

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

Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-K/A

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.

**Table of Contents**

	Page No.
<b><u>PART I</u></b>	
ITEM 1. <u>BUSINESS</u>	3
ITEM 1A. <u>RISK FACTORS</u>	11
ITEM 2. <u>PROPERTIES</u>	20
ITEM 3. <u>LEGAL PROCEEDINGS</u>	20
ITEM 4. <u>MINE SAFETY DISCLOSURES</u>	20
<b><u>PART II</u></b>	
ITEM 5. <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	21
ITEM 6. <u>SELECTED FINANCIAL DATA</u>	22
ITEM 7. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	23
ITEM 7A. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u>	30
ITEM 8. <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	31
	<u>INDEX TO FINANCIAL STATEMENTS</u> 31
	<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u> 32
ITEM 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	50
ITEM 9A. <u>CONTROLS AND PROCEDURES</u>	50
ITEM 9B. <u>OTHER INFORMATION</u>	51
<b><u>PART III</u></b>	
ITEM 10. <u>DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE</u>	52
ITEM 11. <u>EXECUTIVE COMPENSATION</u>	58
ITEM 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	62
ITEM 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE</u>	63
ITEM 14. <u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	64
<b><u>PART IV</u></b>	
ITEM 15. <u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	65
<u>SIGNATURES</u>	66



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

*Forward-Looking Statements*

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

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

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

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

**Recent Developments**

*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 December 31,		% Change	
	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 commitments, and scaling of the biologistex joint venture, development or acquisition of new products and technologies, and continuing to strengthen our balance sheet and competitive position. We may also seek equity or debt financing opportunistically for these purposes if we believe that market conditions are conducive to obtaining such financing.

On December 31, 2015, we had \$3.8 million in cash, cash equivalents and short term investments, compared to cash, cash equivalents and short term investments of \$9.9 million at December 31, 2014. 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.

#### ***Net Cash Used In Operating Activities***

During the year ended December 31, 2015, we used \$5.0 million in cash from operations, compared to \$3.2 million for the year ended December 31, 2014. Operating cash was primarily used to fund net losses.

#### ***Net Cash Provided/( Used) by Investing Activities***

Net cash provided by investing activities in 2015 was \$4.2 million, compared to cash used in investing activities of \$8.1 million in 2014. In 2015, the primary source of cash was proceeds from the maturity of available-for-sale securities, net of purchases. In 2014, the primary use of cash was the purchase of available-for-sale securities. Cash used in investing activities was used to purchase short term investments classified as available-for-sale with the proceeds from our stock offering in the first quarter of 2014. In addition, during 2015, we used \$1.3 million in cash related to the development of our biologistex software system and \$0.1 million related to purchases of equipment. In 2014, we used \$0.6 million in investing activities related to the purchase of equipment and tenant improvements to our leased facility.

#### ***Net Cash Provided by Financing Activities***

Net cash provided by financing activities was \$0.4 million and \$13.7 million in 2015 and 2014, respectively. In 2015, cash provided by financing activities was the result of proceeds from exercises of warrants and employee stock

options. In 2014, cash provided by financing activities included gross proceeds of \$15.4 million received in the registered public stock offering completed on March 25, 2014, net of placement agent fees of \$1.2 million and offering costs of \$0.6 million, and \$0.1 million from the exercise of stock options.

### **Critical Accounting Policies and Significant Judgments and Estimates**

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

#### ***Share-based Compensation***

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

### ***Income Taxes***

We follow the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and on the expected future tax benefits to be derived from net operating loss carryforwards measured using current tax rates. A valuation allowance is established if it is more likely than not that some portion or all of the deferred tax assets will not be realized. We have not recorded any liabilities for uncertain tax positions or any related interest and penalties. Our tax returns are open to audit for the years ending December 31, 2012 to 2015.

### ***Internal Use Software***

We capitalize costs associated with the development of the biologistex web and mobile applications, which we consider internal-use software. Capitalization of costs began in the first quarter of 2015, when we reached the application development stage. Such capitalized costs include external direct costs utilized in developing or obtaining the applications and payroll and payroll-related expenses for employees, who are directly associated with the development of the applications. Capitalization will cease once we have completed all substantial testing, at which time the applications are complete and ready for their intended use.

Maintenance and enhancement costs, including those costs in the post-implementation stages, will be expensed as incurred, unless such costs relate to substantial upgrades and enhancements to the software that result in added functionality, in which case the costs are capitalized. Capitalized costs will be amortized on a straight-line basis over estimated useful life of three years once the software has been commercially deployed.

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

As of December 31, 2015, we did not have any off-balance sheet arrangements.

### **Contractual Obligations**

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

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Not applicable.

30

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page No.</b>
<u>Report of Independent Registered Public Accounting Firm</u>	32
<u>Consolidated Balance Sheets</u>	33
<u>Consolidated Statements of Operations</u>	34
<u>Consolidated Statements of Comprehensive Loss</u>	35
<u>Consolidated Statements of Shareholders' Equity</u>	36
<u>Consolidated Statements of Cash Flows</u>	37
<u>Notes to Consolidated Financial Statements</u>	38

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders

BioLife Solutions, Inc.

Bothell, Washington

We have audited the accompanying consolidated balance sheets of BioLife Solutions, Inc. and Subsidiary ("the Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

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

/S/ PETERSON SULLIVAN LLP

Seattle, Washington

February 25, 2016

32

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

	December 31, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	\$2,173,258	\$2,538,758
Short term investments	1,651,341	7,399,636
Accounts receivable, trade, net of allowance for doubtful accounts of \$0 at December 31, 2015 and 2014	929,289	901,623
Inventories	1,834,635	965,224
Prepaid expenses and other current assets	384,414	360,521
Total current assets	6,972,937	12,165,762
Property and equipment		
Leasehold improvements	1,284,491	1,284,491
Furniture and computer equipment	557,666	476,788
Manufacturing and other equipment	1,025,521	972,386
Subtotal	2,867,678	2,733,665
Less: Accumulated depreciation	(1,421,279 )	(1,078,060 )
Net property and equipment	1,446,399	1,655,605
Internal use software	1,698,735	—
Intangible asset	2,215,385	2,215,385
Long term deposits	36,166	36,166
Total assets	\$12,369,622	\$16,072,918
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	\$1,029,373	\$474,662
Accrued expenses and other current liabilities	146,438	121,869
Accrued compensation	419,766	535,029
Deferred rent, current portion	130,216	130,216
Total current liabilities	1,725,793	1,261,776
Deferred rent, long term	784,458	874,825
Total liabilities	2,510,251	2,136,601
Commitments and Contingencies (Note 10)		
Shareholders' equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized, 12,448,391 and 12,084,859 shares issued and outstanding at December 31, 2015 and 2014	12,447	12,084
Additional paid-in capital	72,823,398	71,911,328
Accumulated other comprehensive loss	(451 )	(6,448 )



Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-K/A

Accumulated deficit	(64,326,923 )	(60,112,987 )
Total BioLife Solutions, Inc. shareholders' equity	8,508,471	11,803,977
Total non-controlling interest equity	1,350,900	2,132,340
Total shareholders' equity	9,859,371	13,936,317
Total liabilities and shareholders' equity	\$ 12,369,622	\$ 16,072,918

