Provide regenerative, high energy substrates to stimulate recovery upon warming
- Avoid the creation of an acidic state (acidosis)
- Inhibit the onset of apoptosis and necrosis

A key feature of our preservation media products is their “fully-defined” profile. All of our cGMP products are serum-free, protein-free and are formulated and filled using aseptic processing, utilizing USP/Multicompendial grade or highest quality available synthetic components. All of these features benefit prospective customers by facilitating the qualification process required to incorporate our products into their regulatory filings and hence patient delivery processes.

The results of independent testing demonstrate that our biopreservation media products significantly extend shelf-life and improve cell and tissue post-thaw viability and function, which may, in turn, improve clinical and commercial outcomes for existing and new cell and tissue therapy applications. Our products have demonstrated improved biopreservation outcomes for a broad array of cell and tissue types including stem cells isolated from umbilical and peripheral blood, bone marrow, adipose tissue, liver, tendon, and umbilical cord tissue, and also for induced pluripotent stem cells including hepatocytes, endothelial cells, and neuronal cells, hepatocytes isolated from non-transplantable livers, chondrocytes isolated from cartilage, and dermal fibroblasts and muscle cells isolated from tissue biopsies.

Competing biopreservation media products are often formulated with simple isotonic media cocktails, animal serum, potentially a single sugar or human protein. A key differentiator of our proprietary HypoThermosol FRS formulation is the engineered optimization of the key ionic component concentrations for low temperature environments, as opposed to normothermic body temperature around 37°C, as found in culture media or saline-based isotonic formulas. Competing cryopreservation freeze media is often comprised of a single permeating cryoprotectant such as dimethyl sulfoxide (“DMSO”). Our CryoStor formulations incorporate multiple permeating and non-permeating cryoprotectant agents, which allow for multiple mechanisms of protection and reduces the dependence on a single cryoprotectant.

Across a broad spectrum of cell and tissue types, our products have proven more effective in reducing post-preservation and post-thaw necrosis and apoptosis as compared to commercial and home-brew isotonic and extracellular formulations. This results in greatly extended shelf life and improved post-preservation viability.

Biopreservation Media Opportunity

According to Global Market Insights, “Biopreservation Market Size” published in September 2016, the total biopreservation market is expected to be \$9.7 billion by 2024, with our current addressable media market expected to be \$1.3 billion by 2024. Our current addressable portion of the market is the demand for reagents used to store, ship and freeze source material and manufactured doses of cell-based products and therapies.

Regenerative Medicine

The emerging field of regenerative medicine is unique in its aim to augment, repair, replace or regenerate organs and tissue that have been damaged by disease, injury or even the natural aging process. This rapidly evolving, interdisciplinary field is transforming healthcare by translating fundamental science into a variety of regenerative technologies including biologics, chemical compounds, materials and devices. It differs from other fields of medicine in the array of disciplines it brings together and in its ability to create or harness the body’s innate healing capacity.

We continue to educate the regenerative medicine market about the impact of effective biopreservation on the ability to create commercially viable manufactured products with participation in scientific conferences and industry trade events by exhibiting, presenting scientific and business lectures, and sponsoring industry association events. We are a corporate or affiliate member of the Alliance for Regenerative Medicine, the BEST Collaborative, and the International Society for Cellular Therapy.

We have secured a valuable position as a supplier of critical reagents to several commercial companies and estimate that our biopreservation media products are incorporated in over 250 applications for new cell and tissue-based regenerative medicine products and therapies. A significant number of applications involve CAR-T cells and other types of T cells and mesenchymal stem cells targeting blood cancers, solid tumors and other leading causes of death and disability. We estimate that annual revenue from each application in which our products are used could range from \$0.5 million to \$2.0 million, if approved and our customer commences large scale commercial manufacturing of the biologic based therapy.

Drug Discovery

Our customers in the drug screening market are pharmaceutical companies that grow and preserve various cell types to measure pharmacologic effects and toxicity of new drug compounds, and also cell suppliers that provide preserved live cells for end-user testing in pharmaceutical companies. Our products specifically address this need by enhancing yield, viability and functionality of previously preserved cells.

Biobanking

The biobanking industry includes public and private cord blood banks, adult stem cell banks, tissue banks, hair transplant centers, cryopreservation of platelets and biorepositories. To continue to generate awareness of the need for effective preservation, we are a sponsor and member of the AABB and the Cord Blood Association. We also provide expertise when needed to the top biobanking enterprises.

Principal Products

HypoThermosol® FRS biopreservation media is a novel, engineered, optimized hypothermic storage and shipping media product. This proprietary, optimized formulation mitigates temperature-induced molecular cell stress responses that occur during chilling and re-warming of biologics, intermediate products, and final cell products intended for research and clinical applications. Serum-free, protein-free HypoThermosol FRS is designed to provide maximum storage and shipping stability for biologics at 2°-8°C. HypoThermosol FRS is manufactured under cGMP and is tested to USP <71> Sterility and USP <85> Endotoxin standards.

CryoStor® cryopreservation freeze media products have been designed to mitigate temperature-induced molecular cell stress responses during freezing and thawing. CryoStor proprietary freeze media products are intended for

cryopreservation of biologics at subzero temperatures (most often utilized within the range of -80 to -196°C). All CryoStor products are pre-formulated with USP/EP grade DMSO, a permeating cryoprotective agent which helps mitigate damage from the formation of intracellular and extracellular ice. CryoStor is offered in several packages and pre-formulated with DMSO in final concentrations of 2%, 5%, and 10%. CryoStor is manufactured under cGMP and is tested to USP <71> Sterility and USP <85> Endotoxin standards.

BloodStor® freeze media is a series of generic cGMP freeze media products used to cryopreserve stem and other cells isolated from umbilical cord blood, peripheral blood, and bone marrow where the processing methods require addition of high concentration DMSO. BloodStor 55-5 is pre-formulated with 55% (w/v) DMSO USP/EP, 5% (w/v) Dextran-40 USP/EP, and Water for Injection (WFI) quality water. BloodStor 100 contains 100% (w/v) DMSO USP/EP. BloodStor 27 NaCl is pre-formulated with 27% (w/v) DMSO in saline USP-grade components and Water for Injection (WFI) quality water. BloodStor is manufactured under cGMP and tested to USP <71> Sterility and USP <85> Endotoxin standards.

Cell Thawing Media provides Dextran and saline for washing cryopreserved cells and tissues to dilute or remove cryoprotectants. Cell thawing media is pre-formulated with 10% Dextran 40 in 0.9% NaCl and 10% Dextran 40 in 5% Dextrose.

biologistex™ cold-chain management service includes unlimited use of the evo Smart Shipper and the integrated track and trace cloud-based web application, mybiologistex.com and is sold by BioLife to the regenerative medicine space. The line of evo Smart Shippers are reusable and designed for the shipment of materials which must be maintained at precision temperature ranges including frozen at -80°C, chilled at 2-8°C, and at controlled room temperature (CRT) temperatures. The evo Smart Shippers include a NIST traceable thermocouple embedded within the payload cavity to monitor the environmental conditions within the payload and a fiber optic sensor enabling monitoring whether the container is opened at any time during shipment, and upon arrival at the destination. The monitoring data and GPS location is transmitted in real time to our cloud based web application, giving our customers the ability to pack, ship, and independently track their precious starting material and manufactured cell products and other biologic material throughout transit to its destination. BioLife receives a revenue share on biologistex subscriptions sold into the regenerative medicine market. For further information regarding our business relationship with SAVSU, see Item 7 of Part II “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

Competition

Biopreservation Media

We believe that in-house formulated biopreservation media, whereby the user purchases raw ingredients and manually mixes the ingredients, satisfies the large majority of the annual worldwide demand. Commercial competitors, in most cases, are supplying isotonic, non-optimized preservation media and include VWR, Sigma-Aldrich, Lonza, Life

Technologies, STEMCELL Technologies, and several smaller companies. Several of our competitors also distribute our premium products. These and other companies may have developed or could in the future develop new technologies that compete with our products or even render our products obsolete.

We believe that our products offer significant advantages over in-house formulations including, time saving, improved quality of components, more rigorous quality control release testing, and improved preservation efficacy. We believe that a company's competitive position in the markets we compete in is determined by product function, product quality, speed of delivery, technical support, price, and distribution capabilities. Our customers are diverse and may place varying degrees of importance on the competitive attributes listed above. While it is difficult to rank these attributes for all our customers in the aggregate, we believe we are well positioned to compete in each category. We expect competition to intensify with respect to the areas in which we are involved as the market expands and technical advances are made and become more widely known.

BUSINESS OPERATIONS

Sales and Marketing

We market and sell our products directly using our sales force and through our website at www.biolifesolutions.com. Our products are also marketed and distributed by STEMCELL Technologies, Sigma-Aldrich, and several other regional distributors under non-exclusive agreements. We are committed to becoming and remaining a trusted, critical supplier to our customers. This requires us to employ scientific team members in sales and support roles. Our technical application support team consists of individuals with extensive experience in cell processing, biopreservation, and cryobiology.

We also market and sell the evo® Smart Shippers and related cloud based data tracking application through a subscription model where customers purchase access to the Smart Shipper and related cloud based data tracking software for a specified period of time. We have a revenue share agreement in place based on gross revenue generated directly by our sales efforts to the regenerative medicine market.

In 2016 and 2015, we derived approximately 12% and 10%, respectively, of our revenue from our relationship with one distributor of our products.

At December 31, 2016, three customers accounted for 45% of gross accounts receivable.

Manufacturing and Distribution

We maintain and operate two independent cGMP clean room production suites for our biopreservation media products. Since December 2009, our quality management system (QMS) has remained certified to ISO 13485:2003. Our QMS is compliant with applicable sections of 21 CFR Part 820 - Quality System Regulation for Good Manufacturing Practice of medical devices, 21 CFR Parts 210 and 211 covering GMP for Aseptic Production, Volume 4, EU Guidelines, Annex 1 for the Manufacture of Sterile Medicinal Products, ISO 13408 for aseptic processing of healthcare products, and ISO 14644, clean rooms and associated controlled environments. We rely on outside suppliers for all of our manufacturing supplies, parts and components. To date, we have not experienced significant difficulties in obtaining raw materials for the manufacture of our biopreservation media products.

The evo® Smart Shippers are manufactured and supplied by biologistex CCM, LLC dba SAVSU (“SAVSU”), based in Albuquerque, NM. The evo web application is a subscription-based model which does not require physical manufacturing or distribution of the software component of the service. For further information regarding our business relationship with SAVSU, see “Item 7 - Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

Support

We provide product support through a combination of channels including phone, chat, web, social media, and email. These support services are delivered by our customer care and scientific teams. These teams are responsible for providing timely, high-quality technical expertise on all our products.

Product Approval Regulation

None of our products are subject to any specific United States Food and Drug Administration (“FDA”) or other non-US pre-market approval for drugs, devices, or biologics. We are not required to sponsor formal prospective, controlled clinical-trials in order to establish safety and efficacy. However, to support our current and prospective clinical customers, we manufacture and release our products in compliance with cGMP and other relevant quality standards.

To assist customers with their regulatory applications, we maintain Type II Master Files at the FDA for CryoStor®, HypoThermosol® FRS, and our Cell Thawing Media products, which provide the FDA with information regarding our manufacturing facility and process, our quality system, and stability and safety testing that has been performed. Customers engaged in clinical applications may notify the FDA of their intention to use our products in their product development and manufacturing process by requesting a cross-reference to our master files.

There can be no assurance that we will not be required to obtain approval from the FDA or foreign regulatory authorities prior to marketing any of our products in the future.

