

BIOLIFE SOLUTIONS INC  
Form 10-K/A  
December 09, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-K/A**

**(Amendment No. 1)**

**(Mark One)**

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

For the year ended December 31, 2015

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

For the transition period from    to

Commission File Number 0-18170

**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

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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

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 \$11,641,545.

As of January 31, 2016, 12,448,391 shares of the registrant's common stock were outstanding.

EXPLANATORY NOTE

This Amendment No. 1 to our Annual Report on Form 10-K of BioLife Solutions, Inc. (“BioLife”, “we”, “our”, “us”, or the “Company”) is being filed to amend the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which was originally filed with the Securities and Exchange Commission (the “SEC”) on February 25, 2016 (the “Original Filing”). We are filing this amendment solely to include corrected certifications by our principal executive officer and principal financial officer as required by Items 601(b)(31) and (32) of Regulation S-K.

Except for the amendments described above, we have not modified or updated disclosures presented in the Original Filing in this Form 10-K. Accordingly, this Form 10-K does not reflect events occurring after the filing of the Original Filing or modify or update those disclosures affected by subsequent events. Information not affected by these amendments remain unchanged and reflects the disclosures made at the time the Original Filing was filed. We have included the full Form 10-K originally filed on February 25, 2016 with corrected certifications in this filing.

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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.*

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. We have one majority-owned subsidiary, biologistex CCM, LLC, a Delaware limited liability company (“biologistex”).

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 and a related cloud hosted biologistics cold chain management app for smart shippers.

We facilitate 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
- Cold chain logistics services incorporating precision thermal packaging products and cloud-hosted web applications
  - Contract aseptic manufacturing formulation, fill, and finish services of liquid media products

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)/Multicompendial 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 improved post-preservation cell and tissue viability and function. We believe that our products have been incorporated into the manufacturing, storage, shipping, freezing, and clinical delivery processes of over 200 cell-based clinical trial stage regenerative medicine applications.



## 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***

#### *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. Most regenerative medicine therapies are working through the clinical trial process, with less than 50 approved therapies and over 500 clinical trials underway.

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.

In July 2015, Frost & Sullivan forecasted that the stem cell therapy market is expected to be worth \$40 billion by 2020 and \$180 billion by 2030. Our 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. 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 200 pre-clinical validation projects and human clinical trials 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. We estimate that annual revenue from each clinical 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, and biorepositories. To continue to generate awareness of the need for effective preservation, we are a sponsor and member of the AABB and provide expertise when needed to the top biobanking enterprises.

### *Cold Chain Logistics Opportunity*

Transporting biologic material, which is inherently fragile, requires precise control over temperature and other environmental conditions. Temperature excursions can impact the quality and efficacy of the product and/or the data generated for clinical trial evaluation. Suboptimal packaging and packout errors due to complex packaging are leading causes of biologic material temperature excursions. Despite this fact, biologic materials for clinical trial testing, as well as active drug substances, are regularly transported using packaging and temperature conditions that are suboptimal.

Often temperature excursions are not discovered because data is not being monitored in real time. While some clinicians use data loggers to track temperatures, these are often not reviewed until after a patient has received the therapeutic dose. We believe that real time monitoring is needed to ensure that patients do not receive doses that have experienced a temperature excursion that is outside the safety protocol, or that it has not been exposed to other damaging environmental conditions.

In clinical trials, where following protocols is so essential to obtaining meaningful results, maintaining the cold chain also preserves the validity of the tests. While it costs more to keep products at 2–8 °C or at frozen temperatures than it does to keep them at uncontrolled ambient conditions, more to pack and transport them cold, and more to be able to demonstrate by process qualification or by measurement of each shipment that they stayed cold, we believe that industry and society benefit when temperature-sensitive drugs and biological products can be made in efficient large batches, shipped around the world, and delivered as needed to the point of purchase or use.

Pharmaceutical Commerce estimates that in 2015, \$10 billion was spent on cold chain logistics of pharmaceuticals, with \$7 billion for transportation and \$3 billion for specialized packaging and instrumentation. BioLife's addressable market is comprised of the demand for small payload shipping containers and related temperature monitoring and location tracking devices.

### ***Cold Chain Logistics Strategy***

Our biologistex service addresses these needs with the combination of the evo Smart Shippers, 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, and an integrated cloud based application that provides real time GPS location monitoring and critical data on a number of payload and environmental conditions.