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

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

	Years Ended December 31,	
	2015	2014
Product sales	\$6,448,910	\$6,190,698
Cost of product sales	2,634,700	3,155,288
Gross profit	3,814,210	3,035,410
Operating expenses		
Research and development	1,378,807	871,100
Sales and marketing	2,583,731	1,329,746
General and administrative	4,868,801	3,970,254
Total operating expenses	8,831,339	6,171,100
Operating loss	(5,017,129 )	(3,135,690 )
Other income (expenses)		
Interest income	21,753	20,825
Interest expense	—	(177,308 )
Amortization of deferred financing costs	—	(13,022 )
Gain on disposal of property and equipment	—	4,400
Total other income (expenses)	21,753	(165,105 )
Net Loss	(4,995,376 )	(3,300,795 )
Net Loss attributable to non-controlling interest	781,440	83,045
Net Loss attributable to BioLife Solutions, Inc.	\$(4,213,936 )	\$(3,217,750 )
Basic and diluted net loss per common share attributable to BioLife Solutions, Inc.	\$(0.35 )	\$(0.31 )
Basic and diluted weighted average common shares used to calculate net loss per common share	12,177,396	10,447,030

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

**BioLife Solutions, Inc.****Consolidated Statements of Comprehensive Loss**

	Years Ended December 31,	
	2015	2015
Net Loss	\$ (4,995,376 )	\$ (3,300,795 )
Other comprehensive income (loss)		
Unrealized gain (loss) on available-for-sale investments	5,997	(6,448 )
Total other comprehensive income (loss)	5,997	(6,448 )
Comprehensive Loss	\$ (4,989,379 )	\$ (3,307,243 )
Comprehensive loss attributable to non-controlling interest	781,440	83,045
Comprehensive Loss attributable to BioLife Solutions, Inc.	\$ (4,207,939 )	\$ (3,224,198 )

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

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

	BioLife Solutions, Inc. Shareholders' Equity (Deficiency)					Total BioLife Solutions, Inc. Shareholders' Equity (Deficiency)	Non-Controlling Interest Equity	Total Shareholders' Equity (Deficiency)
	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit			
Balance, December 31, 2013	5,031,336	\$5,030	\$43,618,686	\$-	\$(56,895,237)	\$(13,271,521)	\$-	\$(13,271,521)
Stock-based compensation			229,679			229,679		229,679
Stock issued for services	74,720	75	209,925			210,000		210,000
Stock option exercises	68,520	69	83,525			83,594		83,594
Stock issued in connection with public registered stock offering March 25, 2014, net of transaction costs	3,588,878	3,589	13,592,641			13,596,230		13,596,230
Stock issued in connection with conversion of outstanding notes and interest on March 25, 2014, net of unamortized deferred financing costs of \$101,852	3,321,405	3,321	14,176,872			14,180,193		14,180,193
Other comprehensive loss				(6,448)		(6,448)		(6,448)
						-	2,215,385	2,215,385

Capital contribution of non- controlling interest in biologistex CCM, LLC joint venture									
Net loss					(3,217,750 )	(3,217,750 )	(83,045 )	(3,300,795 )	
Balance, December 31, 2014	12,084,859	12,084	71,911,328	(6,448)	(60,112,987)	11,803,977	2,132,340	13,936,317	
Stock-based compensation			511,457			511,457		511,457	
Stock options/warrant exercises	363,532	363	400,613			400,976		400,976	
Other comprehensive income				5,997		5,997		5,997	
Net loss					(4,213,936 )	(4,213,936 )	(781,440 )	(4,995,376 )	
Balance, December 31, 2015	12,448,391	\$12,447	\$72,823,398	\$(451 )	\$(64,326,923)	\$8,508,471	\$1,350,900	\$9,859,371	

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

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

	Years Ended December 31,	
	2015	2014
Cash flows from operating activities		
Net loss	\$(4,995,376 )	\$(3,300,795 )
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	343,218	258,119
Gain on disposal of property and equipment	—	(4,400 )
Stock-based compensation expense	511,457	229,679
Stock issued for services	—	210,000
Amortization of deferred financing costs	—	13,022
Lease incentives, net of amortization of deferred rent related to lease incentives	(126,999 )	(37,704 )
Accretion and amortization on available for sale investments	90,125	98,006
Change in operating assets and liabilities		
(Increase) Decrease in		
Accounts receivable, trade	(27,666 )	107,693
Inventories	(869,411 )	(544,300 )
Prepaid expenses and other current assets	15,192	(23,123 )
Increase (Decrease) in		
Accounts payable	194,386	(392,408 )
Accrued compensation and other current liabilities	(145,419 )	7,078
Accrued interest, related parties	—	177,308
Deferred rent	36,632	39,509
Net cash used in operating activities	(4,973,861 )	(3,162,316 )
Cash flows from investing activities		
Purchase of available-for-sale investments	(1,409,695 )	(7,952,119 )
Sales/maturities of available-for-sale investments	7,067,000	402,376
Cash received from sale of property and equipment	—	4,400
Costs associated with internal use software development	(1,283,685 )	—
Purchase of property and equipment	(134,012 )	(589,680 )
Net cash provided by (used in) investing activities	4,239,608	(8,135,023 )
Cash flows from financing activities		
Proceeds from exercise of common stock options and warrants	368,753	83,594
Proceeds from sale of common stock, net of expenses	—	13,596,230
Net cash provided by financing activities	368,753	13,679,824
Net increase (decrease) in cash and cash equivalents	(365,500 )	2,382,485
Cash and cash equivalents - beginning of year	2,538,758	156,273
Cash and cash equivalents - end of year	\$2,173,258	\$2,538,758
Non-cash investing and financing activities		

Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-K/A

Acquisition of intangible asset from non-controlling interest (See Note 1)	\$—	\$2,215,385
Conversion of notes payable and related party accrued interest to equity, net of unamortized deferred finance costs (See Note 1)	\$—	\$14,180,193
Costs incurred for capitalized internal use software not paid as of year-end (amounts are included in liabilities)	\$415,050	\$—
Proceeds from issuance of common stock on exercise of common stock options not received as of year-end	\$32,223	\$—

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. Organization and Significant Accounting Policies

#### Business

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

#### Recent Developments

##### *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. Unless otherwise noted, all share and per share data in these consolidated financial statements give effect to the 1-for-14 reverse stock split of our common stock.

##### *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 \$4.30 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, \$9.1



million was allocated to common stock and \$6.3 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 the Company’s public offering of units, the Company 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, the Company’s \$14.3 million indebtedness to the Note Holders under the terms of the Company’s previously disclosed facility agreements was extinguished, all remaining unamortized deferred finance costs of \$101,852 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.

## **Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its majority-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

### **Use of estimates**

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

### **Net loss per share**

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated using the weighted average number of common shares outstanding plus dilutive common stock equivalents outstanding during the period. Common stock equivalents are excluded for the years ending December 31, 2015 and 2014 since the effect is anti-dilutive due to the Company's net losses. Common stock equivalents include stock options and warrants.

Basic weighted average common shares outstanding, and the potentially dilutive securities excluded from loss per share computations because they are antidilutive, are as follows for the years ended December 31, 2015 and 2014:

	2015	2014
Basic and diluted weighted average common stock shares outstanding	12,177,396	10,447,030
Potentially dilutive securities excluded from loss per share computations:		
Common stock options	2,555,263	1,390,770
Common stock purchase warrants	7,195,997	7,428,141

### **Cash and cash equivalents**

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

No cash was paid for either interest expense or income taxes for the years ended December 31, 2015 and 2014.