Principal Offices

Our principal executive offices are located at 3303 Monte Villa Parkway, Suite 310, Bothell, Washington 98021 and the telephone number is (425) 402-1400. Information about us is available on our website <http://www.biolifesolutions.com>. The information contained on our website or that can be accessed through our website does not constitute part of this annual report and is not incorporated in any manner into this annual report.

Intellectual Property

Currently, we have five issued and unexpired U.S. patents, two issued Australian patents, one issued European patent, one issued Japanese patent, and several pending patent applications. We have also obtained certain trademarks and tradenames for our products to distinguish our genuine products from our competitors' products and we maintain certain details about our processes, products, and strategies as trade secrets. While we believe that the protection of patents and trademarks is important to our business, we also rely on a combination of trade secrets, nondisclosure and confidentiality agreements, scientific expertise and continuing technological innovation to maintain our competitive position. Despite these precautions, it may be possible for unauthorized third parties to copy certain aspects of our products and/or to obtain and use information that we regard as proprietary. The laws of some foreign countries in which we may sell our products do not protect our proprietary rights to the same extent as do the laws of the United States.

Product Development

Currently, we employ a team of three researchers, all of whom hold Ph.D. degrees in molecular biology or related fields who are responsible for bringing new biopreservation products to market. We also conduct collaborative research with several leading academic and commercial entities in our strategic markets.

During 2016, we incurred costs of approximately \$2.7 million on research and development activities, including \$0.7 million in cost related to the development of internal use software which were capitalized by our joint venture, biologistex CCM, LLC. The capitalized costs related to biologistex internal use software are no longer included in our consolidated financial statements after December 31, 2016 due to the deconsolidation of biologistex. See Note 1 to the

Company's Consolidated Financial Statements in Item 8 of this form 10-K for additional information about the biologistex joint venture restructuring on December 31, 2016. During 2015, we incurred costs of approximately \$3.1 million on research and development activities, including \$1.7 million in cost related to the development of internal use software which were capitalized.

Employees

As of February 1, 2017, we had 35 full time employees and one part-time employee. Our employees are not covered by any collective bargaining agreement. We consider relations with our employees to be good.

Available Information

We maintain a website at <http://www.biolifesolutions.com>. The information contained on or accessible through our website is not part of this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are available free of charge on our website as soon as reasonably practicable after we electronically file such reports with, or furnish those reports to, the Securities and Exchange Commission (the "SEC"). Any information we filed with the SEC may be accessed and copied at the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549. Information may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at <http://www.sec.gov>.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this annual report, before deciding to invest in our common stock. If any of the following risks materialize, our business, financial condition, results of operation and future prospects will likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

Risks Related to Our Business

The majority of our net sales come from a relatively small number of customers and a limited number of market sectors; if we lose any of these customers or if there are problems in those market sectors, our net sales and operating results could decline significantly.

In 2016 and 2015, we derived approximately 12% and 10%, respectively, of our revenue from our relationship with one distributor of our products. No other customer accounted for more than 10% of revenue in 2016 or 2015. Our principal customers may vary from period to period, and our principal customers may not continue to purchase products from us at current levels, or at all. Significant reductions in net sales to any of these customers or our failure to make appropriate choices to the customers we serve, could seriously harm our business. In addition, we focus our sales to customers in only a few market sectors. Each of these sectors is subject to macroeconomic conditions as well as trends and conditions that are sector specific. Shifts in the performance of a sector served by us, as well as the economic, business and/or regulatory conditions that affect the sector, or our failure to choose appropriate sectors can particularly impact us. Any weakness in the market sectors in which our customers are concentrated could affect our business and results of operations.

We have a history of losses and may never achieve or maintain profitability.

We have incurred annual consolidated operating losses since inception, and may continue to incur operating losses. For the fiscal years ended December 31, 2016 and December 31, 2015, we had consolidated net losses attributable to BioLife of \$6.9 million and \$4.2 million, respectively. As of December 31, 2016, our consolidated accumulated deficit was approximately \$71.2 million. We may not be able to successfully achieve or sustain profitability. Successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure.

We may need additional capital to reach and maintain a sustainable level of positive cash flow and if we raise such additional capital through the issuance of equity or convertible debt securities, your ownership will be diluted, and equity securities issued may have rights, preferences and privileges superior to the shares of common stock.

If we are unable to achieve profitability sufficient to permit us to fund our operations and other planned actions, we may be required to raise additional capital. There can be no assurance that such capital would be available on favorable terms, or at all. If we raise additional capital through the issuance of equity or convertible debt securities, the percentage ownership held by existing stockholders may be reduced, and the market price of our common stock could fall due to an increased number of shares available for sale in the market. Further, our board has the authority to

establish the designation of additional shares of preferred stock that may be convertible into common stock without any action by our stockholders, and to fix the rights, preferences, privileges and restrictions, including voting rights, of such shares. Any such additional shares of preferred stock may have rights, preferences and privileges senior to those of outstanding common stock, and the issuance and conversion of any such preferred stock would further dilute the percentage ownership of our stockholders. Debt financing, if available, may involve restrictive covenants, which may limit our operating flexibility with respect to certain business matters. If we are unable to secure additional capital as circumstances require, we may not be able to fund our planned activities or continue our operations.

There is uncertainty surrounding our ability to successfully commercialize our HypoThermosol® FRS and CryoStor® biopreservation media products.

Our growth depends on our continued ability to successfully develop, commercialize and market our HypoThermosol® FRS, CryoStor®, and BloodStor® biopreservation media products. Even in markets that do not require us to obtain regulatory approvals, our products will not be used unless they present an attractive alternative to competitive products and the benefits and cost savings achieved through their use outweigh the cost of our products. If we are unable to develop and sustain a market for our products, this will have a material adverse effect on our results of operations and our ability to continue and grow our business.

The success of our HypoThermosol® FRS and CryoStor® biopreservation media products is dependent, in part, on successful customer regulatory approvals and commercial success of new regenerative medicine products and therapies.

Our HypoThermosol® FRS and CryoStor® biopreservation media products are marketed to biotechnology companies and research institutions engaged in research and development of cell, gene and tissue engineering therapies. The end-products or therapies developed by these biotechnology companies and research institutions are subject to substantial regulatory oversight by the FDA and other regulatory bodies, and many of these therapies are years away from commercialization. Thus demand, if any, for HypoThermosol® FRS and CryoStor® is expected to be limited for several years. Failure of the end-products that use our biopreservation media products to receive regulatory approvals and be successfully commercialized will have an adverse effect in the demand for our products.

We face significant competition.

The life sciences industry is highly competitive. We anticipate that we will continue to face increased competition as existing companies develop new or improved products and as new companies enter the market with new technologies. Many of our competitors are significantly larger than us and have greater financial, technical, research, marketing, sales, distribution and other resources than us. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more effective or commercially attractive than any that are being developed or marketed by us, or that such competitors will not succeed in obtaining regulatory approval, or introducing or commercializing any such products, prior to us. Such developments could have a material adverse

effect on our business, financial condition and results of operations. Also, even if we are able to compete successfully, there can be no assurance that we could do so in a profitable manner.

We are dependent on outside suppliers for all of our manufacturing supplies.

We rely on outside suppliers for all of our manufacturing supplies, parts and components. Although we believe we could develop alternative sources of supply for most of these components within a reasonable period of time, there can be no assurance that, in the future, our current or alternative sources will be able to meet all of our demands on a timely basis. Unavailability of necessary components could require us to re-engineer our products to accommodate available substitutions, which could increase costs to us and/or have a material adverse effect on manufacturing schedules, products performance and market acceptance. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products. We might not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all. If we fail to obtain a supplier for the components of our products, our operations could be disrupted.

Our investment in SAVSU may be adversely impacted by the failure of SAVSU.

We own an equity interest in SAVSU, formerly referred to as the biologistex joint venture, and are a party to a revenue share agreement with SAVSU based on gross sales from customers directly obtained by BioLife from the sale of evo product in the regenerative medicine market. We only have limited control over management decisions, accordingly, our ability to generate revenue from SAVSU or profit from SAVSU will be largely dependent on the current management of SAVSU. SAVSU faces all of the inherent risks associated with the development, marketing and operation of a new product line. In addition, we face the risk that SAVSU will not be able to fulfill product orders based on our sales effort. If SAVSU fails to fulfill its obligations due to strategic business interests, financial condition or otherwise, SAVSU may be required to raise additional capital, which will dilute our ownership, or SAVSU may not be able to continue its operations, in which case we may suffer losses.

Our success will depend on our ability to attract and retain key personnel.

In order to execute our business plan, we must attract, retain and motivate highly qualified managerial, scientific, manufacturing, and sales personnel. If we fail to attract and retain skilled scientific and sales personnel, our sales efforts will be hindered. Our future success depends to a significant degree upon the continued services of key scientific and technical personnel. If we do not attract and retain qualified personnel we will not be able to achieve our growth objectives.

If we were to be successfully sued related to our products, operations or other activities, we could face substantial liabilities that may exceed our resources.

We may be held liable if any of our products or operations cause injury or death. We are subject to certain litigation described under “Item 3. Legal Proceedings”, and may also face other types of litigation, including those related to alleged breaches of contract or applicable laws or of our duties to third parties. We currently maintain commercial general and umbrella liability policies and a product liability insurance policy. When necessary for our products, we intend to obtain additional product liability insurance. Insurance coverage may be prohibitively expensive, may not fully cover potential liabilities or may not be available in the future. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products. If we were to be sued for any injury caused by or associated with our products or operations or in connection with other matters, or if our existing litigation proceeds, the litigation could consume substantial time and attention of our management, and the resulting liability could have a material adverse effect on us.

Regulatory or other difficulties in manufacturing could have an adverse effect upon our expenses and our product revenues.

We currently manufacture all of our biopreservation media products. The manufacture of these products is difficult, complex and highly regulated. To support our current and prospective clinical customers, we intend to comply with cGMP in the manufacture of our products. Our ability to adequately and in a timely manner manufacture and supply our biopreservation media products is dependent on the uninterrupted and efficient operation of our facilities and those of third-parties producing supplies upon which we rely in our manufacturing. The manufacture of our products may be impacted by:

- availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;
- the ongoing capacity of our facilities;
- our ability to comply with regulatory requirements, including our ability to comply with cGMP;
- inclement weather and natural disasters;
- changes in forecasts of future demand for product components;
- potential facility contamination by microorganisms or viruses;
- updating of manufacturing specifications; and
- product quality success rates and yields.

If efficient manufacture and supply of our products is interrupted, we may experience delayed shipments or supply constraints. If we are at any time unable to provide an uninterrupted supply of our products to customers, our customers may be unable to supply their end-products incorporating our products to their patients and other customers, which could materially and adversely affect our product sales and results of operations.

We are registered with FDA as a contract manufacturer. Our contract-manufacturing customers may require us to comply with cGMP requirements and may audit our compliance with cGMP standards. If a customer finds us to be out of compliance with cGMP standards, this could have a material adverse effect on our ability to retain and attract

contract manufacturing customers.

If we become subject to additional regulatory requirements, the manufacture and sale of our products may be delayed or prevented, or we may become subject to increased expenses.

None of our products are subject to FDA or other regulatory approvals. In particular, we are not required to sponsor formal prospective, controlled clinical-trials in order to establish safety and efficacy. However, there can be no assurance that we will not be required to obtain approval from the FDA, or foreign regulatory authorities, as applicable, prior to marketing any of our products in the future. Any such requirements could delay or prevent the sale of our products, or may subject us to additional expenses.