### **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.

**PrepaStor**® is a flush solution specifically designed for use during the transitions from normothermic to mild hypothermic conditions (37°C to 20°C) to rinse culture media and native fluids from tissue and whole organ systems prior to suspension in a preservation solution. PrepaStor is also used to support the transition from hypothermic to normothermic temperatures following the preservation interval.

*biologistex*™ *cold-chain management service*, launched in the third quarter of 2015, includes unlimited use of the evo Smart Shipper and the integrated track and trace cloud-based web application, mybiologistex.com. 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.

## **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.

### *Cold Chain Logistics*

Current commercial alternatives range from Styrofoam and EPS "beer cooler" type containers inside a cardboard box, up to and including vacuum panel insulation cartons, coupled with throw-in-the-box data loggers that are not able to

monitor the payload conditions with the same level of precision and can be accidentally discarded at the destination. These alternatives provide inferior temperature stability performance due to the form factor design and/or materials used and do not provide real time monitoring.

Traditional freight and “cold chain” shipper companies such as Sonoco Thermosafe, Cryopak, Pelican Technologies, and others maintain well-established positions in the marketplace, and possess significant financial, sales, marketing, and distribution resources in comparison. We expect to continue to experience significant and increasing levels of competition in the future. In addition, there may be other companies which are currently developing competitive products and services or which may in the future develop technologies and products that are comparable, superior or less costly than our own. Additionally, some specialty couriers with greater resources currently provide transportation and may develop other products in the future, both of which may compete with our products. A competitor that has greater resources than us may be able to bring its product to market faster than we can and offer its product at a lower price than us to establish market share. We may not be able to successfully compete with a competitor that has greater resources and such competition may adversely affect our business.



## **BUSINESS OPERATIONS**

### **Sales and Marketing**

We market and sell our products directly using our sales force and through our website at [www.biolifesolutions.com](http://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.

Our biologistex service is sold through a software subscription model where our customers purchase access to the product for a specified period of time during which they have rights to use the most recent version of the product.

In 2015 and 2014, we derived approximately 10% and 11%, respectively, of our revenue from our relationship with one distributor of our products. In 2014, we also derived 18% of our revenue from our relationship with one contract-manufacturing customer.

At December 31, 2015, three customers accounted for 53% 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 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.

Our evo® Smart Shippers are manufactured and supplied by our joint venture partner, SAVSU Technologies, LLC (“SAVSU”), based in Albuquerque, NM. Our biologistex 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 biologistex and our 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 service team. This team is responsible for providing timely, high-quality technical expertise on all our products.

## **Product Approval Regulation**

None of our products are subject to any specific 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.

We regard our biologistex software as proprietary and protect it under the laws of copyrights, trademarks and trade secrets. We have a number of domestic and foreign patents and pending applications that relate to various aspects of our products and technology. We protect the source code of our software programs as trade secrets.

Our biologistex web application will be licensed to end users under a SaaS or on-demand model, where hosted software is provided on demand to customers, generally through a web browser. The use of these products is governed by either the online terms of use or a license agreement associated with the product.

### **Product Development**

Currently, we employ a team of researchers, all of which 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.

We develop our software for the biologistex web application internally. As the software industry is characterized by rapid technological change, a continuous high level of investment is required for the enhancement of existing products and services and the development of new products and services.

During 2015, we spent 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. During 2014 and 2013, we spent approximately \$0.9 million and \$0.5 million, respectively, on research and development activities.

## **Employees**

As of February 1, 2016, we had 43 employees, all of whom were full time. 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 2015 and 2014, we derived approximately 10% and 11%, respectively, of our revenue from our relationship with one distributor of our products, StemCell Technologies, Inc. In 2014, we also derived 18% of our revenue from our relationship with one contract-manufacturing customer. The contract with that customer was terminated in May 2014, which had a significant adverse effect on our revenue in 2014. No other customer accounted for more than 10% of revenue in 2015 or 2014. 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 as to the customers we serve could seriously harm our business. In addition, we focus our net 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, 2015 and December 31, 2014, we had consolidated net losses of \$4,213,936 and \$3,217,750, respectively. As of December 31, 2015, our consolidated accumulated deficit was approximately \$64.3 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, and our biologistex cold chain logistics service.***