### **Investments**

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

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

## **Inventories**

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

## **Accounts receivable**

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

## **Property and equipment**

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

## **Intangible asset**

Our intangible asset represents exclusive distribution rights to the Smart Containers associated with our biologistex CCM, LLC joint venture discussed previously. The intangible asset was recorded at its fair value of \$2,215,385 at the date contributed. We will review the intangible asset for impairment whenever an impairment indicator exists. We will assess recoverability by determining whether the carrying value of such asset will be recovered through the undiscounted expected future cash flows. If the future undiscounted cash flows are less than the carrying amount of these assets, we will recognize an impairment loss based on any excess of the carrying amount over the fair value of the assets. We did not recognize any intangible asset impairment charges in 2015 or 2014. We will amortize this asset over its estimated useful life of 20 years, the life of the distribution agreement with SAVSU with expected amortization of \$0.1 million per year. Amortization is expected to begin in the first quarter of 2016 with the initial commercial shipments of the Smart Containers. Amortization is based on the pattern in which the economic benefits of the intangible asset will be consumed or on a straight-line basis when the consumption pattern is not apparent.

### **Internal Use Software**

We capitalize costs associated with the development of the biologistex web and mobile applications, which we consider internal-use software. Capitalization of costs began in the first quarter of 2015, when we reached the application development stage. Such capitalized costs include external direct costs utilized in developing or obtaining the applications and payroll and payroll-related expenses for employees, who are directly associated with the development of the applications. Capitalization will cease once we have completed all substantial testing, at which time the applications are complete and ready for their intended use.

In 2015, we capitalized \$1.7 million in costs related to the development of the biologistex web and mobile applications. Of this amount, \$0.3 million was unpaid as of December 31, 2015. Maintenance and enhancement costs, including those costs in the post-implementation stages, will be expensed as incurred, unless such costs relate to substantial upgrades and enhancements to the software that result in added functionality, in which case the costs are capitalized. Capitalized costs will be amortized on a straight-line basis over estimated useful life of three years once the software has been commercially deployed.

### **Deferred rent**

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

### **Revenue recognition**

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

### **Income taxes**

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

We have not recorded any liabilities for uncertain tax positions or any related interest and penalties. Our tax returns are open to audit for years ending December 31, 2012 to 2015.

### **Advertising**

Advertising costs are expensed as incurred and totaled \$69,091 and \$19,584 for the years ended December 31, 2015 and 2014, respectively.

## **Operating segments**

As described above, our activities are directed in the life sciences field of biopreservation products and services. As of December 31, 2015 and 2014 this is the Company's only operating unit and segment.

## **Concentrations of credit risk and business risk**

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. At December 31, 2015, three customers accounted for 53% of gross accounts receivable. At December 31, 2014, two customers accounted for 28% of gross accounts receivable.

## **Research and development**

Research and development costs are expensed as incurred.

## **Stock Based Compensation**

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



The fair value of options at the date of grant is determined under the Black-Scholes option pricing model. During the years ended December 31, 2015 and 2014, the following weighted-average assumptions were used:

Assumptions	2015		2014	
Risk-free rate	1.77	%	2.01	%
Annual rate of dividends	—		—	
Historical volatility	105.20	%	105.20	%
Expected life	7.0 years		7.0 years	

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

We recognize compensation expense for only the portion of options that are expected to vest. Therefore, management applies an estimated forfeiture rate that is derived from historical employee termination data. The estimated forfeiture rate applied for the years ended December 31, 2015 and 2014 was 7.00%. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods. Our stock price volatility, option lives and expected forfeiture rates involve management's best estimates at the time of such determination, all of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option.

## Recent accounting pronouncements

In January 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities: Topic 825 (ASU 2016-01). The updated guidance enhances the reporting model for financial instruments, which includes amendments to address aspects of recognition, measurement, presentation and disclosure. Adoption of ASU 2016-01 is required for fiscal reporting periods beginning after December 15, 2017, including interim reporting periods within those fiscal years. The Company is currently evaluating the potential impact of the pending adoption of ASU 2016-01 on its consolidated financial statements.

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

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

On May 28, 2014, FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, Topic 606, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP

when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. Early adoption is not permitted. The updated standard becomes effective for us in the first quarter of fiscal 2018. We have not yet selected a transition method and we are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

With the exception of the new revenue standard discussed above, there have been no new accounting pronouncements not yet effective that have significance, or potential significance, to our Consolidated Financial Statements.

## 2. Accumulated Other Comprehensive Loss

The following table shows the changes in Accumulated Other Comprehensive Loss by component for the years ended December 31, 2015 and 2014:

	2015	2014
Beginning balance	\$(6,448)	\$—
Unrealized Gain (loss) on investments, current period	5,997	(6,448)
Ending balance	\$(451 )	\$(6,448)

### 3. Fair Value Measurement

In accordance with FASB ASC Topic 820, "Fair Value Measurements and Disclosures," ("ASC Topic 820"), the Company measures its cash and cash equivalents and short term investments at fair value on a recurring basis. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, ASC Topic 820 establishes a three-tier value fair hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than quoted prices included in Level 1 for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3 – Unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

As of December 31, 2015 and 2014, the Company does not have liabilities that are measured at fair value.

The following tables set forth the Company's financial assets measured at fair value on a recurring basis as of December 31, 2015 and December 31, 2014, based on the three-tier fair value hierarchy:

As of December 31, 2015	Level 1	Level 2	Total
Bank deposits	\$440,809	\$ —	\$440,809
Money market funds	1,732,449	—	1,732,449
Cash and cash equivalents	2,173,258	—	2,173,258
Corporate debt securities	1,401,453	—	1,401,453
Commercial paper	249,888	—	249,888
Short term investments	1,651,341	—	1,651,341
Total	\$3,824,599	\$ —	\$3,824,599

As of December 31, 2014	Level 1	Level 2	Total
Bank deposits	\$972,891	\$ —	\$972,891
Money market funds	1,565,867	—	1,565,867
Cash and cash equivalents	2,538,758	—	2,538,758
Corporate debt securities	6,799,702	—	6,799,702
Commercial paper	599,934	—	599,934
Short term investments	7,399,636	—	7,399,636
Total	\$9,938,394	\$ —	\$9,938,394

The fair values of bank deposits, money market funds, corporate debt securities and commercial paper classified as Level 1 were derived from quoted market prices as active markets for these instruments exist. The Company has no level 2 or level 3 financial assets. The Company did not have any transfers between Level 1 and Level 2 of the fair value hierarchy during the twelve months ended December 31, 2015 and December 31, 2014.

Investments in debt securities at December 31, 2015, are investment grade and carried a long-term rating of BBB+ or higher.

#### 4. Short Term Investments

The amortized cost and fair value of short term investments as of December 31, 2015 were as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	\$ 1,401,904	\$ —	\$ (451)	) \$ 1,401,453
Commercial paper	249,888	—	—	249,888
Total marketable securities	\$ 1,651,792	\$ —	\$ (451)	) \$ 1,651,341

As of December 31, 2015, there are no short term investments, classified and accounted for as available-for-sale securities that have been in a continuous unrealized loss position in excess of twelve months.