We may be adversely affected if we violate privacy and security regulations or suffer a data breach.

Federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the unauthorized use and disclosure of such information. In particular, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing privacy, security, and breach notification regulations (collectively, HIPAA Standards), govern the use and disclosure of protected health information by “covered entities,” which are healthcare providers that submit electronic claims, health plans and healthcare clearinghouses, as well as their “business associates” and their subcontractors. Our employee health benefit plans are considered “covered entities” and, therefore, are subject to the HIPAA Standards.

We may be adversely affected if our internal control over financial reporting fails or is circumvented.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. We are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting, but as a smaller reporting company we are exempt from the requirement to have our independent accountants attest to our internal control over financial reporting. If it were to be determined that our internal control over financial reporting is not effective, such shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively affect the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding. The effect of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board and our

board committees and as executive officers.

Risks Related to Our Intellectual Property

Expiration of our patents may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our products have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. In some of the larger economic territories, such as the United States and Europe, patent term extension/restoration may be available. We cannot, however, be certain that an extension will be granted or, if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U.S. and non-U.S. patents.

US Patent 6,045,990, which provides patent coverage relating to HypoThermosol® FRS, will expire in April 2019, and its foreign patent counterparts will expire in July 2019, reducing the barrier to entry for competition for this product, which may materially affect the pricing of HypoThermosol® FRS and our ability to retain market share. We may file extensions for this patent. We hold various trade secrets and other confidential know-how related to the manufacturing and testing of our products which limit our exposure upon the expiration of US patent 6,045,990.

Our proprietary rights may not adequately protect our technologies and products.

Our commercial success will depend on our ability to obtain patents and/or regulatory exclusivity and maintain adequate protection for our technologies and products in the United States and other countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We intend to apply for additional patents covering both our technologies and products, as we deem appropriate. We may, however, fail to apply for patents on important technologies or products in a timely fashion, if at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, the patent positions of life science industry companies are highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty. In addition, we cannot guarantee that:

we were the first to make the inventions covered by each of our issued patents and pending patent applications;
we were the first to file patent applications for these inventions;
others will not independently develop similar or alternative technologies or duplicate any of our technologies;
any of our pending patent applications will result in issued patents;
any of our patents will be valid or enforceable;
any patents issued to us will provide us with any competitive advantages, or will not be challenged by third parties;
and
we will develop additional proprietary technologies that are patentable, or the patents of others will not have an adverse effect on our business.

The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends on many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. Our ability to maintain and solidify our proprietary position for our products will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated, unenforceable or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. We also rely on trade secrets to protect some of our technology, especially where it is believed that patent protection is inappropriate or unobtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

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

Filing, prosecuting and defending patents on all of our products in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products. These products may compete with our products, and may not be covered by any patent claims or other intellectual property rights.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

If we fail to protect our intellectual property rights, our competitors may take advantage of our ideas and compete directly against us.

Our success will depend to a significant degree on our ability to secure and protect intellectual property rights and enforce patent and trademark protections relating to our technology. While we believe that the protection of patents and trademarks is important to our business, we also rely on a combination of copyright, trade secret, nondisclosure and confidentiality agreements, know-how and continuing technological innovation to maintain our competitive position. From time to time, litigation may be advisable to protect our intellectual property position. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any litigation in this regard could be costly, and it is possible that we will not have sufficient resources to fully pursue litigation or to protect our intellectual property rights. This could result in the rejection or invalidation of our existing and future patents. Any adverse outcome in litigation relating to the validity of our patents, or any failure to pursue litigation or otherwise to protect our patent position, could materially harm our business and financial condition. In addition, confidentiality agreements with our employees, consultants, customers, and key vendors may not prevent the unauthorized disclosure or use of our technology. It is possible that these agreements will be breached or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Enforcement of these agreements may be costly and time consuming. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are invalid or unenforceable and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity or enforceability of these patents is upheld, the court will refuse to stop the other party on the grounds that such other party's activities do not infringe our rights.

If we wish to use the technology claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity or enforceability of the patents or incur the risk of litigation in the event that the owner asserts that we infringed its patents. The failure to obtain a license to technology or the failure to challenge an issued patent that we may require to discover, develop or commercialize our products may have a material adverse effect on us.

If a third party asserts that we infringed its patents or other proprietary rights, we could face a number of risks that could seriously harm our results of operations, financial condition and competitive position, including:

- patent infringement and other intellectual property claims, which would be costly and time consuming to defend, whether or not the claims have merit, and which could delay a product and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that our product or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our technologies unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; and
- if a license is available from a third party, we may have to pay substantial royalties or lump-sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license.

The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent, and/or that the patent claims are invalid, and/or that the patent is unenforceable and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

U.S. patent laws as well as the laws of some foreign jurisdictions provide for provisional rights in published patent applications beginning on the date of publication, including the right to obtain reasonable royalties, if a patent subsequently issues and certain other conditions are met.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology.

Patent applications filed by third parties that cover technology similar to ours may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party files a U.S. patent application on an invention similar to ours, we may elect to participate in or be drawn into an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. We cannot predict whether third parties will assert these claims against us, or whether those claims will harm our business. If we are forced to defend against these claims, whether they are with or without any merit and whether they are resolved in favor of or against us, we may face costly litigation and diversion of management's attention and resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, if at all, which could seriously harm our business or financial condition.

Risks Related to our Common Stock and Other Securities

The market for our common stock is limited and our stock price is volatile.

Our common stock, traded on the NASDAQ Capital Market, has historically traded at low average daily volumes, resulting in a limited market for the purchase and sale of our common stock.

The market prices of many publicly traded companies, including emerging companies in the life sciences industry, have been, and can be expected to be, highly volatile. The future market price of our common stock could be significantly impacted by numerous factors, including, but not limited to:

- Future sales of our common stock or other fundraising events;
- Sales of our common stock by existing shareholders;
- Changes in our capital structure, including stock splits or reverse stock splits;
- Announcements of technological innovations for new commercial products by our present or potential competitors;
- Developments concerning proprietary rights;
- Adverse results in our field or with clinical tests of our products in customer applications;
- Adverse litigation;
- Unfavorable legislation or regulatory decisions;
- Public concerns regarding our products;
- Variations in quarterly operating results;
- General trends in the health care industry; and
- Other factors outside of our control.

A significant percentage of our outstanding common stock is held by two stockholders, and these stockholders therefore have significant influence on us and our corporate actions.

As of December 31, 2016, two of our existing stockholders, Taurus4757 GmbH (“Taurus”) and WAVI Holdings AG (“WAVI”), beneficially owned, collectively, approximately 61.9% of our outstanding shares. Taurus and WAVI were previously secured lenders to our Company, and the chairman of Taurus, Mr. Girschweiler, is a member of our board. Accordingly, these stockholders have had, and will continue to have, significant influence in determining the outcome of any corporate transaction or other matter submitted to the stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions. In addition, without the consent of these stockholders, we could be prevented from entering into transactions that could be beneficial to us. We also have an outstanding note payable to WAVI for \$3.0 million as of December 31, 2016. Subsequent to year end, on March 1, 2017, we drew down the remaining \$1.0 million Advance related to the credit facility.

We may be at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following an extraordinary corporate action or a decline in the market price of its securities. This risk is especially relevant for us because our stock price and those of other biotechnology and life sciences companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business. We do maintain insurance, but the coverage may not be sufficient and may not be available in all instances.

Anti-takeover provisions in our charter documents and under Delaware law could make a third-party acquisition of us difficult.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions include the ability of our board to designate the terms of and issue new series of preferred stock without stockholder approval and to amend our bylaws without stockholder approval. Further, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless certain specific requirements are met as set forth in Section 203. Collectively, these provisions could make a third-party acquisition of us difficult or could discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

Future sales or the potential for future sales of our securities in the public markets may cause the trading price of our common stock to decline and could impair our ability to raise capital through future equity offerings.

Sales of a substantial number of shares of our common stock or other securities in the public markets, or the perception that these sales may occur, could cause the market price of our common stock or other securities to decline and could materially impair our ability to raise capital through the sale of additional securities. We have a substantial number of warrants exercisable to purchase shares of common stock outstanding. Many of the shares of common stock issuable upon exercise of those warrants will be freely tradable. We have agreed to use our best efforts to keep a registration statement registering the issuance and resale of many such shares effective during the term of the warrants. In addition, we have a significant number of shares of our common stock reserved for issuance pursuant to other outstanding options and rights. If such shares are issued upon exercise of options, warrants or other rights, or if we issue additional securities in a public offering or a private placement, such sales or any resales of such securities could further adversely affect the market price of our common stock. The sale of a large number of shares of our common stock or other securities also might make it more difficult for us to sell equity or equity-related securities in the future at a time and at the prices that we deem appropriate.

We do not anticipate declaring any cash dividends on our common stock.

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and earnings for use in the operation and expansion of our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 30,000 square feet of property being used in current operations in our Bothell, Washington principal location which contains office, manufacturing, storage and laboratory facilities.

We consider the facilities to be in a condition suitable for their current uses. Because of anticipated growth in the business and due to the increasing requirements of customers or regulatory agencies, we may need to acquire additional space or upgrade and enhance existing space prior to the expiry of the lease in 2021. We believe that adequate facilities will be available upon the conclusion of our leases.

All of our products and services are manufactured or provided from our Bothell, Washington facility.

Additional information regarding our properties is contained in Note 10 to the Financial Statements included in this Annual Report on Form 10-K.

ITEM 3. LEGAL PROCEEDINGS

In 2007, a number of lawsuits were brought against the Company by former employees as follows:

On February 7, 2007, Kristi Snyder, a former employee of the Company filed a complaint in the New York State Supreme Court, County of Broome, against us alleging a breach of an employment agreement and seeking damages of up to \$300,000 plus attorneys' fees.

On April 6, 2007, we were served with a complaint filed by John G. Baust, our former Chief Executive Officer and President, and thereafter, until January 8, 2007, the Chairman, Sr. Vice President and Chief Scientific Officer, in the New York State Supreme Court, County of Tioga, against us seeking, among other things, damages under his employment agreement to be determined upon trial of the action plus attorneys' fees, a declaratory judgment that he did not breach his fiduciary duties to the Company, and that his covenant not to compete is void as against public policy or unenforceable as a matter of law, and to enjoin us from commencing an action against him in Delaware courts seeking damages for breaches of his fiduciary obligations to us. The parties have engaged in extensive motion practice. By decision of December 18, 2009, Justice Tait rejected Plaintiff Baust's efforts to obtain partial summary judgment.

On June 15, 2007, BioLife filed a lawsuit in the State of New York Supreme Court, County of Tioga, against Cell Preservation Services, Inc. ("CPSI") and Coraegis Bioinnovations, Inc. ("Coraegis"), both of which are owned and controlled by John M. Baust, a former employee of the Company. John M. Baust is the son of John G. Baust; both John G. Baust's and John M. Baust's employment with BioLife was terminated on January 8, 2007. On approximately August 21, 2007, CPSI filed six counterclaims and Coraegis filed one counterclaim against BioLife. Four of the six counterclaims brought by CPSI were based on breach of contract, one was based on BioLife's alleged negligence, and one was based on BioLife's alleged malicious institution and maintenance of the lawsuit against CPSI and Coraegis. Coraegis joined in the last counterclaim against BioLife, which sought both compensatory and punitive

damages.

On December 4, 2007, John M. Baust, the son of John G. Baust, filed a complaint in the New York State Supreme Court, County of Tioga, against the Company and Michael Rice, our Chief Executive Officer and former chairman of the board, alleging, among other things, a breach of an employment agreement and defamation of character and seeking damages against us in excess of \$300,000 plus attorney's fees.