Our growth depends, in part, on our continued ability to successfully develop, commercialize and market our HypoThermosol® FRS, CryoStor®, and BloodStor® biopreservation media products, and biologistex cold chain logistics service. 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 United States Food and Drug Administration (“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 and cold chain industries are 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 investments in our biologistex joint venture may be adversely affected by our lack of sole decision-making authority and disputes between us and our joint venture partner.***

We are a party to the biologistex LLC Agreement with SAVSU. Under the LLC Agreement, each of the Company and SAVSU are entitled to appoint two members to the biologistex board of managers. The approval of at least three of the four managers is generally required for any matter subject to a board of managers vote. Accordingly, we are not in a position to exercise sole decision-making authority regarding the joint venture. Decisions of the joint venture may relate to, among other subjects, ownership, prosecution and enforcement of intellectual property that is owned by biologistex and/or jointly developed by SAVSU and the Company during the joint venture. Our joint venture partner SAVSU may have different economic or other business interests or goals which are inconsistent with our business interests and goals, and may take actions contrary to our policies or objectives, which may result in poor or delayed business decisions. Further, our biologistex investment has the potential risk of an impasse on decisions, such as a sale, because neither we, nor SAVSU has full control over the joint venture. The LLC Agreement includes a mechanism whereby, in the event of certain impasses between the members, or within the board of managers, the joint venture may be dissolved or the members may agree that one member will sell its units of biologistex to the other member. Accordingly, in the event of an impasse, we may need to buy SAVSU's interest in biologistex or sell our own interest to SAVSU. Dissolution of the joint venture could lead to uncertainties, disputes or other issues with respect to each of the joint venture partners' rights, including rights to jointly developed intellectual property and any intellectual property owned by biologistex.

***We may be adversely impacted by the failure of the biologistex joint venture or by our failure, or the failure of our joint venture partner, to fulfill our obligations to the joint venture.***

We participate in the biologistex joint venture with SAVSU. The biologistex joint venture 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 either we, or SAVSU will not meet our obligations under the LLC Agreement, the Supply and Distribution Agreement or the Services Agreement. We depend on SAVSU, among other things, for its intellectual property with respect to the Smart Containers and for its manufacturing of the Smart Containers. If SAVSU fails to fulfill its obligations due to strategic business interests, financial condition or otherwise, we may be required to spend additional resources, or biologistex may not be able to continue its operations, in which case we may suffer losses. Such expenses or losses may be significant and may have an adverse effect on our financial position or results of operations. In addition, we have committed to certain financial and operational milestones with respect to biologistex. For example, under the Services Agreement, we have agreed to manage biologistex to achieve certain minimum sales targets. If we are not able to fulfill these obligations due to market conditions, our financial position or otherwise, we may be required to spend additional resources, or 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.

Additionally, we may function as a "business associate" in our commercial arrangements with healthcare providers using our cold-chain management services or other services, and, in this capacity, may be subject to the HIPAA Standards. Violations of the HIPAA Standards are punishable by civil penalties up to an annual limit of \$1.5 million for all identical violations and criminal penalties up to an annual limit of \$250,000 and ten years' imprisonment for certain knowing violations. Failure to comply with any laws regarding personal data protection may also result in significant fines or penalties, lawsuits, costs associated with mitigating any privacy or security breach, and/or negative publicity. Any future significant compromise or breach of our data security, whether external or internal, or misuse of customer, employee, supplier or other identifiable data, could result in additional significant costs, lost sales, fines, lawsuits and damage to our reputation. In addition, as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could also result in additional costs.

*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 effect the pricing of HypoThermosol® FRS and our ability to retain market share. We

do not plan to reformulate HypoThermosol® FRS nor apply for any term extension.

*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.



***SAVSU and/or biologistex may fail to obtain or maintain intellectual property protection with respect to the Smart Containers, or SAVSU may take adverse actions with respect to intellectual property generated through the biologistex joint venture.***

Each of SAVSU and biologistex owns certain intellectual property related to the biologistex joint venture, and new intellectual property may be developed by the Company, SAVSU, or the joint venture partners jointly during the biologistex joint venture. If either SAVSU or biologistex fails to obtain and/or maintain intellectual property protection with respect to the biologistex joint venture, including due to a failure of the joint venture partners to agree on matters of prosecution and/or enforcement, competition in this market may be increased and we may not be able to obtain sufficient revenue to cover expenses. In addition, SAVSU may have rights in new intellectual property created during the biologistex joint venture. SAVSU may have different economic or other business interests or goals for the new intellectual property which are inconsistent with our business interests and goals, and may take actions contrary to our policies or objectives, which may have a material adverse effect on the value of the new intellectual property and/or our ability to independently exploit the new intellectual property. Further complications may arise due to uncertainty or disputes over the joint venture partners' rights to intellectual property owned by biologistex in the event of dissolution of the joint venture.