As of December 31, 2015, the amortized cost and fair value of short term investments by contractual maturity were as follows:

	Amortized Cost	Fair Value
Due in 1 year or less	\$ 1,651,792	\$ 1,651,341
Total marketable securities	\$ 1,651,792	\$ 1,651,341

The amortized cost and fair value of short term investments as of December 31, 2014 were as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	\$ 6,806,150	\$ —	\$ (6,448)	) \$ 6,799,702
Commercial paper	599,934	—	—	599,934
Total marketable securities	\$ 7,406,084	\$ —	\$ (6,448)	) \$ 7,399,636

#### 5. Inventories

Inventories consist of the following at December 31, 2015 and 2014:

Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-K/A

	2015	2014
Raw materials	\$299,952	\$362,656
Work in progress	666,124	79,012
Finished goods	868,559	523,556
Total	\$1,834,635	\$965,224

## 6. Deferred Rent

Deferred rent consists of the following at December 31, 2015 and 2014:

	2015	2014
Landlord-funded leasehold improvements	\$1,124,790	\$1,124,790
Less accumulated amortization	(375,530 )	(248,531 )
Total (current portion \$130,216 at December 31, 2015 and 2014)	749,260	876,259
Straight line rent adjustment	165,414	128,782
Total deferred rent	\$914,674	\$1,005,041

During 2014, the Company recorded \$125,000 in deferred rent relating to leasehold improvements funded by the Company's landlord as incentives under the facility lease, offset by payments to the landlord of \$47,237. During 2015, the Company did not receive landlord funded lease incentives. During the years ended December 31, 2015 and 2014, the Company recorded \$126,999 and \$115,468, respectively, in deferred rent amortization of these landlord funded leasehold improvements.

In addition, during the years ended December 31, 2015 and 2014, the Company recorded deferred rent of \$36,632 and \$39,509, which represented the difference between cash rent payments and the recognition of rent expense on a straight-line basis over the terms of the lease.

## 7. Income Taxes

Income tax benefit reconciled to tax calculated at statutory rates is as follows:

	2015	2014
Federal tax (benefit) at statutory rate	\$(1,698,428)	\$(1,122,270)
Change in valuation allowance	1,430,291	1,122,900
Add back tax benefit on loss attributable to non-controlling interest in subsidiary	265,690	—
Other	2,447	(630 )
Benefit for income taxes, net	\$—	\$—

At December 31, 2015 and 2014, the components of the Company's deferred taxes are as follows:

2015	2014
------	------



Deferred tax assets (liabilities)		
Net operating loss carryforwards	\$ 11,080,303	\$ 10,046,713
Accrued compensation	120,344	170,161
Depreciation	21,835	14,282
Section 263a inventory adjustment	79,110	20,233
Stock-based compensation	565,349	434,740
Suspended loss of subsidiary	246,241	—
Other	25,323	22,085
Total	12,138,505	10,708,214
Less: Valuation allowance	(12,138,505)	(10,708,214)
Net deferred tax asset	\$—	\$—

The Company has the following net operating loss tax carryforwards available at December 31, 2015:

Year of Expiration	Net Operating Losses
2018	\$ 1,425,000
2019	1,234,000
2020	2,849,000
2021	4,168,000
2023	1,217,000
2024	646,000
2025	589,000
2026	873,000
2027	2,607,000
2028	2,512,000
2029	2,196,000
2030	1,232,000
2031	1,028,000
2032	437,000
2033	37,000
2034	6,427,000
2035	3,112,000
Total	\$ 32,589,000

In the event of a significant change in the ownership of the Company, the utilization of such loss and tax credit carryforwards could be substantially limited.

## 8. Warrants

The following table summarizes warrant activity for the years ended December 31, 2015 and 2014:

	Year Ended December 31, 2015		Year Ended December 31, 2014	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price
Outstanding at beginning of year	7,428,141	\$ 4.49	517,858	\$ 1.02
Granted	—	—	6,910,283	4.75
Exercised	(232,144 )	1.03	—	—
Forfeited/Expired	—	—	—	—

Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-K/A

Outstanding and exercisable at end of year    7,195,997    \$ 4.60        7,428,141    \$ 4.49

As discussed in Note 1, during the year ended December 31, 2014, we issued 3,588,878 warrants with an expiration date of March 25, 2021 in connection with the Company's public offering of units on March 25, 2014. Each whole warrant is exercisable for a period of seven years to acquire one share of common stock with an exercise price of \$4.75 per share. In addition, we issued 3,321,405 warrants with an expiration date of March 25, 2021 in connection with the conversion of approximately \$14.3 million of indebtedness to the Company's existing Note Holders into equity on March 25, 2014. Each whole warrant is exercisable for a period of seven years to acquire one share of common stock with an exercise price of \$4.75 per share.

The outstanding warrants have expiration dates between August 2016 and March 2021.

## 9. Stock-Based Compensation

### *Stock Compensation Plans*

Our stock-based compensation programs are long-term retention programs that are intended to attract, retain and provide incentives for talented employees, officers and directors, and to align stockholder and employee interests. We have the following stock-based compensation plans and programs:

During 1998, we adopted the 1998 Stock Option Plan (the “1998 Plan”). An aggregate of 285,714 shares of common stock were reserved for issuance upon the exercise of options granted under the 1998 Plan. In September 2005, the shareholders approved an increase in the number of shares available for issuance to 714,285 shares. The 1998 Plan expired on August 31, 2008. The options are exercisable for up to ten years from the grant date. As of December 31, 2015, there were outstanding options to purchase 359,995 share of Company common stock under the 1998 Plan.

Subsequent to the expiration of the 1998 Plan, the Company issued, outside of the 1998 Plan, non-incentive stock options for an aggregate of 1,243,584 shares of Company common stock. Of this amount, 782,960 remain outstanding.

During 2013, we adopted the 2013 Performance Incentive Plan (the “2013 Plan”), which allows us to grant options or restricted stock units to all employees, including executive officers, outside consultants and non-employee directors. An aggregate of 3.1 million shares of common stock are reserved for issuance upon the exercise of options granted under the 2013 Plan. Option vesting periods are generally four years for the 2013 Plan. Options granted under this plan generally expire ten years from the effective date of grant. As of December 31, 2015, there were outstanding options to purchase 1,412,308 shares of Company common stock and no unvested restricted stock units outstanding under the 2013 Plan.

### *Issuance of Shares*

When options and warrants are exercised, it is the Company’s policy to issue new shares.

### *Stock Option Activity*

The following is a summary of stock option activity under our stock option plans for 2015 and 2014, and the status of stock options outstanding at December 31, 2015 and 2014:

	Year Ended December 31, 2015		Year Ended December 31, 2014	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price
Outstanding at beginning of year	1,390,770	\$ 1.50	1,417,309	\$ 1.36
Granted	1,300,881	2.06	95,000	3.36
Exercised	(131,388 )	1.23	(68,520 )	1.22
Forfeited	(3,438 )	3.77	(49,895 )	1.51
Expired - vested	(1,562 )	3.77	(3,124 )	2.23
Outstanding at end of year	2,555,263	\$ 1.80	1,390,770	\$ 1.50
Stock options exercisable at year end	1,185,582	\$ 1.42	1,225,358	\$ 1.33

Weighted average fair value of options granted was \$1.75 and \$2.84 per share for the years ended December 31, 2015 and 2014, respectively.