These legal proceedings, which were filed almost 10 years ago, are currently in discovery. We will vigorously defend our position related to these legal proceedings.

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

Price Range of Common Stock

Our common stock is traded on the NASDAQ Capital Market exchange under the ticker symbol "BLFS."

As of February 14, 2017, there were approximately 405 holders of record of our common stock. We have never paid cash dividends on our common stock and do not anticipate that any cash dividends will be paid in the foreseeable future.

The following table sets forth the range of high and low quarterly closing sales prices of our common stock for the periods indicated:

	High	Low
Year ended December 31, 2016		
4th Quarter	\$1.83	\$1.45
3rd Quarter	2.37	1.57
2nd Quarter	1.96	1.47
1st Quarter	2.10	1.57
Year ended December 31, 2015		
4th Quarter	\$2.48	\$2.04
3rd Quarter	2.75	1.96
2nd Quarter	2.79	1.50
1st Quarter	2.34	1.61

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2016 relating to all of our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options (in thousands)	Weighted Average exercise price of outstanding options	Number of securities remaining available for future issuance (in thousands)
Equity compensation plans approved by security holders	1,842	\$ 1.96	1,634
Equity compensation plans not approved by security holders (1)	672	\$ 1.28	—
Total	2,514	\$ 1.78	1,634

(1) Represents shares of common stock issuable pursuant to non-plan stock option agreements entered into prior to the adoption of our 2013 Performance Incentive Plan. Prior to the adoption of our 2013 Performance Incentive Plan, we granted certain individuals stock options pursuant to stock option agreements that were not issued under a stockholder-approved plan. Each agreement entitles the holder to purchase from us a fixed number of shares of common stock at a fixed purchase price per share for a fixed period of time, which may not exceed ten (10) years. The

specific terms and conditions of each option, including when the right to exercise the option vests, the number of shares subject to the option, the exercise price per share, the method of exercise, exercisability following termination, disability and death, and adjustments upon stock splits, combinations, mergers, consolidation and like events are specified in each agreement. In the event of a liquidation of the Company, or a merger, reorganization, or consolidation of the Company with any other corporation in which we are not the surviving corporation or we become a wholly-owned subsidiary of another corporation, any unexercised options shall be deemed canceled unless the surviving corporation elects to assume the options or to issue substitute options in place thereof. In the event of the forgoing, the holder will have the right to exercise the option during a ten-day period immediately prior to such liquidation, merger, or consolidation.

Recent Sales of Unregistered Securities

On August 8, 2016, the Company issued 142,856 shares of common stock of the Company pursuant to the exercise of outstanding warrants at an exercise price of \$0.84 per share.

On October 17, 2016, the Company issued Life Sci Advisors 84,375 shares of our common stock as compensation for services.

The foregoing transactions were exempt from registration pursuant to Section 4(a)(2) of the Securities Act.

Issuer Repurchases of Equity Securities

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Forward-Looking Statements

This Annual Report on Form 10-K contains “forward-looking statements”. These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, revenues, costs and expenses, interest rates, outcome of contingencies, business strategies, regulatory filings and requirements, performance and market acceptance of our products, the estimated potential size of markets, capital requirements, the terms of any capital financing agreements and other statements that are not historical facts. You can find many of these statements by looking for words like “believes,” “expects,” “anticipates,” “estimates,” “may,” “should,” “will,” “could,” “intend,” or similar expressions in this Annual Report on Form 10-K. We intend that such forward-looking statements be subject to the safe harbors created thereby.

These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include those discussed under “Risk Factors,” as well as those discussed elsewhere in the Annual Report on Form 10-K.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K or, in the case of documents referred to or incorporated by reference, the date of those documents.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Recent Developments

Restructuring of biologistex Joint Venture

Contribution Agreement:

On December 31, 2016, we entered into a Contribution Agreement (the “Contribution Agreement”) with Savsu Technologies, LLC, a Delaware limited liability company (“STLLC”) and biologistex CCM, LLC, a Delaware limited liability company (“biologistex” or “SAVSU”). The closing of the transactions contemplated by the Contribution Agreement occurred on December 31, 2016 (the “Closing Date”), simultaneously with the entrance into the Contribution Agreement.

Biologistex is a joint venture entered into by the Company and STLLC on or about September 29, 2014 for the purpose of acquiring, developing, maintaining, owning, operating, leasing and selling an integrated platform of a cloud-based information service and precision thermal shipping products based on STLLC’s next generation EVO

smart container shipment platform. Prior to the Closing Date, biologistex was owned 52% by the Company and 48% by STLLC.

Pursuant to the Contribution Agreement, STLLC contributed certain of its patent and trademark rights, personal property and related contracts to biologistex in exchange for the issuance from biologistex to STLLC of an additional 7% membership interest in biologistex, so that upon the closing thereunder, STLLC owned 55% of biologistex and the Company owned 45% of biologistex. Other than liabilities for obligations to be performed pursuant to the contracts which were contributed to biologistex by STLLC, biologistex did not assume any liabilities of STLLC in connection with the Contribution Agreement.

In connection with the Contribution Agreement, we (i) contributed to biologistex as a capital contribution outstanding loans owed by biologistex to the Company in the aggregate amount of \$6,557,776 and (ii) terminated any requirement which the Company may have had to purchase any additional inventory from STLLC or contribute any inventory to biologistex.

In addition, pursuant to the Contribution Agreement, the Company agreed that it will transfer to STLLC (i) on the first anniversary of the Closing Date, 11.11% of its membership interest in biologistex owned as of the Closing Date, such that on the first anniversary of the Closing Date the Company will own 40% of biologistex (assuming that there are no other issuances or transfers of biologistex equity interests after the Closing Date), and (ii) on the second anniversary of the Closing Date, 33.33% of its membership interest in biologistex owned as of the Closing Date, such that on the second anniversary of the Closing Date the Company will own 25% of biologistex (assuming that there are no other issuances or transfers of biologistex equity interests after the Closing Date). However, if certain liquidity events, such as change in control or initial public offering, occur with respect to biologistex between the second anniversary and third anniversary of the Closing Date, STLLC will pay to the Company an amount of the net proceeds therefrom as if the Company had only transferred to STLLC on the second anniversary of the Closing Date an amount of membership interests in biologistex equal to 11.11% of the Company's membership interest in biologistex owned as of the Closing Date, such that the Company would be treated for such purposes as if it owned 35% of biologistex (assuming that there are no other issuances or transfers of biologistex equity interests after the Closing Date).

Restructuring Amended and Restated Biologistex Operating Agreement:

In connection with the Contribution Agreement, on the Closing Date, the Company, STLLC and biologistex entered into an Amended and Restated Operating Agreement of biologistex (the "Amended JV Operating Agreement"), amending and restating the limited liability company operating agreement of biologistex initially entered into by such parties on September 29, 2014. The Amended JV Operating Agreement provides that as of the Closing Date, biologistex's membership interests are owned 45% by the Company and 55% by STLLC.

Pursuant to the Amended JV Operating Agreement, biologistex will be managed by a three member management committee, initially consisting of Dana Barnard and Bruce McCormick, both designated by STLLC, and Michael

Rice, designated by the Company (the “Management Committee”). Certain fundamental actions by the Management Committee require approval of members holding at least 60% of the membership interests of biologistex (including both STLLC and the Company). Biologistex’s membership interests are also subject to transfer restrictions in the Amended JV Operating Agreement, including drag-along and tag-along rights.

Services Agreement:

In connection with the Contribution Agreement, on the Closing Date, the Company and biologistex entered into a Services Agreement (the “Services Agreement”) whereby the Company will provide certain sales and marketing services to biologistex in exchange for payment by biologistex to the Company of (i) a cash fee for the first year of the contract only in the amount of \$100,000, (ii) a commission (the “Commissions”), paid quarterly, equal to 20% of the gross revenues of biologistex from any customer account resulting from sales activity or a marketing lead generated by the Company (“BioLife Customer Revenue”), and (iii) reimbursement of pre-approved reasonable direct costs and expenses incurred by the Company by or on behalf of biologistex in connection with the services. After the third anniversary of the Closing Date, the Commissions will decrease to 10% of the BioLife Customer Revenue.

The Services Agreement continues until terminated by either party. The Services Agreement can be terminated (a) by mutual agreement, (b) beginning 90 days prior to the third anniversary of the Closing Date, by either party with 90 days’ notice, (c) by biologistex with 90 days’ notice if (i) there are certain changes to the management of the Company or its subsidiaries, (ii) the Company transfers all of its equity interests in biologistex or (iii) there is a change of control of the Company, (d) by the Company with 90 days’ notice if (i) STLLC transfers all of its equity interest in biologistex or (ii) there is a change of control of STLLC or (e) by either party (i) for a material breach of the Services Agreement by the other party that is not cured within 30 days or (ii) if the other party is subject to certain bankruptcy/insolvency events. If the Services Agreement is terminated by biologistex under items (b) or (c) of the preceding sentence, or by the Company under items (d) or (e) of the preceding sentence, the Company will be entitled to receive Commissions equal to 10% of the BioLife Customer Revenue during the 12 month period following such termination.

Credit Facility

On May 12, 2016, we entered into a \$4 million unsecured credit facility (the “Original Note”) with our largest shareholder, WAVI. Under the related commitment letter, WAVI has agreed to make a series of four \$1 million advances on June 1, 2016, September 1, 2016, December 1, 2016 and March 1, 2017. The Original Note is unsecured, carries an annual interest rate of 10%, and matures on June 1, 2017. In addition, we have agreed not to permit any liens on our assets, subject to certain exceptions. As partial compensation for WAVI entering into the commitment letter, we issued WAVI a detachable common stock purchase warrant exercisable to purchase up to 550,000 shares of common stock at an exercise price of \$1.75 per share. The warrant expires on May 12, 2021.

Amendment of Credit Facility

On January 9, 2017, the Company issued an amended and restated promissory note (the “Note”) to WAVI. The Note, which amends and restates the Original Note, extends the maturity date of the Note from June 1, 2017 to June 1, 2022 and includes a long-term repayment schedule as follows: beginning September 1, 2017 to June 1, 2018, the Company will make four quarterly cash interest only payments of \$106,250 and from September 1, 2018 through June 1, 2022, the Company will make quarterly cash principal payments of \$265,625, in addition to ongoing interest payments. All other terms of the Original Note, including the \$4 million principal amount of the Note and the 10% per annum interest rate on the Original Note, remain the same.

Overview

Management’s discussion and analysis provides additional insight into the Company and is provided as a supplement to, and should be read in conjunction with, our audited financial statements and accompanying footnotes thereto.

We strive to be the leading provider of biopreservation tools for cells, tissues, and organs; to facilitate basic and applied research and commercialization of new therapies by maintaining the health and function of biologic source material and finished products during manufacturing, distribution and clinical administration.

Results of Operations

Overview for 2016

In 2016, we reported financial results that were consistent with the continued execution of our long-term plans. We believe we are the market leader for pre-formulated, clinical grade biopreservation media products. Our patented biopreservation media products are formulated to reduce preservation-induced, delayed-onset cell damage and death. Our platform enabling technology provides our customers significant shelf life extension of biologic source material and final cell products, and also greatly improved post-preservation cell, tissue, and organ viability and function. Our products continue to be widely adopted by this segment. We believe that our products have been incorporated in over 250 applications for new cell and tissue-based regenerative medicine products and therapies.

We continue to implement strategies that will increase awareness of the need for improved biopreservation and, through SAVSU, cold chain logistics monitoring and tracking.