***Our biologistex service may utilize open source software.***

We may make use of Free and Open Source Software ("FOSS") in the development of the biologistex web and mobile applications and related operational information technology systems. The law surrounding the use of FOSS is in a state of evolution and the legal ramifications of such use remain uncertain. The use of FOSS may therefore lead to legal consequences that may have a material adverse effect on our proprietary technology and intellectual property, or those of our joint venture partners and collaborative partners. Such material adverse effects may include, among others, the requirement to disclose the source code for and a loss of our or our partners' proprietary positions in relation to the said applications and systems, and the possibility of intellectual property infringement claims or breach of contract claims from FOSS licensors or from our third party suppliers or collaborative partners.

***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, 2015, two of our existing stockholders, Thomas Girschweiler and Walter Villiger, beneficially owned, collectively, approximately 61.5% of our outstanding shares. Messrs. Girschweiler and Villiger were previously secured lenders to our Company, and 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 are at risk of securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because 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 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 MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS  
5. 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 24, 2016, there were approximately 415 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 (as adjusted for our reverse stock split):

	High	Low
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
Year ended December 31, 2014		
4th Quarter	\$2.30	\$1.64
3rd Quarter	2.85	2.06
2nd Quarter	3.90	1.89
1st Quarter	9.00	3.69

**Equity Compensation Plan Information**

The following table sets forth information as of December 31, 2015 relating to all of our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options and warrants (in thousands)	Weighted Average exercise price of outstanding options and warrants	Number of securities remaining available for future issuance (in thousands)
Equity compensation plans approved by security holders	1,772	\$ 2.02	1,696
Equity compensation plans not approved by security holders (1)	783	\$ 1.28	—
Total	2,555	\$ 1.80	1,696

(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 foregoing, 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 October 6, 2015 and November 28, 2015, the Company issued an aggregate of 142,858 shares of common stock of the Company pursuant to the exercise of outstanding warrants at an exercise price of \$0.98 per share.

On November 6, 2015, the Company issued 89,286 shares of common stock of the Company pursuant to the exercise of outstanding warrants at an exercise price of \$1.12 per share.

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

*Reverse Stock Split*

On January 17, 2014, our Board of Directors approved an amendment to our certificate of incorporation to effect a reverse stock split by a ratio of 1-for-14, with no reduction in the number of shares of common stock that were previously authorized in our certificate of incorporation. The reverse stock split was effective on January 29, 2014. No fractional shares of our common stock were issued as a result of the reverse stock split. In the event the reverse stock split left a stockholder with a fraction of a share, the number of shares due to the stockholder was rounded up to the nearest whole share. Unless otherwise noted, all share and per share data in this Annual Report on Form 10-K give effect to the 1-for-14 reverse stock split of our common stock and are subject to the foregoing adjustments for fractional shares.

*Public Offering of Units*

On March 25, 2014, we closed a registered public offering of 3,588,878 units for gross proceeds of \$15,432,175. Each unit consisted of one share of the Company's common stock and one warrant, each warrant exercisable for seven years to purchase one share of the Company's common stock at an exercise price of \$4.75. Net of placement agent fees of \$1,211,734 and offering costs of \$624,211, we received net proceeds of \$13,596,230. Of the gross proceeds, \$9,124,109 million was allocated to common stock and \$6,308,066 million was allocated to warrants, based on relative fair values.

*Conversion of Notes and Interest to Equity*

Pursuant to note conversion agreements with WAVI Holding AG and Taurus4757 GmbH (the “Note Holders”), concurrently with the closing of our public offering of units, we converted approximately \$14.3 million of indebtedness, including accrued interest, to the Note Holders into equity, issuing to the Note Holders an aggregate of 3,321,405 units having terms substantially similar to the public offering units. In connection with the note conversion, our \$14.3 million indebtedness to the Note Holders under the terms of our previously disclosed facility agreements was extinguished, all remaining unamortized deferred finance costs were recorded to additional paid in capital, and the Note Holders agreed to release all security interests. Of the total conversion amount, \$8.4 million was allocated to common stock and \$5.8 million was allocated to warrants, based on relative fair values.