During the year ended December 31, 2015, stock options covering 131,388 shares of common stock with a total intrinsic value of \$127,312 were exercised. During the year ended December 31, 2014, stock options covering 68,520 shares of common stock with a total intrinsic value of \$155,704 were exercised.

As of December 31, 2015, there was \$1,252,704 of aggregate intrinsic value of outstanding stock options, including \$1,106,275 of aggregate intrinsic value of exercisable stock options. Intrinsic value is the total pretax intrinsic value for all “in-the-money” options (i.e., the difference between the Company’s closing stock price on the last trading day of 2015 and the exercise price, multiplied by the number of shares) that would have been received by the option holders had all option holders exercised their options as of December 31, 2015. This amount will change based on the fair market value of the Company’s stock.

The following table summarizes information about stock options outstanding at December 31, 2015:

Range of Exercise Prices	Number Outstanding at December 31, 2015	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$ 0.49-\$1.00	167,853	1.95	\$ 0.92
\$ 1.01-\$1.30	670,651	3.63	\$ 1.14
\$ 1.31-\$2.00	290,167	4.57	\$ 1.43
\$ 2.01-\$10.75	1,426,592	9.25	\$ 2.28
	2,555,263	6.76	\$ 1.80

The weighted average remaining contractual life of exercisable options at December 31, 2015, is 3.8 years. Total unrecognized compensation cost at December 31, 2015 of \$2,075,593 is expected to be recognized over a weighted average period of 3.2 years.

#### *Restricted Stock Units*

As of December 31, 2015, there were no restricted stock units outstanding. There were no restricted stock units granted, exercised or forfeited during 2014 or 2015.

## **10. Commitments and Contingencies**

### **Leases**

On August 19, 2014 we signed an amendment to our lease agreement, which expanded the premises leased by the Company from the landlord from approximately 26,000 to approximately 30,000 rentable square feet. The term of the lease continues until July 31, 2021 with two options to extend the term of the lease, each of which is for an additional

period of five years, with the first extension term commencing, if at all, on August 1, 2021, and the second extension term commencing, if at all, immediately following the expiration of the first extension term. In accordance with the amended lease agreement, our monthly base rent increased to approximately \$59,700 effective January 1, 2015, with scheduled annual increases each August and again in October for the most recent amendment. The Company is also required to pay an amount equal to the Company's proportionate share of certain taxes and operating expenses.

The following is a schedule of future minimum lease payments required under the facility leases as of December 31, 2015:

Year Ending  
December 31

2016	\$676,000
2017	690,000
2018	704,000
2019	718,000
2020	733,000
Thereafter	433,000
Total	\$3,954,000

Rental expense for this facility lease for the years ended December 31, 2015 and 2014 totaled \$809,464 and \$728,086, respectively. These amounts include the Company's proportionate share of property taxes and other operating expenses as defined by the lease.

### **Employment agreements**

We have employment agreements with the Chief Executive Officer, Chief Financial Officer, Chief Technology Officer, Vice President, Marketing and Vice President, Global Sales. None of these employment agreements is for a definitive period, but rather each will continue indefinitely until terminated in accordance with its terms. The agreements provide for a base annual salary, payable in monthly (or shorter) installments. In addition, the agreement with the Chief Executive Officer provides for incentive bonuses at the discretion of the Board of Directors. Under certain conditions and for certain of these officers, we may be required to pay additional amounts upon terminating the officer or upon the officer resigning for good reason.

### **biologistex**

Our agreement to form the biologistex joint venture requires us to make an initial capital contribution of \$2.4 million. As of December 31, 2015 the remaining capital contribution commitment is \$2.2 million. In addition, we agreed to pay SAVSU \$1 million in consideration of SAVSU's participation in biologistex. As of December 31, 2015, we have recorded the entire amount and have no further commitment. In addition, biologistex is required to purchase approximately \$2.6 million in Smart Containers from SAVSU, of which \$0.2 million has been purchased as of December 31, 2015. See "Note 1. Organization and Significant Accounting Policies – Recent Developments – biologistex Joint Venture" for more information.

### **Litigation**

From time to time, the Company is subject to various legal proceedings that arise in the ordinary course of business, none of which are currently material to the Company's business.

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



None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### ***Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to ensure that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding required disclosure. During the year ended December 31, 2015 we carried out an evaluation, under the supervision and with the participation of our management, including the chief executive officer and chief financial officer, as required by the rules and regulations under the Exchange Act, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2015, our disclosure controls and procedures were effective.

### **Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of the financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. This process includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

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

Our management, including our chief executive officer and chief financial officer, conducted an evaluation of the design effectiveness of our internal control over financial reporting based on the framework in “Internal Control — Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission, as of December 31, 2015. Based on our assessment, we conclude that as of December 31, 2015 our internal control over financial reporting was effective.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management’s report in this annual report.

#### ***Changes in Internal Control Over Financial Reporting***

There were no changes that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the three months ended December 31, 2015.

#### ***Limitations on Controls***

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that our objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

#### **ITEM 9B. OTHER INFORMATION**

None.



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

The following table and text set forth the names and ages of our directors and executive officers as of February 25, 2016. The board is comprised of only one class. Also provided herein are brief descriptions of the business experience of each director and executive officer during the past five years (based on information supplied by them) and an indication of directorships held by each director in other public companies subject to the reporting requirements under the Federal securities laws. During the past ten years, none of our directors or executive officers has been involved in any legal proceedings that are material to an evaluation of the ability or integrity of such person:

<b>Name</b>	<b>Age</b>	<b>Position and Offices With the Company</b>
Todd Berard	47	Vice President, Marketing
Aby J. Mathew, Ph.D.	44	Chief Technology Officer and Senior Vice President
Michael Rice	53	Chief Executive Officer, President, and Director
Matt Snyder	64	Vice President, Global Sales
Daphne Taylor	49	Secretary, Chief Financial Officer and Vice President, Finance and Administration
Raymond Cohen	56	Chairman of the Board
Thomas Girschweiler	58	Director
Andrew Hinson	52	Director
Joseph Schick	54	Director
Rick Stewart	63	Director

**Todd Berard** has been Vice President of Marketing since February 2015, responsible for corporate branding, product branding, marketing and launch strategy, and product management. He is also a key team member in the management and growth of all product launches; including biologistex. Before his appointment as Vice President of Marketing, Mr. Berard had served as Senior Director of Marketing since July 2014. Previous to BioLife, Mr. Berard served as Director of Marketing at Verathon Medical; a division of Roper Inc., from September 2010 until July 2014, overseeing the global marketing, product development, and product launch strategies for a portfolio of six medical device brands. He also managed all strategic partnerships for product development, and helped guide the organization. Verathon had global sales in 2014 of roughly \$180M; and Mr. Berard oversaw a creative and product management team of 12. Responsibilities included all global marketing initiatives and campaigns, strategy, product portfolio management, and strategic planning. He has over twenty years of experience in life sciences, health care, and technology; working for both global leaders and small technology startups, including the University of Washington School of Medicine, DuPont, and Medtronic. He has a Bachelor of Science Degree in Biochemistry from the University of Vermont and an MBA from the University of Washington Foster School of Business

**Aby J. Mathew, Ph.D.**, has been Senior Vice President and Chief Technology Officer since February 2011. From January 2007 through February 2011, Dr. Mathew served as Senior Scientist, Director of Strategic Relations, and Senior Director of Strategic Relations. From June 2003 through January 2007, Dr. Mathew served as Director of Manufacturing. From September 2000 through June 2003, Dr. Mathew served as Clinical Accounts Manager and Director of Hypothermic Preservation for Cryomedical Sciences/BioLife Solutions. Dr. Mathew has been actively engaged in research on low temperature biopreservation of mammalian cells, tissues and organs since 1994, and his studies contributed to the development of our current commercial HypoThermosol® and CryoStor® product platforms and intellectual property foundation.