Our strategies to achieve this objective include:

Utilize Existing Biopreservation Media Sales, Distribution and Manufacturing Infrastructure. We have developed a direct sales and distribution network for our products which we utilize to expand sales to existing customers and to gain additional customers. We believe that our products have been incorporated into over 250 applications for new cell and tissue-based regenerative medicine products and therapies. A significant number involve CAR-T cells and other types of T cells and mesenchymal stem cells targeting blood cancers, solid tumors and other leading causes of death and disability. In 2016, key product adoption announcements included:

TissueGene, Inc., specializing in regenerative therapies for the treatment of various orthopedic diseases, signed a 10-year supply agreement with for CryoStor® use in Invossa™ Osteoarthritis Cell-Mediated Gene Therapy. TissueGene will be entering a Phase 3 clinical trial for Invossa, an allogeneic cell therapy for osteoarthritis of the knee.

Promethera Biosciences, a clinical stage biopharmaceutical company and the global leader in cell therapy and regenerative medicine for the treatment of inborn and acquired liver diseases with no effective therapeutic cure, has embedded the Company's clinical grade CryoStor® cryopreservation freeze media into its manufacturing process for HepaStem, a cell-based treatment targeting several metabolic liver disorders such as hemophilia and large clinical indications including acute or chronic liver failure (ACLF), fibrosis and nonalcoholic steatohepatitis (NASH).

Kolon Life Science, a developer of innovative cell and gene therapies including Invossa, incorporated CryoStor® cryopreservation freeze media into its manufacturing process for Invossa, a cell-mediated gene therapy for knee osteoarthritis to be marketed by Kolon Life Science.

Bellicum Pharmaceuticals, a clinical stage biopharmaceutical company focused on discovering and developing first- and best-in-class cellular immunotherapies for hematological cancers and solid tumors, as well as orphan inherited blood diseases, signed a 10-year supply agreement for CryoStor® for several cellular immunotherapies targeting blood cancers and solid tumors.

Cook MyoSite, a subsidiary of the Cook Group, developer and subsequent commercialization of technology related to the collection, selection, and expansion of human skeletal muscle cells for the treatment of a variety of disorders, embedded BioLife media products into a Phase III trial for an autologous cell therapy for treatment of female stress urinary incontinence.

Kite Pharma, a leading developer of chimeric antigen receptor (CAR) and T cell receptor (TCR) products for various cancers, signed a 10-year supply agreement for CryoStor® for use in CAR T cell therapies.

Continuously show the scientific results of using our media products in cell and tissue storage. We are continuously testing our products internally and showing the benefits of using our media products to the scientific community. Additionally, we communicate the results of independent third party testing of our media products.

External studies: selected articles published in 2016 showing results from using our media products include:

The article, “Successful expansion of functional and stable regulatory T Cells for immunotherapy in liver transplantation”, was published in the journal *Oncotarget* and completed at MRC Centre for Transplantation, Division of Transplantation Immunology and Mucosal Biology, King's College London, Guy's Hospital, Great Maze Pond, London, and the Institute of Liver Studies, King's College Hospital, Denmark Hill, London. In this study, Treg cells were frozen in CryoStor, then thawed and assessed for viability and suppressive function. The authors concluded:

We report the enrichment of a pure, stable population of Tregs (>95% CD4+CD25+FOXP3+), reaching adequate numbers for their clinical application.

Our protocol proved successful in influencing the expansion of superior functional Tregs, as compared to freshly isolated cells, whilst also preventing their conversion to Th17 cells under pro-inflammatory conditions.

We conclude with the manufacture of the final Treg product in the clinical research facility (CRF), a prerequisite for the clinical application of these cells.

The article, “Widespread Myocardial Delivery of Heart-Derived Stem Cells by Nonocclusive Triple-Vessel Intracoronary Infusion in Porcine Ischemic Cardiomyopathy: Superior Attenuation of Adverse Remodeling Documented by Magnetic Resonance Imaging and Histology, a study using CryoStor” was completed at Cedars-Sinai Heart Institute in Los Angeles, and Keio University School of Medicine in Tokyo, Japan. The authors concluded:

We have addressed a number of issues that are central to the delivery of cell therapy (safety and efficacy of stop-flow versus continuous-flow, and of single- versus triple-vessel infusion).

Our findings give reason to believe that global cell infusion may be a promising translational tool, particularly to treat generalized cardiac disorders.

These data provide preclinical validation for nonocclusive multi-vessel cell delivery, as is being utilized in the phase 2a DYNAMIC (Dilated cardiomyopathy Intervention with Allogeneic Myocardially regenerative Cells) trial of allogeneic CDCs in patients with ischemic and non-ischemic heart failure.

Financial Performance Summary for 2016

We grew our revenue 28% over 2015. This increase was driven by a 56% increase in revenue from the regenerative medicine market. We also drove more sales through our distributors, with an increase of 30% in revenue from distributors in 2016 compared to 2015.

Gross margin in 2016 was 58%, compared to 59% in 2015, the margin was slightly lower due to higher overhead costs and larger write off of expired finished goods, offset by underutilization adjustments in 2015.

Our 2016 consolidated operating expenses were \$9.6 million compared to \$8.8 million in 2015. The increase in expense is primarily the result of increased stock based compensation and biologistex development and marketing expenses.

Our 2016 consolidated net loss was \$8.0 million and net loss attributable to BioLife was \$6.9 million. This is compared to a consolidated net loss of \$5.0 million in 2015, of which \$4.2 million was attributable to BioLife. The increase in the loss is primarily the result of a loss on deconsolidation related to the restructuring of the biologistex joint venture as well as increased headcount throughout most of 2016 and spending related to development and marketing activities related to the biologistex joint venture.

Our cash and cash equivalents balance was \$1.4 million at December 31, 2016 with an outstanding note payable of \$3.0 million compared to \$3.8 million in cash, cash equivalents and short term investments at December 31, 2015. Our cash burn decreased in 2016 compared to 2015 primarily as the result of increased cash receipts from higher sales, decreased spending on software development and decreased participation fees to STLLC; partially offset by increases in employee expenses, including severance.

Comparison of Annual Results of Operations

Percentage comparisons have been omitted within the following table where they are not considered meaningful.

Revenue and Gross Margin

Our revenue and gross margin for the years ended December 31, 2016 and 2015 were as follows (in thousands):

	Year Ended December 31,		% Change	
	2016	2015		
Product revenue				
Core product sales	\$8,227	\$6,361	29	%
Contract manufacturing services	—	88	(100	%)
Total revenue	8,227	6,449	28	%
Cost of sales	3,448	2,635	31	%
Gross profit	\$4,779	\$3,814	25	%
Gross margin %	58.1 %	59.1 %		

Core Product Sales. Our core products are sold through both direct and indirect channels to the customers in the biobanking, drug discovery, and regenerative medicine markets. Sales to our core customers in 2016 increased compared to 2015 due to increases in volume and a higher average selling price per liter. The increase was primarily in sales to our regenerative medicine customers and distributors, which increased 56% and 30%, respectively, in 2016 compared to 2015. Revenue from the regenerative medicine market and our distributors should increase in the next two to five years as some customers receive regulatory and marketing approvals for their clinical cell and tissue-based products.

Contract Manufacturing Services. In 2016, we recorded \$0 in contract manufacturing revenue. In 2015, we recorded revenue from one contract manufacturing customer of \$0.1 million. The contract with this customer was terminated in May 2015.

Cost of Sales. Cost of sales consists of raw materials, labor and overhead expenses. Cost of sales in 2016 increased compared to 2015 due to increased sales volume, higher raw material costs and write off of finished goods; partially offset by a net overutilization adjustment in 2016, whereas in 2015, we had an underutilization adjustment.

Gross Margin. Gross margin as a percentage of revenue decreased slightly to 58.1% in 2016 compared to 59.1% in 2015. Gross margin as a percentage of revenue decreased slightly in 2016, due to higher overhead costs and expired inventory adjustments.

Revenue Concentration. In 2016 and 2015, we derived approximately 12% and 10%, respectively, of our revenue from our relationship with one distributor of our products. Revenue from customers located in foreign countries represented 17% and 21% of total revenue during the years ended December 31, 2016 and 2015, respectively. All sales to foreign customers are denominated in United States dollars.

Operating Expenses

Our operating expenses for the years ended December 31, 2016 and 2015 were as follows (in thousands):

	Year Ended December 31,		% Change	
	2016	2015		
Operating Expenses:				
Research and development	\$2,028	\$1,379	47	%
Sales and marketing	3,010	2,584	16	%
General and administrative	4,592	4,868	(6	%)
Operating Expenses	9,630	8,831	9	%
% of revenue	117	% 137	%	

Research and Development. Research and development expenses consist primarily of salaries and other personnel-related expenses, consulting and other outside services, laboratory supplies, and other costs. We expense all research and development costs as incurred with the exception of the costs associated with the development of customized internal-use software systems, which are capitalized. Research and development expenses for 2016 increased compared to 2015 due primarily to biologistex development costs, media development costs and share-based compensation expense. In 2016, we capitalized \$0.7 million in costs associated with the development of our biologistex web application.

Sales and Marketing. Sales and marketing expenses consist primarily of salaries, trade association sponsorships, and other personnel-related expenses, consulting, trade shows and advertising. The increase in sales and marketing expenses in 2016 compared to 2015 was primarily due to biologistex personnel costs, share-based compensation expense and marketing costs related to biologistex, partially offset by lower recruitment costs.

General and Administrative Expenses. General and administrative expenses consist primarily of personnel-related expenses, non-cash stock-based compensation for administrative personnel and members of the board of directors, professional fees, such as accounting and legal, corporate insurance, and participation fees to STLLC related to the biologistex joint venture. The decrease in general and administrative expenses in 2016 compared to 2015 was primarily due to joint venture participation fees of \$0 in 2016 compared to approximately \$0.7 million in 2015, in addition, there was a reversal of the 2015 accrued bonuses in 2016 due to a later determination to pay reduced bonuses and no bonuses accrued in 2016. Offsetting these items was an increase in general and administrative costs in 2016 compared to 2015 due to share-based compensation expense and severance payouts.

Based on the restructuring of the biologistex joint venture on December 31, 2016, we expect an annual cost reduction in operating expenses between \$1.6 million and \$2.0 million.

Other Income (Expenses)

Interest Income. We earn interest on our money market account and short-term investments.

Interest Expense. In 2016, interest expense was related to our credit facility financing arrangement entered into in May 2016.

Amortization of Deferred Financing Costs. Amortization of deferred financing costs represented the amortization of the allocated value of the detachable warrants associated with the credit facility financing arrangement entered into in May 2016.

Write off of deferred financing costs. The write off of deferred financing costs was the write off of deferred costs related to Registration Statement on Form S-3 filed with the SEC on January 8, 2016.

Loss on disposal of property and equipment. The loss on asset disposal was the disposal of property and equipment at net book value.

Loss on deconsolidation of biologistex. As a result of our Contribution Agreement with STLLC, BioLife no longer has a controlling financial interest over the biologistex JV, as defined under ASC 810, *Consolidation*, and has deconsolidated biologistex as of December 31, 2016. This resulted in a loss on deconsolidation of \$2.8 million, which includes approximately \$0.1 million in related restructuring charges. The loss on deconsolidation includes derecognizing the carrying amounts of biologistex's assets and liabilities that were previously consolidated on BioLife's consolidated balance sheet and the impact recorded to the retained interest in biologistex. Subsequent to deconsolidation, BioLife accounts for ownership in SAVSU using the equity method, which has been initially reflected at the fair value of our ownership interest on BioLife's balance sheet as of December 31, 2016. See Note 1 to the Company's Consolidated Financial Statements in Item 8 of this form 10-K for additional information.