*Listing of Common Stock on NASDAQ Capital Market*

On March 26, 2014, our common stock was listed on the NASDAQ Capital Market under the symbol BLFS.

*biologistex Joint Venture*

On September 29, 2014, we entered into an LLC Agreement with SAVSU to create biologistex, a 20-year joint venture for the purpose of acquiring, developing, maintaining, owning, operating, marketing and selling an integrated platform of a cloud-based information service and precision thermal shipping products based on SAVSU’s next generation evo Smart Shippers.

The joint venture vehicle, biologistex CCM, LLC, is structured as a Delaware limited liability company. We will make a capital contribution of \$2.4 million in such amounts and at such times as will be necessary for the purpose of funding biologistex’s purchase of products from SAVSU under a separate Supply and Distribution Agreement. SAVSU contributed exclusive distribution rights to the Smart Shippers under the separate Supply and Distribution Agreement. As at December 31, 2015, our remaining capital contribution commitment is \$2.2 million.

We were also required to pay SAVSU \$1 million in consideration of SAVSU’s participation in biologistex. As at December 31, 2015, we have satisfied this obligation in full.

The Company and SAVSU are the only members of biologistex, holding 52% and 48%, respectively, of the outstanding units. Distributions of net cash flow, if any, are to be made in proportion to the members' ownership of units.

On September 29, 2014, biologistex and SAVSU also entered into the Supply and Distribution Agreement whereby biologistex became the exclusive, worldwide distributor of Smart Shippers. Pursuant to the Supply and Distribution Agreement, biologistex agrees to purchase a minimum number of Smart Shippers for an aggregate purchase price of approximately \$2.6 million. Under the terms of the agreement, SAVSU must fulfill all obligations required of it to permit biologistex to make the products available for marketing, sales and acceptance of customer orders. The Supply and Distribution Agreement has an initial term of 20 years unless terminated early by its terms.

On September 29, 2014, the Company and biologistex also entered into a Services Agreement whereby we will provide services to biologistex related to operations, sales, marketing, administration and development of a cloud-based software system for tracking and managing the products. The Services Agreement has an initial term of 20 years unless terminated early by its terms.

Pursuant to the Services Agreement, we agreed to manage biologistex to achieve certain minimum sales targets. biologistex will pay us monthly for expenses incurred and certain overhead expenses.

To date, we have funded biologistex's obligations to us and certain of biologistex's other obligations as an interest-free, inter-company loan to biologistex. We anticipate that we may be required to continue funding such obligations on an ongoing basis until biologistex has achieved revenues sufficient to pay such expenses. As at December 31, 2015, the principal balance of this loan, which is eliminated upon consolidation, is \$3.5 million.

We launched the biologistex cold-chain management service including unlimited use of the evo Smart Shipper and the integrated track and trace cloud-based web application, mybiologistex.com, during the third quarter of 2015, with deployment of shippers to customers and access to the biologistex web app for validation.



## **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 2015*

In 2015, we reported financial results that were consistent with the continued execution of our long-term plans. 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 into over 200 pre-clinical validation projects and human clinical trials for new cell and tissue-based regenerative medicine products and therapies.

While continuing to manufacture and distribute our best-in-class preservation media, we have created an innovative subscription-based cold chain logistics offering that we believe will disrupt the market for cold chain management of time and temperature sensitive biologic materials. Our biologistex services delivers value with the combination of the best available insulating shipping container with built in electronic monitoring and tracking and a web-based application that allow real time access to the monitoring information.

We continue to implement strategies that will increase awareness of the need for improved biopreservation and 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 200 pre-clinical validation projects and human clinical trials 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 2015, key product adoption announcements included:

UK-based TC Biopharm Ltd, a developer of anti-cancer immunotherapies, announced that it has incorporated our CryoStor clinical and commercial grade freeze media in its manufacturing and clinical delivery processes of ImmuniCell, a novel T cell based immunotherapy targeting various cancers.

Cardio3 BioSciences, a leader in engineered cell therapy with clinical programs initially targeting indications in cardiovascular disease and oncology, has embedded the Company's clinical grade CryoStor cryopreservation freeze media in its ongoing *Congestive Heart Failure Cardiopoietic Regenerative Therapy (CHART-1)* phase III clinical trial in Europe and Israel and the pending CHART-2 phase III clinical trial to be conducted in the United States.