**Michael Rice** has been President and Chief Executive Officer and a director of the Company since August 2006, and was chairman of the board from August 2007 to November 2013. Mr. Rice has more than 30 years of leadership and entrepreneurial experience in the medical and high tech industries. He was most recently the senior business development manager for medical and wireless products at AMI Semiconductor, from October 2004 to August 2006. From October 2000 to October to August 2006, Mr. Rice also served as the director of marketing and business development at Cardiac Science, Inc., a manufacturer of automated external defibrillators. Prior to that, from May 1998 to October 2000, he was the Vice President, Sales and Marketing for TEGRIS Corporation, a privately held network services provider. Mr. Rice also spent 12 years, from May 1986 to May 1998 at Physio Control Corporation in several sales and marketing management roles prior to its acquisition by Medtronic Inc. The board has determined that Mr. Rice should serve as a director because it values management's insight.

**Matt Snyder** has been the Vice President, Global Sales, since February 2015. Prior to February 2015, he served as Senior Director of Sales Operations of the Company since November of 2012. From January 2011 through March 2012, he was the Director of North American Distribution at Medical Device Systems, and from August 2009 through October 2010, he was the Business Development Manager for Antek Healthware. Mr. Snyder has over 30 years of leadership and entrepreneurial experience in the pharmaceutical, biotech and medical capital equipment industries. Prior to joining the Company, Mr. Snyder served in various sales management positions at Genentech, Cardiac Science, SpaceLabs Medical and Medical Graphics.

**Daphne Taylor** has been Vice President, Finance & Administration, and Chief Financial Officer since August 2011, and Secretary since January 30, 2013 and from March 2011 through July 2011 she served as Corporate Controller. Prior to joining the Company, Ms. Taylor served as Vice President, Corporate Controller and Chief Accounting Officer of Cardiac Science Corporation from November 2005 through January 2009. From April 2002 through November 2005, she held various positions, including Vice President and Corporate Controller for LookSmart, Inc.

**Raymond W. Cohen** joined the board in May 2006, and has served as chairman of the board since November 2013. Mr. Cohen is an accredited public company director and has extensive international medical device experience holding several Chairman and Chief Executive Officer positions on the boards of both publicly listed and private life sciences companies in the United States and Europe. Mr. Cohen currently serves as the Chief Executive Officer and member of the board of directors of Irvine, CA based Axonics Modulation Technologies, Inc., a privately held venture backed developer of neuromodulation devices. Since July 2013, Mr. Cohen also currently serves as the non-executive Chairman of Lombard Medical (NASDAQ:EVAR) a manufacturer and marketer of endovascular stent graphs. Mr. Cohen also currently serves as a non-executive director, chairman of the compensation committee and member of the audit committee of Spectrum Pharmaceuticals, Inc. (NASDAQ:SPPI), a developer and marketer of oncology and hematology drugs. Cohen also currently serves as a director and chairman of the audit committee at JenaValve Technology, Inc., a private venture backed developer, manufacturer and marketer of transcatheter aortic valve systems; and non-executive Chairman of Synchroness, Inc., a contract engineering firm. From mid-2010 to late 2012, Mr. Cohen served as Chief Executive Officer of Vessix Vascular, Inc., a developer of a novel percutaneous radiofrequency balloon catheter renal denervation system used to treat uncontrolled hypertension. In November 2012, during his tenure as Chief Executive Officer, Boston Scientific Corporation (NYSE:BSX) acquired the company. Previously, from 1997 to 2006, Mr. Cohen served as Chairman and Chief Executive Officer of NASDAQ listed Cardiac Science, Inc., which in 2004 was ranked as the 4th fastest growing technology company in North America on Deloitte & Touche's Fast 500 listing. In 2008, Mr. Cohen was named by AeA as the Private Company Life Science CEO of the Year. Mr. Cohen was named Entrepreneur of the Year in 2002 by the Orange County Business Journal and was a finalist for Ernst & Young's Entrepreneur of the Year in the medical company category in 2004. Mr. Cohen holds a B.S. in Business Management from Binghamton University. The board has determined that Mr. Cohen should serve as a director because of his extensive experience with public companies.

**Thomas Girschweiler** was a member of our board from 2003 to March 2014 and joined the board again in May 2015. Mr. Girschweiler has been engaged in corporate financing activities on his own behalf since 1996. From 1981 to 1996, he was an investment banker with Union Bank of Switzerland. Mr. Girschweiler is a graduate of the Swiss Banking School. The board has determined that Mr. Girschweiler should serve as a director because of his experience

in corporate financing activities and his status as a significant shareholder.

**Andrew Hinson** joined the board in February 2007. He is currently the Vice President of Clinical and Regulatory Affairs for LoneStar Heart, Inc., a global developer of medical devices, small molecule, and cellular-based therapies for cardiovascular disease. Mr. Hinson joined CardioPolymers, now a wholly-owned subsidiary of LoneStar Heart, in November 2004. From 2001 to 2004, Mr. Hinson served as the Senior Director of research and clinical development at AnGes MG, Inc. (TSE: 4563) a biotechnology firm engaged in the development and commercialization of novel gene and cell therapies for the treatment of cardiovascular disease. Prior to that Mr. Hinson had a long career with Procter & Gamble Pharmaceutical (NYSE:PG) holding multiple technical and management positions in research, clinical development and medical affairs. Mr. Hinson has diverse experience in the cell and gene therapy markets and extensive experience with regulatory affairs and clinical development of new therapies for cardiac, neurologic, and gastrointestinal diseases. The board has determined that Mr. Hinson should serve as a director because of his experience and knowledge of companies in the biotechnology space.

**Joseph Schick** joined the board in November 2013. He is currently the Chief Financial Officer of Corbis, a global digital media company, since May 2013. Prior to his position at Corbis, from March 2009 through July 2013, Mr. Schick was Chief Financial Officer at Talyst, a pharmacy automation hardware and software company. Mr. Schick served as Chief Financial Officer at Vertafore from October 2006 through January 2009, an enterprise software company for the insurance industry. Mr. Schick was also in various roles at travel company Expedia (NASDAQ: EXPE), including Senior Vice President of Finance. Mr. Schick has significant experience with SEC reporting, strategic planning, and mergers and acquisitions. Mr. Schick started his career with Arthur Andersen and is a CPA who received his B.S. in Accounting from the University of Illinois. The board has determined that Mr. Schick should serve as a director because of his financial expertise.