Liquidity and Capital Resources

On December 31, 2016, we had \$1.4 million in cash and cash equivalents, compared to cash, cash equivalents and short term investments of \$3.8 million at December 31, 2015. Based on our current expectations with respect to our revenue and expenses and the final \$1.0 million Advance on the WAVI credit facility received subsequent to year end, we expect that our current level of cash and cash equivalents will be sufficient to meet our liquidity needs for the next twelve months. If our revenues do not grow as expected and if we are not able to manage expenses sufficiently, including required payment pursuant to the terms of the Note issued to WAVI, we may be required to obtain additional equity or debt financing. In addition, we currently have an S-3 registration statement filed with the SEC to potentially raise more capital.

We continue to monitor and evaluate opportunities to strengthen our balance sheet and competitive position over the long term. These actions may include acquisitions or other strategic transactions that we believe would generate significant advantages and substantially strengthen our business. The consideration we pay in such transactions may include, among other things, shares of our common stock, other equity or debt securities of our Company or cash. We may elect to seek debt or equity financing in anticipation of, or in connection with, such transactions or to fund or invest in any operations acquired thereby. We may also seek equity or debt financing opportunistically for these purposes if we believe that market conditions are conducive to obtaining such financing.

Net Cash Used In Operating Activities

During the year ended December 31, 2016, we used \$4.3 million in cash from operations, compared to \$5.0 million for the year ended December 31, 2015. Operating cash was primarily used to fund net losses.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was \$0.4 million and \$4.2 million in 2016 and 2015, respectively. The primary source of cash was proceeds from the maturity of available-for-sale securities, net of purchases. In addition, during 2016, we used \$1.1 million in cash related to the development of the biologistex software system and \$0.1 million related to purchases of equipment. In 2015, we used \$1.3 million related to the development of the biologistex software system and \$0.1 million related to purchases of equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$3.2 million and \$0.4 million in 2016 and 2015, respectively. In 2016, cash provided by financing activities was the result of borrowings of \$3.0 million from our Credit Facility Agreement and \$0.3 million from exercises of warrants and stock options. In 2016, we used \$0.1 million in cash related to costs associated with potential stock offering, including, filing an S-3 registration statement. In 2015, cash provided by financing activities was the result of proceeds from exercises of warrants and employee stock options.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate estimates, including, but not limited to those related to accounts receivable allowances, determination of fair value of share-based compensation, contingencies, income taxes, and expense accruals. We base our estimates on historical experience and on other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Share-based Compensation

We account for share-based compensation by estimating the fair value of share-based compensation using the Black-Scholes option pricing model on the date of grant. We utilize assumptions related to stock price volatility, stock option term and forfeiture rates that are based upon both historical factors as well as management's judgment. Non-cash compensation expense is recognized on a straight-line basis over the applicable requisite service period of one to four years, based on the fair value of such share-based awards on the grant date.

Income Taxes

We follow the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and on the expected future tax benefits to be derived from net operating loss carryforwards measured using current tax rates. A valuation allowance is established if it is more likely than not that some portion or all of the deferred tax assets will not be realized. We have not recorded any liabilities for uncertain tax positions or any related interest and penalties. Our tax returns are open to audit for the years ending December 31, 2013 to 2016.

Internal Use Software

We capitalize costs associated with the development of the biologistex web and mobile applications, which we consider internal-use software. Capitalization of costs began in the first quarter of 2015, when we reached the application development stage. Such capitalized costs include external direct costs utilized in developing or obtaining the applications and payroll and payroll-related expenses for employees, who are directly associated with the development of the applications. We capitalized internal use software costs of \$2.4 million and \$1.7 million at the end of 2016 and 2015, respectively. Based on the deconsolidation of biologistex, effective December 31, 2016, there is no internal use software on our balance sheet as of December 31, 2016.

Off-Balance Sheet Arrangements

As of December 31, 2016, we did not have any off-balance sheet arrangements.

Contractual Obligations

For information regarding our current contingencies and commitments, see note 10 to the consolidated financial statements included in Item 8.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders

BioLife Solutions, Inc.

Bothell, Washington

We have audited the accompanying consolidated balance sheets of BioLife Solutions, Inc. and Subsidiary ("the Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BioLife Solutions, Inc. and Subsidiary as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the consolidated financial statements, due to the restructuring of biologistex CCM, LLC ("biologistex") on December 31, 2016, the Company deconsolidated biologistex from its consolidated financial

statements and began to account for its investment in biologistex using the equity method. Accordingly, the assets and liabilities of biologistex are not included in the consolidated balance sheet of the Company as of December 31, 2016.

/S/ PETERSON SULLIVAN LLP

Seattle, Washington

March 15, 2017

BioLife Solutions, Inc.**Consolidated Balance Sheets**

	December 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	\$1,405,826	\$2,173,258
Short term investments	—	1,651,341
Accounts receivable, trade, net of allowance for doubtful accounts of \$0 at December 31, 2016 and 2015	1,193,646	929,289
Inventories	1,757,784	1,834,635
Prepaid expenses and other current assets	270,814	384,414
Total current assets	4,628,070	6,972,937
Property and equipment		
Leasehold improvements	1,284,491	1,284,491
Furniture and computer equipment	650,912	557,666
Manufacturing and other equipment	922,220	1,025,521
Subtotal	2,857,623	2,867,678
Less: Accumulated depreciation	(1,670,245)	(1,421,279)
Net property and equipment	1,187,378	1,446,399
Internal use software	—	1,698,735
Intangible asset	—	2,215,385
Investment in SAVSU	2,075,000	—
Long term deposits	36,166	36,166
Total assets	\$7,926,614	\$12,369,622
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	\$710,719	\$1,029,373
Accrued expenses and other current liabilities	116,399	146,438
Accrued compensation	175,829	419,766
Deferred rent, current portion	130,216	130,216
Total current liabilities	1,133,163	1,725,793
Promissory note payable to related party, net of discount of \$155,996 at December 31, 2016	2,844,004	—
Accrued interest, related party	97,857	—
Deferred rent, long term	685,450	784,458
Total liabilities	4,760,474	2,510,251

Commitments and Contingencies (Note 10)

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Shareholders' equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 12,863,824 and 12,448,391 shares issued and outstanding at December 31, 2016 and 2015	12,864	12,447
Additional paid-in capital	74,355,645	72,823,398
Accumulated other comprehensive loss	—	(451)
Accumulated deficit	(71,202,369)	(64,326,923)
Total BioLife Solutions, Inc. shareholders' equity	3,166,140	8,508,471
Total non-controlling interest equity	—	1,350,900
Total shareholders' equity	3,166,140	9,859,371
Total liabilities and shareholders' equity	\$7,926,614	\$12,369,622

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements

BioLife Solutions, Inc.**Consolidated Statements of Operations**

	Years Ended December 31,	
	2016	2015
Product sales	\$8,226,992	\$6,448,910
Cost of product sales	3,448,294	2,634,700
Gross profit	4,778,698	3,814,210
Operating expenses		
Research and development	2,028,465	1,378,807
Sales and marketing	3,009,537	2,583,731
General and administrative	4,592,235	4,868,801
Total operating expenses	9,630,237	8,831,339
Operating loss	(4,851,539)	(5,017,129)
Other income (expenses)		
Interest income	2,420	21,753
Interest expense, related party	(100,000)	—
Loss on deconsolidation of biologistex	(2,785,910)	—
Write off of deferred financing costs	(86,736)	—
Amortization of debt discount	(218,394)	—
Loss on disposal of property and equipment	(1,213)	—
Total other income (expenses)	(3,189,833)	21,753
Net Loss	(8,041,372)	(4,995,376)
Net Loss attributable to non-controlling interest	1,165,926	781,440
Net Loss attributable to BioLife Solutions, Inc.	\$(6,875,446)	\$(4,213,936)
Basic and diluted net loss per common share attributable to BioLife Solutions, Inc.	\$(0.54)	\$(0.35)
Basic and diluted weighted average common shares used to calculate net loss per common share	12,642,996	12,177,396

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements

BioLife Solutions, Inc.

Consolidated Statements of Comprehensive Loss

	Years Ended December	
	31,	
	2016	2016
Net Loss	\$(8,041,372)	\$(4,995,376)
Other comprehensive income		
Unrealized gain on available-for-sale investments	451	5,997
Total other comprehensive income	451	5,997
Comprehensive Loss	\$(8,040,921)	\$(4,989,379)
Comprehensive loss attributable to non-controlling interest	1,165,926	781,440
Comprehensive Loss attributable to BioLife Solutions, Inc.	\$(6,874,995)	\$(4,207,939)

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements

BioLife Solutions, Inc.**Consolidated Statements of Shareholders' Equity**

BioLife Solutions, Inc. Shareholders' Equity								
	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total BioLife Solutions, Inc. Shareholders' Equity	Non-Controlling Interest Equity	Total Shareholders' Equity
Balance, December 31, 2014	12,084,859	\$12,084	\$71,911,328	\$(6,448)	\$(60,112,987)	\$11,803,977	\$2,132,340	\$13,936,317
Stock-based compensation			511,457			511,457		511,457
Stock options/warrant exercises	363,532	363	400,613			400,976		400,976
Other comprehensive income				5,997		5,997		5,997
Net loss					(4,213,936)	(4,213,936)	(781,440)	(4,995,376)
Balance, December 31, 2015	12,448,391	12,447	72,823,398	(451)	(64,326,923)	8,508,471	1,350,900	9,859,371
Stock-based compensation			776,994			776,994		776,994
Stock options/warrant exercises	246,164	247	246,033			246,280		246,280
Stock Issued – on vested RSUs	84,894	86	(86)			—		—
Warrants Issued with Debt - WAVI			374,390			374,390		374,390
Stock Issued for Services	84,375	84	134,916			135,000		135,000
Other comprehensive income				451		451		451
							(184,974)	(184,974)

Elimination of
remaining
non-controlling
interest equity
on
deconsolidation

Net loss					(6,875,446)	(6,875,446)	(1,165,926)	(8,041,372)
Balance,								
December 31,	12,863,824	\$12,864	\$74,355,645	\$—	\$(71,202,369)	\$3,166,140	\$—	\$3,166,140
2016								

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements

BioLife Solutions, Inc.**Consolidated Statements of Cash Flows**

	Years Ended December 31,	
	2016	2015
Cash flows from operating activities		
Net loss	\$(8,041,372)	\$(4,995,376)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	368,102	343,218
Loss on disposal of property and equipment	1,213	—
Stock-based compensation expense	776,994	511,457
Stock issued for services	135,000	—
Write off of deferred financing costs	86,736	—
Amortization of debt discount	218,394	—
Loss on deconsolidation of biologistex	2,785,910	—
Amortization of deferred rent related to lease incentives	(126,997)	(126,999)
Accretion and amortization on available for sale investments	1,792	90,125
Change in operating assets and liabilities		
(Increase) Decrease in		
Accounts receivable, trade	(264,357)	(27,666)
Inventories	(290,838)	(869,411)
Prepaid expenses and other current assets	73,255	15,192
Increase (Decrease) in		
Accounts payable	233,482	194,386
Accrued compensation and other current liabilities	(410,151)	(145,419)
Accrued interest, related party	97,857	—
Deferred rent	27,989	36,632
Net cash used in operating activities	(4,326,991)	(4,973,861)
Cash flows from investing activities		
Purchase of available-for-sale investments	—	(1,409,695)
Sales/maturities of available-for-sale investments	1,650,000	7,067,000
Costs associated with internal use software development	(1,113,675)	(1,283,685)
Purchase of property and equipment	(143,533)	(134,012)
Net cash provided by investing activities	392,792	4,239,608
Cash flows from financing activities		
Proceeds from note payable to related party	3,000,000	—
Proceeds from exercise of common stock options and warrants	278,503	368,753
Deferred costs related to potential stock issuance	(111,736)	—
Net cash provided by financing activities	3,166,767	368,753
Net decrease in cash and cash equivalents	(767,432)	(365,500)