Cord Blood Registry (CBR ®), the world's largest newborn stem cell company, announced the adoption of BioLife's CryoStor clinical grade cryopreservation freeze media in its process for cryogenic storage of umbilical cord tissue stem cells.

Several new customers disclosed the use of the Company's CryoStor and HypoThermosol biopreservation media products in pre-clinical validation projects and clinical trials at the recent International Society for Cellular Therapy (ISCT) conference as follows:

GSK – Overcoming automation and formulation challenges in the manufacture and distribution of next generation ex vivo gene therapy products.

HemaCare Bioresearch Products & Services – Cryopreserved Leukopaks (LP) Maintain Cell Viability & Functionality.

MaSTherCell (for their customer Imcyse) – Technology Transfer and Process Development for an Autologous Cell Therapy Against Multiple Sclerosis.

RoosterBio – poster: Cryopreserved hMSC maintain comparable in vitro functional activity compared to fresh hMSC.

Use of CryoStor cryopreservation freeze media with a dendritic cell based vaccine was published in the journal Oncotarget.

We announced that our CryoStor cell freeze media was utilized in a Mayo Clinic porcine animal study of umbilical cord blood-derived mononuclear cells (UBC-MNC) to evaluate the safety and feasibility of these cells for cardiac regeneration in pediatric congenital heart disease (CHD).

***Develop or invest in innovative new products.*** We are continuously seeking to utilize the unique nature of our technologies to develop new products and are also evaluating complementary and competing technologies developed outside of the Company.

*Product Innovation:* New products and service launches completed in 2015 include:

biologistex – We commercially launched the biologistex cold chain management service, which includes access to our biologistex web app and use of the evo Smart Shipper.

Cell Thawing Media - We commenced GMP manufacturing and sales of low molecular weight dextran solutions for use in thawing human cells. We gained about 50 new customers for this product in 2015.

BloodStor 27 NaCl Freeze Media – We launched the new product targeting end user cryopreservation applications including freezing of platelets for clinical administration. The first substantial order for BloodStor® 27 NaCl was shipped to The Netherlands Ministry of Defense in the late fourth quarter of 2015.

*Intellectual Property.* Expanding our intellectual property protection:

We were granted a new Australian patent number 2009228056 titled, “Materials and Methods for Hypothermic Collection of Whole Blood”.

We filed a patent application with claims related to novel features for next generations of the evo™ Smart Shipper and future releases of the biologistex™ cloud based cold chain management app.

*Innovation Recognition.* We received recognition for our innovative products:

We received the 2015 Silver Award for Achievement in Medical Technology from Seattle Business Magazine.

The evo™ Smart Shipper, designed and manufactured by SAVSU and marketed by BioLife, was the silver award recipient at the recent Medical Design Excellence Awards competition for the category Medical Product Packaging, Graphic Instructions, and Labeling Systems.

We were recognized by Seattle Business Magazine, which included BioLife in its annual list of the 100 best companies to work for in Washington state for 2015.

### ***Financial Performance Summary for 2015***

We grew our biopreservation media business 29% over 2014. This substantial increase was driven by a 45% increase in revenue from the regenerative medicine segment. At the end of 2014, we estimated that BioLife products were incorporated into the storage, shipping, freezing, and/or clinical administration processes and protocols of 175 regenerative medicine pre-clinical projects and clinical trials. This increased to over 200 by the end of 2015. We also drove more sales through our distributors, with an increase of 20% in revenue from distributors in 2015 compared to 2014.

Gross margin in 2015 was 59%, compared to 49% in 2014, driven by the significant increase in our biopreservation media revenue and the elimination of low margin contract-manufacturing revenue.

Our 2015 consolidated net loss was \$5.0 million and net loss attributable to BioLife was \$4.2 million. This is compared to a consolidated net loss of \$3.3 million in 2014, of which \$3.2 million was attributable to BioLife. The increase in the loss is primarily the result of increased headcount and spending related to the development and launch activities of our biologistex joint venture.

We used \$6.1 million in cash and short term investments in 2015 and ended the year with \$3.8 million in cash and short term investments. The increased cash burn is primarily the result of increased headcount and spending related to the development and launch activities of our biologistex joint venture.