**Rick Stewart** joined the board in February 2013. Mr. Stewart is currently the Managing Director of West Summit Advisors. Prior to November 2015, he served as President and Chief Executive Officer, and a member of the board of directors of Cardiac Dimensions, a medical device company from 2001 to November 2015. From 1998 to 2001 he was President and Chief Executive Officer of Tegriss Corporation, a leading IT infrastructure and enterprise applications provider for vertical markets. Prior to that Mr. Stewart had a long career within Eli-Lilly in its Medical Device and Diagnostics Unit, holding multiple executive positions in general and technical management, sales, marketing and business development. Mr. Stewart was a member of the senior team that led a buyout of the Physio-Control subsidiary from Eli-Lilly in 1994 which shortly thereafter was taken public. He received an MBA from the University of Washington. The board has determined that Mr. Stewart should serve as a director because his experience in the medical device field and executive acumen.

Except as otherwise provided by law, each director shall hold office until either their successor is elected and qualified, or until he or she sooner dies, resigns, is removed or becomes disqualified. Officers serve at the discretion of the Board.

There are no family relationships between any of our director nominees or executive officers and any other of our director nominees or executive officers.

#### **SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE**

Section 16(a) of the Exchange Act requires our directors, certain officers and holders of 10% or more of any class of our stock to report to the SEC, by a specified date, initial reports of ownership and reports of changes in ownership of our stock and other equity securities. Based solely on a review of the copies of these reports furnished to the Company and written representation from the reporting persons, the Company believes that during the 2015 fiscal year, Thomas Girschweiler and Taurus4757 GmbH filed one Form 4 late relating to one transaction.



## **BOARD OF DIRECTORS**

### **Overview**

Our Bylaws provide that the size of our Board is to be determined from time to time by resolution of the Board but shall consist of at least three members. Our Board presently consists of six members. Our Board has determined four of our directors – Messrs. Cohen, Hinson, Schick and Stewart – to be independent under the rules of the NASDAQ Stock Market, after taking into consideration, among other things, those transactions described under “Certain Transactions”. Mr. Cohen serves as Chairman of the Board. The Board does not have a lead director; however, recognizing that the Board consists of a majority of independent directors, in addition to the Board’s strong committee system (as described more fully below), we believe this leadership structure is appropriate for the Company and allows the Board to maintain effective oversight of management.

At each annual meeting of stockholders, members of our Board are elected to serve until the next annual meeting and until their successors are duly elected and qualified.

## Committees of the Board of Directors

The Board has established an Audit Committee, a Compensation Committee, and a Nominating and Governance Committee. Each committee operates pursuant to a written charter that may be viewed on our website at [www.biolifesolutions.com](http://www.biolifesolutions.com).

The following table sets forth the current composition of the three standing committees of our Board:

Name	Board	Audit	Compensation	Nominating and Governance
Mr. Rice	X			
Mr. Cohen	Chair	X	X	X
Mr. Hinson	X		X	Chair
Mr. Schick (financial expert)	X	Chair		
Mr. Stewart	X	X	Chair	
Mr. Girschweiler	X			

**Audit Committee.** Our Audit Committee’s role includes the oversight of our financial, accounting and reporting processes; our system of internal accounting and financial controls; and our compliance with related legal, regulatory and ethical requirements. The Audit Committee oversees the appointment, compensation, engagement, retention, termination and services of our independent registered public accounting firm, including conducting a review of its independence; reviewing and approving the planned scope of our annual audit; overseeing our independent registered public accounting firm’s audit work; reviewing and pre-approving any audit and non-audit services that may be performed by our independent registered public accounting firm; reviewing with management and our independent registered public accounting firm the adequacy of our internal financial and disclosure controls; reviewing our critical accounting policies and the application of accounting principles; and monitoring the rotation of partners of our independent registered public accounting firm on our audit engagement team as required by regulation.

In addition, the Audit Committee’s role includes meeting to review our annual audited financial statements and quarterly financial statements with management and our independent registered public accounting firm. The Audit Committee has the authority to obtain independent advice and assistance from internal or external legal, accounting and other advisors, at the Company’s expense.

The Board has determined that all members of our Audit Committee meet the independence and financial literacy standards of the NASDAQ Stock Market and applicable SEC rules. The Board of Directors has determined that Mr. Schick is an “audit committee financial expert” as defined by the rules of the SEC.

**Compensation Committee** . The purpose of the Compensation Committee is to provide guidance to management and to assist the Board in the discharge of its fiduciary responsibilities relating to the compensation of executive officers, the organizational structure, succession, retention and training policies and review and oversight of benefit programs. Our Compensation Committee is responsible for reviewing the recommendations of our Chief Executive Officer and Chief Financial Officer, making recommendations to the Board, regarding the compensation of our executive officers, and ensuring that the total compensation paid to the executive officers is reasonable and competitive, and does not promote excessive risk taking. In making its recommendation to the Board, the Compensation Committee considers the results of the most recent stockholder advisory vote on executive compensation. The Chief Executive Officer may not be present during voting or deliberation on his compensation. The Compensation Committee is also responsible for reviewing and making recommendations to the Board regarding director and committee member compensation. In addition, the Compensation Committee approves and has oversight over our bonus plans for executive officers and/or stock based compensation plans and oversight of our overall compensation plans and benefit programs, including approval and oversight of grants.

In discharge of its duties related to administration of executive bonus plans, the Compensation Committee may, subject to the terms of each plan, delegate authority to management for the day-to-day non-material administration of such plans. Further, the Compensation Committee may, subject to the terms of each plan, delegate authority to management to make grants to non-executive officers under stock-based compensation plans.

The Compensation Committee has the authority to obtain independent advice and assistance from internal or external legal, accounting and other advisors, at the Company's expense. The Compensation Committee may select, or receive advice from, a compensation consultant, legal counsel or other adviser to the Committee, other than in-house legal counsel, only after taking into consideration the six factors outlined in Rule 10C-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Compensation Committee engaged Radford, an Aon Hewitt company and independent compensation consultant ("Radford"), to assist it in: (i) an assessment of the Company's executive compensation program; (ii) developing a peer group of companies for compensation comparison purposes; (iii) completing a market assessment of director and executive officer compensation; (iv) evaluating the Company's equity-based compensation plan; and (v) recommending the amount and form of director and executive officer compensation. Radford reported to and was accountable to the Compensation Committee. Radford did not provide any services to us in the year ended December 31, 2015 beyond its engagement as an advisor to the Compensation Committee. After review and consultation with Radford, the Compensation Committee determined that Radford is independent, and there is no conflict of interest resulting from retaining Radford. In reaching this conclusion, the Compensation Committee considered the factors set forth in Rule 10C-1 of the Exchange Act and NASDAQ listing standards.

The members of the Compensation Committee are independent directors within the meaning of the listing standards of the NASDAQ Stock Market.

***Nominating and Governance Committee*** . Our Nominating and Governance Committee's primary purpose is to evaluate candidates for membership on our Board and make recommendations to our Board regarding candidates; make recommendations with respect to the composition of our Board and its committees; provide guidance to our human resources, legal, and finance departments relating to director orientation programs; recommend corporate governance principles applicable to the Company; manage periodic review, discussion and evaluation of the performance of our Board, its committees and its members and oversee and monitor compliance with our Code of Business Conduct and Ethics. The Nominating and Governance Committee has the authority to obtain independent advice and assistance from internal or external legal, accounting and other advisors, at the Company's expense.