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Cash and cash equivalents - beginning of year	2,173,258	2,538,758
Cash and cash equivalents - end of year	\$1,405,826	\$2,173,258
Non-cash investing and financing activities		
Costs incurred for capitalized internal use software not paid as of year-end (amounts are included in liabilities)	\$—	\$415,050
Proceeds from issuance of common stock on exercise of common stock options not received as of year-end	\$—	\$32,223
Debt discount related to warrants	\$374,390	\$—
Deferred costs related to stock issuance not yet paid	\$26,975	\$—

The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Significant Accounting Policies

Business

BioLife Solutions, Inc. ("BioLife," "us," "we," "our," or the "Company") is a developer, manufacturer and marketer of proprietary clinical grade cell and tissue hypothermic storage and cryopreservation freeze media. Our proprietary HypoThermosol® and CryoStor® platform of solutions are highly valued in the biobanking, drug discovery, and regenerative medicine markets. Our biopreservation media products are serum-free and protein-free, fully defined, and are formulated to reduce preservation-induced cell damage and death. Our enabling technology provides commercial companies and clinical researchers significant improvement in shelf life and post-preservation viability and function of cells, tissues, and organs. Additionally, for our direct, distributor, and contract customers, we perform custom formulation, fill, and finish services.

Recent Developments

Restructuring of biologistex Joint Venture

On December 31, 2016, we entered into a Contribution Agreement (the "Contribution Agreement") with Savsu Technologies, LLC, a Delaware limited liability company ("STLLC") and biologistex CCM, LLC, a Delaware limited liability company ("biologistex" or "SAVSU"). The closing of the transactions contemplated by the Contribution Agreement occurred on December 31, 2016 (the "Closing Date"), simultaneously with the entrance into the Contribution Agreement.

Biologistex is a joint venture entered into by the Company and STLLC on or about September 29, 2014 for the purpose of acquiring, developing, maintaining, owning, operating, leasing and selling an integrated platform of a cloud-based information service and precision thermal shipping products based on STLLC's next generation EVO smart container shipment platform. Prior to the Closing Date, biologistex was owned 52% by the Company and 48% by STLLC.

Pursuant to the Contribution Agreement, STLLC contributed certain of its patent and trademark rights, personal property and related contracts to biologistex in exchange for the issuance from biologistex to STLLC of an additional 7% membership interest in biologistex, so that upon the closing thereunder, STLLC owned 55% of biologistex and the Company owned 45% of biologistex. Other than liabilities for obligations to be performed pursuant to the contracts which were contributed to biologistex by STLLC, biologistex did not assume any liabilities of STLLC in connection with the Contribution Agreement.

In connection with the Contribution Agreement, we (i) contributed to biologistex as a capital contribution outstanding loans owed by biologistex to the Company in the aggregate amount of \$6,557,776 and (ii) terminated any requirement which the Company may have had to purchase any additional inventory from STLLC or contribute any inventory to biologistex.

In addition, pursuant to the Contribution Agreement, the Company agreed that it will transfer to STLLC (i) on the first anniversary of the Closing Date, 11.11% of its membership interest in biologistex owned as of the Closing Date, such that on the first anniversary of the Closing Date the Company will own 40% of biologistex (assuming that there are no other issuances or transfers of biologistex equity interests after the Closing Date), and (ii) on the second anniversary of the Closing Date, 33.33% of its membership interest in biologistex owned as of the Closing Date, such that on the second anniversary of the Closing Date the Company will own 25% of biologistex (assuming that there are no other issuances or transfers of biologistex equity interests after the Closing Date). However, if certain liquidity events, such as change in control or initial public offering, occur with respect to biologistex between the second anniversary and third anniversary of the Closing Date, STLLC will pay to the Company an amount of the net proceeds therefrom as if the Company had only transferred to STLLC on the second anniversary of the Closing Date an amount of membership interests in biologistex equal to 11.11% of the Company's membership interest in biologistex owned as of the Closing Date, such that the Company would be treated for such purposes as if it owned 35% of biologistex (assuming that there are no other issuances or transfers of biologistex equity interests after the Closing Date).

Accounting Treatment for the Deconsolidation of biologistex:

As a result of the Contribution Agreement, we deconsolidated the biologistex joint venture from our balance sheet on December 31, 2016 and account for our investment in SAVSU using the equity method. We recognized a \$2.8 million loss on deconsolidation (including approximately \$0.1 million in related restructuring charges), which consisted of a \$2.2 million gain on derecognizing the assets, liabilities and equity of biologistex from our consolidated financial statements and a \$5.0 million loss related to the remeasurement of the retained fair value of our investment in SAVSU. We derived the fair value of our retained investment in SAVSU using level 3 measurements in the fair value hierarchy using a midpoint between a discounted cash flow analysis and a discounted price to revenues multiples. As part of the fair value analysis, we applied a range of discount rates of 30% - 50% to multiple cash flow and terminal value scenarios. An increase in discount rate would result in a decrease in fair value. In addition, we used a range of revenue multiples of 2 times revenue – 6 times revenue, which were applied to a risk adjusted revenue projection. A decrease in revenue multiple would result in a decrease in fair value.

Restructuring Amended and Restated Biologistex Operating Agreement:

In connection with the Contribution Agreement, on the Closing Date, the Company, STLLC and biologistex entered into an Amended and Restated Operating Agreement of biologistex (the “Amended JV Operating Agreement”), amending and restating the limited liability company operating agreement of biologistex initially entered into by such parties on September 29, 2014. The Amended JV Operating Agreement provides that as of the Closing Date, biologistex’s membership interests are owned 45% by the Company and 55% by STLLC.

Pursuant to the Amended JV Operating Agreement, biologistex will be managed by a three member management committee, initially consisting of Dana Barnard and Bruce McCormick, both designated by STLLC, and Michael Rice, designated by the Company (the “Management Committee”). Certain fundamental actions by the Management Committee require approval of members holding at least 60% of the membership interests of biologistex (including both STLLC and the Company). Biologistex’s membership interests are also subject to transfer restrictions in the Amended JV Operating Agreement, including drag-along and tag-along rights.

Services Agreement:

In connection with the Contribution Agreement, on the Closing Date, the Company and biologistex entered into a Services Agreement (the “Services Agreement”) whereby the Company will provide certain sales and marketing services to biologistex in exchange for payment by biologistex to the Company of (i) a cash fee for the first year of the contract only in the amount of \$100,000, (ii) a commission (the “Commissions”), paid quarterly, equal to 20% of the gross revenues of biologistex from any customer account resulting from sales activity or a marketing lead generated by the Company (“BioLife Customer Revenue”), and (iii) reimbursement of pre-approved reasonable direct costs and expenses incurred by the Company by or on behalf of biologistex in connection with the services. After the third anniversary of the Closing Date, the Commissions will decrease to 10% of the BioLife Customer Revenue.

The Services Agreement continues until terminated by either party. The Services Agreement can be terminated (a) by mutual agreement, (b) beginning 90 days prior to the third anniversary of the Closing Date, by either party with 90 days’ notice, (c) by biologistex with 90 days’ notice if (i) there are certain changes to the management of the Company or its subsidiaries, (ii) the Company transfers all of its equity interests in biologistex or (iii) there is a change of control of the Company, (d) by the Company with 90 days’ notice if (i) STLLC transfers all of its equity interest in biologistex or (ii) there is a change of control of STLLC or (e) by either party (i) for a material breach of the Services Agreement by the other party that is not cured within 30 days or (ii) if the other party is subject to certain bankruptcy/insolvency events. If the Services Agreement is terminated by biologistex under items (b) or (c) of the preceding sentence, or by the Company under items (d) or (e) of the preceding sentence, the Company will be entitled to receive Commissions equal to 10% of the BioLife Customer Revenue during the 12 month period following such termination.

Credit Facility

On May 12, 2016, we entered into a \$4 million unsecured credit facility (the “Original Note”) with our largest shareholder, WAVI Holdings, AG (“WAVI”). Under the related commitment letter, WAVI has agreed to make a series of four \$1 million advances on June 1, 2016, September 1, 2016, December 1, 2016 and March 1, 2017. The Original Note is unsecured, carries an annual interest rate of 10%, and matures on June 1, 2017. In addition, we have agreed not to permit any liens on our assets, subject to certain exceptions. As partial compensation for WAVI entering into the commitment letter, we issued WAVI a detachable common stock purchase warrant exercisable to purchase up to 550,000 shares of common stock at an exercise price of \$1.75 per share. The warrant expires on May 12, 2021.

Amendment of Credit Facility

On January 9, 2017, the Company issued an amended and restated promissory note (the “Note”) to WAVI. The Note, which amends and restates the Original Note, extends the maturity date of the Note from June 1, 2017 to June 1, 2022 and includes a long-term repayment schedule as follows: beginning September 1, 2017 to June 1, 2018, the Company will make four quarterly cash interest only payments of \$106,250 and from September 1, 2018 through June 1, 2022, the Company will make quarterly cash principal payments of \$265,625, in addition to ongoing interest payments. All other terms of the Original Note, including the \$4 million principal amount of the Note and the 10% per annum interest rate on the Original Note, remain the same.

Principles of Consolidation

The consolidated financial statements as of and for the year ended December 31, 2015 and the results of operations for 2016 up to December 31, 2016 include the accounts of the Company and its previously majority-owned subsidiary, biologistex. All intercompany balances and transactions have been eliminated in consolidation. On December 31, 2016 we deconsolidated biologistex and began to report our ownership interest of biologistex using the equity method of accounting based on the fair value of our ownership interest in biologistex at the time of the transaction.

Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Net loss per share

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period, excluding, unvested restricted stock outstanding during the period. Diluted earnings per share is calculated using the weighted average number of common shares outstanding plus dilutive common stock equivalents outstanding during the period. Common stock equivalents are excluded for the years ending December 31, 2016 and 2015 since the effect is anti-dilutive due to the Company’s net losses. Common stock equivalents include unvested restricted stock, stock options and warrants.

Basic weighted average common shares outstanding, and the potentially dilutive securities excluded from loss per share computations because they are antidilutive, are as follows for the years ended December 31, 2016 and 2015:

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	2016	2015
Basic and diluted weighted average common stock shares outstanding	12,642,996	12,177,396
Potentially dilutive securities excluded from loss per share computations:		
Common stock options	2,513,861	2,555,263
Common stock purchase warrants	7,603,141	7,195,997
Unvested Restricted Stock	98,439	—

Cash and cash equivalents

Cash equivalents consist primarily of interest-bearing money market accounts. We consider all highly liquid debt instruments purchased with an initial maturity of three months or less to be cash equivalents. We maintain cash balances that may exceed federally insured limits. We do not believe that this results in any significant credit risk.

No cash was paid for either interest expense or income taxes for the years ended December 31, 2016 and 2015.

Investment Securities

At December 31, 2015, the Company's investments consisted primarily of commercial paper, corporate debt, and other debt securities. Investments are classified as available-for-sale and are reported at fair value based on quoted market prices with unrealized gains and losses, net of applicable taxes, recorded in accumulated other comprehensive income (loss), a component of shareholders' equity. The realized gains and losses for available-for-sale securities are included in other income and expense in the Consolidated Statements of Operations. Realized gains and losses are calculated based on the specific identification method.