### 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*

	Year Ended		% Change	
	2015	2014		
	December 31,			
	2015			
	2014			
	('000's)			
Revenue:				
Product revenue				
Core product sales	\$6,361	\$4,913	29	%
Contract manufacturing services	88	1,278	(93)	)%
Total revenue	6,449	6,191	4	%
Cost of sales	2,635	3,155	(16)	)%
Gross profit	\$3,814	\$3,036	26	%
Gross margin %	59.1 %	49.0 %		

*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 2015 increased compared to 2014 due to a 34% increase in volume sold offset by a slight decrease in our average selling price per

liter in 2015. The increase was primarily in sales to our regenerative medicine customers, which increased 45% in 2015 compared to 2014. Revenue from this market should increase over the next three to five years as some customers receive regulatory and marketing approvals for their clinical cell and tissue-based products.

*Contract Manufacturing Services.* In 2015, we recorded \$0.1 million in contract manufacturing revenue from one customer. In 2014, we recorded revenue from sales to one contract manufacturing customer of \$1.1 million. The contract with this customer was terminated in May 2014. In 2014, we also recorded \$0.2 million associated with one other contract manufacturing customer.

*Cost of Sales.* Cost of sales consists of raw materials, labor and overhead expenses. Cost of sales in 2015 decreased compared to 2014 due primarily to the significant reduction in volume in lower margin contract manufacturing services revenue.

*Gross Margin.* Gross margin as a percentage of revenue increased to 59.1% in 2015 compared to 49.0% in 2014. Gross margin as a percentage of revenue increased in 2015, due to the change in the mix of revenue, with sales of our core products having a higher gross margin than the contract manufacturing revenue.

*Revenue Concentration.* In 2015 and 2014, we derived approximately 10% and 11%, respectively, of our revenue from our relationship with one distributor of our products. In 2014, we also derived 18% of our revenue from our relationship with one contract-manufacturing customer. Revenue from customers located in foreign countries represented 21% and 16% of total revenue during the years ended December 31, 2015 and 2014, respectively.

**Operating Expenses**

Our operating expenses for the years ended December 31, 2015 and 2014 were:

	Year Ended December 31,		% Change	
	2015	2014		
	('000's)			
Operating Expenses:				
Research and development	\$ 1,379	\$ 871	58	%
Sales and marketing	2,584	1,330	94	%
General and administrative	4,868	3,970	23	%
Operating Expenses	8,831	6,171	43	%
% of revenue	137	% 100	%	

*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 2015 increased compared to 2014 due primarily to higher personnel costs, with the addition of personnel in the fourth quarter of 2014 and in 2015. In 2015, we capitalized \$1.7 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 2015 compared to 2014 was primarily due to higher personnel costs, with the addition of personnel in 2015, and initial marketing costs related to our new biologistex service.

*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 SAVSU related to the biologistex joint venture. Joint venture participation fees were approximately \$0.7 million in 2015 and \$0.3 million in 2014. The increase in other general and administrative costs in 2015 compared to 2014 was due to higher personnel costs with the addition of personnel in 2015 and higher corporate costs, including insurance, taxes, director fees and consulting fees. We do not expect further joint venture participation fees in 2016.

**Other Income (Expenses)**

*Interest Income.* We earn interest on our short term investments.

*Interest Expense.* In 2014, interest expense was related to interest on two notes payable. The reduction in interest expense from 2014 to 2015 was due to the conversion of the notes and interest into stock as of March 25, 2014.

*Amortization of Deferred Financing Costs.* Amortization of deferred financing costs represented the cost of warrants issued which were amortized over the life of the debt. In connection with the termination of the note facility agreements in 2014, we recorded \$101,852, the remaining unamortized costs, as an adjustment to additional paid in capital.

### **Liquidity and Capital Resources**

Based on our current expectations with respect to our revenue and expenses, including our expectations with respect to revenues from our new biologistex business which does not have a history of revenues, we expect that our current level of cash, cash equivalents and short term investments will be sufficient to meet our liquidity needs for our current operations through 2016. If our revenues, including biologistex revenues, do not grow as expected, and if we are not able to manage expenses sufficiently, we may be required to obtain additional equity or debt financing.

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.



Our future uses of cash, which may vary from time to time based on market conditions and other factors, are centered on growing our core business, the build out, financial co