The Company monitored its investment portfolio for impairment on a periodic basis. When the amortized cost basis of an investment exceeds its fair value and the decline in value is determined to be an other-than-temporary decline, and when the Company does not intend to sell the debt security and it is not more likely than not that the Company will be required to sell the debt securities prior to recovery of its amortized cost basis, the Company records an impairment charge in the amount of the credit loss and the balance, if any, to other comprehensive income (loss).

The Company had no short term investments as of December 31, 2016.

Equity Method Investments

At December 31, 2016, we account for our investment in SAVSU using the equity method of accounting as we have ability to exercise significant influence, but not control, over operating and financial policies of SAVSU. Judgment regarding the level of influence over the equity method investments includes considering key factors such as the Company's ownership interest, representation on the Management Committee, participation in policy-making decisions and material intercompany transactions. Our retained investment in SAVSU was initially recorded at fair value as of December 31, 2016 and our proportionate share of the net income or loss as reported by SAVSU is included in consolidated net loss, which had no activity as of December 31, 2016. As of December 31, 2016, SAVSU had current assets and total assets of \$0.5 million and \$3.2 million, respectively. As of December 31, 2016, SAVSU had no material liabilities. The carrying value of our investment in SAVSU is in excess of the underlying equity in net assets of SAVSU as of December 31, 2016, due to the company's investment recorded at fair value while the underlying net assets of SAVSU are recorded at historical cost. Net assets of SAVSU include significant unrecorded internally developed intangibles contributed by STLLC at December 31, 2016.

Inventories

Inventories represent biopreservation solutions, raw materials used to make biopreservation solutions and are stated at the lower of cost or market. Cost is determined using the first-in, first-out (“FIFO”) method.

Accounts receivable

Accounts receivable are stated at principal amount, do not bear interest, and are generally unsecured. We provide an allowance for doubtful accounts based on an evaluation of customer account balances past due ninety days from the date of invoicing. Accounts considered uncollectible are charged against the established allowance.

Property and equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over estimated useful lives of three to ten years.

Intangible asset

At December 31, 2015, our intangible asset represented exclusive distribution rights to STLLC’s Smart Containers associated with our biologistex CCM, LLC joint venture discussed previously. The intangible asset was recorded at its fair value of \$2,215,385 at the date contributed to the joint venture by STLLC. We reviewed the intangible asset for impairment whenever an impairment indicator exists. We assessed recoverability by determining whether the carrying value of such asset 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 would recognize an impairment loss based on any excess of the carrying amount over the fair value of the assets. The intangible asset was not amortized due to no sales generated from the biologistex joint venture.

The Company had no intangible assets as of December 31, 2016 due to the deconsolidation of biologistex.

Internal Use Software

We capitalized costs associated with the development of the biologistex web and mobile applications, which we considered internal-use software. Capitalization of costs began in the first quarter of 2015, when we reached the application development stage. Such capitalized costs included external direct costs utilized in developing or obtaining the applications and payroll and payroll-related expenses for employees, who are directly associated with the

development of the applications. Capitalization ceases once we have completed all substantial testing, at which time the applications are complete and ready for their intended use. The Company did not amortize any software development costs due to no sales generated from the biologistex joint venture.

In 2016 and 2015, we capitalized \$0.7 million and \$1.7 million, respectively, in costs related to the development of the biologistex web and mobile applications. Maintenance and enhancement costs were expensed as incurred, unless such costs relate to substantial upgrades and enhancements to the software that result in added functionality, in which case the costs are capitalized.

The Company had no internal use software as of December 31, 2016 due to the deconsolidation of biologistex.

Deferred rent

For our operating leases, we recognize rent expense on a straight-line basis over the terms of the leases and, accordingly, we record the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Landlord-funded leasehold improvements, to the extent the improvements are not landlord property upon lease termination, are also recorded as deferred rent liabilities and are amortized as a reduction of rent expense over the non-cancelable term of the related operating lease.

Revenue recognition

We recognize product revenue, including shipping and handling charges billed to customers, upon shipment of product when title and risk of loss pass to customers. Shipping and handling costs are classified as part of cost of product sales. We may also receive fees from our contract manufacturing customers for validation of the manufacturing process. This typically occurs prior to production for those customers and revenue is recognized upon successful completion of all obligations related to the validation process.

Income taxes

We account for income taxes using an asset and liability method which generally requires recognition of deferred tax assets and liabilities for the expected future tax effects of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are recognized for the future tax effects of differences between tax bases of assets and liabilities, and financial reporting amounts, based upon enacted tax laws and statutory rates applicable to the periods in which the differences are expected to affect taxable income. We evaluate the likelihood of realization of deferred tax assets and provide an allowance where, in management's opinion, it is more likely than not that the asset will not be realized. We have not recorded any liabilities for uncertain tax positions or any related interest and penalties. Our tax returns are open to audit for years ending December 31, 2013 to 2016.

Advertising

Advertising costs are expensed as incurred and totaled \$74,916 and \$69,091 for the years ended December 31, 2016 and 2015, respectively.

Fair value of financial instruments

The principal balance of the note payable and related accrued interest approximate their fair value (determined based on level 3 inputs in the fair value hierarchy) because the interest rate of the note payable approximates market interest rates.

Operating segments

As described above, our activities are directed in the life sciences field of biopreservation products and services. As of December 31, 2016 and 2015 this is the Company's only operating unit and segment.

Concentrations of credit risk and business risk

In 2016 and 2015, we derived approximately 12% and 10%, respectively, of our revenue from our relationship with one distributor of our products. Revenue from customers located in foreign countries represented 17% and 21% of total revenue during the years ended December 31, 2016 and 2015, respectively. All revenue from foreign customers are denominated in United States dollars. At December 31, 2016, three customers accounted for 45% of gross accounts receivable. At December 31, 2015, three customers accounted for 53% of gross accounts receivable.

Research and development

Research and development costs are expensed as incurred.

Stock Based Compensation

We use the Black-Scholes option pricing model as our method of valuation for stock option awards. Restricted stock unit grants are valued at the fair value of our common stock on the date of grant. Share-based compensation expense is based on the value of the portion of the stock-based award that will vest during the period, adjusted for expected forfeitures. Our determination of the fair value of stock option awards on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the expected life of the award, expected stock price volatility over the term of the award and historical and projected exercise behaviors. The estimation of share-based awards that will ultimately vest requires judgment, and to the extent actual or updated results differ from our current estimates,

such amounts will be recorded in the period estimates are revised. Although the fair value of stock option awards is determined in accordance with authoritative guidance, the Black-Scholes option pricing model requires the input of highly subjective assumptions and other reasonable assumptions could provide differing results. Share-based compensation expense is recognized ratably over the applicable requisite service period based on the fair value of such share-based awards on the grant date.

The fair value of options at the date of grant is determined under the Black-Scholes option pricing model. During the years ended December 31, 2016 and 2015, the following weighted-average assumptions were used:

Assumptions	2016	2015
Risk-free rate	1.51 %	1.77 %
Annual rate of dividends	—	—
Historical volatility	75 %	105.20 %
Expected life	7.0 years	7.0 years

The risk-free interest rate was based on the U.S. Treasury yield curve in effect at the time of grant. We do not anticipate declaring dividends in the foreseeable future. Volatility was based on historical data. We utilize the simplified method in determining option lives. The simplified method is used due to the fact that we have had significant structural changes in our business such that our historical exercise data may not provide a reasonable basis to estimate option lives.

We recognize compensation expense for only the portion of options that are expected to vest. Therefore, management applies an estimated forfeiture rate that is derived from historical employee termination data. The estimated forfeiture rate applied for the year ended December 31, 2016 was 8.1% and in 2015 was 7.0%. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods. Our stock price volatility, option lives and expected forfeiture rates involve management's best estimates at the time of such determination, all of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option.

Recent accounting pronouncements

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (ASU 2016-15). The updated guidance clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows. Adoption of ASU 2016-15 is required for fiscal reporting periods beginning after December 15, 2017, including interim reporting periods within those fiscal years with early adoption being permitted. We do not expect the adoption of ASU 2016-15 to have a material impact on our consolidated financial statements.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU-2016-09). The updated guidance simplifies and changes how companies account for certain aspects of share-based payment awards to employees,

including accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification of certain items in the statement of cash flows. Adoption of ASU 2016-09 is required for fiscal reporting periods beginning after December 15, 2016, including interim reporting periods within those fiscal years with early adoption being permitted. The Company is currently evaluating the potential impact of the pending adoption of ASU 2016-09 on its consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases: Topic 842 (ASU 2016-02) that replaces existing lease guidance. The new standard is intended to provide enhanced transparency and comparability by requiring lessees to record right-of-use assets and corresponding lease liabilities on the balance sheet. Under the new guidance, leases will continue to be classified as either finance or operating, with classification affecting the pattern of expense recognition in the Consolidated Statements of Operations. Lessor accounting is largely unchanged under ASU 2016-02. Adoption of ASU 2016-02 is required for fiscal reporting periods beginning after December 15, 2018, including interim reporting periods within those fiscal years with early adoption being permitted. The new standard is required to be applied with a modified retrospective approach to each prior reporting period presented with various optional practical expedients. The Company is currently evaluating the potential impact of the pending adoption of ASU 2016-02 on its consolidated financial statements.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities: Topic 825 (ASU 2016-01). The updated guidance enhances the reporting model for financial instruments, which includes amendments to address aspects of recognition, measurement, presentation and disclosure. Adoption of ASU 2016-01 is required for fiscal reporting periods beginning after December 15, 2017, including interim reporting periods within those fiscal years. The Company does not expect adoption of ASU 2016-01 to have a material impact on its consolidated financial statements.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, Balance Sheet Classification of Deferred Taxes: Topic 740 (ASU 2015-17). Current GAAP requires the deferred taxes for each jurisdiction to be presented as a net current asset or liability and net noncurrent asset or liability. This requires a jurisdiction-by-jurisdiction analysis based on the classification of the assets and liabilities to which the underlying temporary differences relate, or, in the case of loss or credit carryforwards, based on the period in which the attribute is expected to be realized. Any valuation allowance is then required to be allocated on a pro rata basis, by jurisdiction, between current and noncurrent deferred tax assets. The new guidance requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. As a result, each jurisdiction will now only have one net noncurrent deferred tax asset or liability. The guidance does not change the existing requirement that only permits offsetting within a jurisdiction. Adoption of ASU 2015-17 is required for fiscal reporting periods beginning after December 15, 2016, including interim reporting periods within those fiscal years, and either prospective or retrospective application is permitted. Early adoption of ASU 2015-17 is permitted. At the time of adoption, all of the Company's deferred tax assets and liabilities, along with any related valuation allowance, will be classified as noncurrent on its Consolidated Balance Sheet. The Company does not expect adoption of ASU 2015-17 to have a material impact on its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory: Topic 330 (ASU 2015-11). Topic 330 currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. ASU 2015-11 requires that inventory measured using either the first-in, first-out (FIFO) or average cost method be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Adoption of ASU 2015-11 is required for fiscal reporting periods beginning after December 15, 2016, including interim reporting periods within those fiscal years. The Company does not expect adoption of ASU 2015-11 to have a material impact on its consolidated financial statements.

On May 28, 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, Topic 606, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. Early adoption is not permitted. The updated standard becomes effective for us in the first quarter of fiscal 2018. The Company does not expect adoptio