All members of our Nominating and Governance Committee are independent under the listing standards of the NASDAQ Stock Market.

The Nominating and Governance Committee will consider candidates recommended by stockholders in accordance with the procedures set forth in our Bylaws, and prior to the date it recommends a slate of director nominees to the Board. Pursuant to the Nominating and Governance Committee Charter, there is no difference in the manner in which a nominee recommended by a stockholder or otherwise is evaluated.

In carrying out its function to nominate candidates for election to our Board, the Nominating and Governance Committee considers the Board's mix of skills, experience, character, commitment and diversity—diversity being broadly construed to mean a variety of opinions, perspectives and backgrounds, such as gender, race and ethnicity differences, as well as other differentiating characteristics, all in the context of the requirements and needs of our Board at that point in time. In reviewing potential candidates, the Committee will also consider all relationships between any proposed nominee and any of our stockholders, competitors, customers, suppliers or other persons with a relationship to the Company. The Nominating and Governance Committee believes that each candidate should be an individual who has demonstrated exceptional ability and judgment, who are willing and able to make a sufficient time commitment to the Company, and who shall be most effective, in conjunction with the other nominees to the Board, in collectively serving the long - term interests of the stockholders.

The Nominating and Governance Committee's methods for identifying candidates for election to our Board include the solicitation of ideas for possible candidates from a number of sources, including from members of our Board, our executive officers, individuals who our executive officers or Board members believe would be aware of candidates who would add value to our Board and through other research. The Nominating and Governance Committee may, from time to time, retain, for a fee, one or more third-party search firms to identify suitable candidates. The Nominating and Governance Committee will consider all candidates identified through the processes described above, and will evaluate each candidate, including incumbents, based on the same criteria.

The Nominating and Governance Committee does not have a formal policy with respect to diversity; however, the Board and the Nominating and Governance Committee believe that it is essential that the Board members represent diverse viewpoints.

### **Number of Meetings**

The Board held a total of six meetings during 2015. Our Audit Committee held four meetings in 2015, our Compensation Committee held two meetings in 2015 and our Nominating and Governance Committee held one meeting during 2015. Each incumbent director attended 75% or more of the aggregate of (i) the total number Board meetings (during the period that he served) and (ii) the total number of Board committee meetings (during the periods that he served).

### **Board Member Attendance at Annual Stockholder Meetings**

Although we do not have a formal policy regarding director attendance at annual stockholder meetings, directors are encouraged to attend these annual meetings absent extenuating circumstances. At our 2015 annual meeting, there were five directors present.

### **Director Compensation**

As confirmed in service agreements we entered into on May 4, 2015 with each of our non-employee directors, during the year ended December 31, 2015, non-employee directors were compensated with an annual retainer fee of \$40,000. In addition, the Board Chairman was compensated an additional \$110,000 for the year. Committee chairpersons were compensated with additional annual retainers as follows:

	Annual Retainer
Audit Committee Chairman	\$ 10,000
Compensation Committee Chairman	\$ 7,500
Nominating and Governance Committee Chairman	\$ 5,000

A total of \$322,500 in cash director compensation was recorded during the year ended December 31, 2015. Our non-employee directors were each granted options to purchase 15,000 shares at \$2.06 per share granted on May 4, 2015 which options vest on May 4, 2016. The following table sets forth information regarding compensation earned by our non-employee directors for the year ended December 31, 2015.

Name	Annual Retainer (\$)	Board and Committee Chair and Committee Membership Fees (\$)	Total Cash Fees Earned (\$)	Restricted Stock Unit Awards (\$)	Option Awards (\$)	Total (\$)
Raymond Cohen	40,000	110,000	150,000	—	26,139	176,139
Thomas Girschweiler	30,000	—	30,000	—	26,139	56,139
Andrew Hinson	40,000	5,000	45,000	—	26,139	71,139
Joseph Schick	40,000	10,000	50,000	—	26,139	76,139
Rick Stewart	40,000	7,500	47,500	—	26,139	73,639

#### Codes of Business Conduct and Ethics

We believe in sound corporate governance practices and have always encouraged our employees, including officers and directors to conduct business in an honest and ethical manner. Additionally, it has always been our policy to comply with all applicable laws and provide accurate and timely disclosure.

Accordingly, the Board has adopted a formal written code of ethics for all employees. The Board has adopted an additional corporate code of ethics for its Chief Executive Officer, Chief Financial Officer and other senior financial officers, which is intended to be a “code of ethics” as defined by applicable SEC rules. The Code of Ethics is publicly available on our website at

<http://biolifesolutions.com/biopreservation-media/CODE-OF-ETHICS-FOR-CEO-AND-SENIOR-FINANCIAL-OFFICERS.L>

.. The code of ethics is designed to deter wrongdoing and promote honest and ethical conduct and compliance with applicable laws and regulations. These codes also incorporate what we expect from our executives so as to enable us to provide accurate and timely disclosure in our filings with the SEC and other public communications. Any amendments made to the Code of Ethics will be available on our website.

### **Stockholder Communications with Directors**

Stockholders wishing to communicate with the Board or with a particular member or committee of the Board should address communications to the Board, or to an individual member or committee as follows: c/o BioLife Solutions, Inc., Attention: Corporate Secretary, 3303 Monte Villa Parkway, Suite 310, Bothell, Washington 98021. All communications will be relayed to that addressee. From time to time, the Board may change the process through which stockholders communicate with the Board or its members or committees. There were no changes in this process in 2015. Please refer to our website at [www.biolifesolutions.com](http://www.biolifesolutions.com) for any future changes in this process. The Board or the particular director or committee of the Board to which a communication is addressed will, if it deems appropriate, promptly refer the matter either to management or to the full Board depending on the nature of the communication.

### **2016 Annual Meeting of Stockholders**

Our 2016 annual meeting of stockholders has been scheduled for May 10, 2016.

## **ITEM 11. EXECUTIVE COMPENSATION**

### **Summary Compensation Table**

The following Summary Compensation Table sets forth certain information regarding the compensation, for services rendered in all capacities to us during 2015 and 2014, of our current principal executive officer and our two other most highly compensated executive officers at the end of 2015 (together, the “named executive officers”).



Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-K/A

Name and Principal Positions (a)	Year (b)	Salary (\$) (c)	Bonus (\$) (d)	Stock Awards (\$) (e)	Option Awards (\$) (f)(1)	All Other Compensation (\$) (i)(7)	Total (\$) (j)
Michael Rice President, Chief Executive Officer and Director (8/06 – present)	2015	400,000	(2)	—	653,478(3)	—	1,053,478
	2014	345,000	150,000	—	—	1,739	496,739
Aby J. Mathew Chief Technology Officer (9/00 – present)	2015	345,000	—	—	400,516(4)	—	745,516
	2014	260,000	128,000	—	31,374 (5)	2,483	421,857
Daphne Taylor Chief Financial Officer (8/11 – present)	2015	285,000	—	—	304,102(6)	—	589,102
	2014	223,560	33,534	—	—	2,221	259,315

(1) See Note 1 for the years ended December 31, 2015 and 2014 for a description on the valuation methodology of stock option awards.

(2) As of February 25, 2016, the amount of bonus for fiscal 2015 has not yet been determined. The actual amount of bonus is expected to be determined by April 1, 2016.

Amount is a result of options to purchase 375,000 shares at \$2.06 per share granted to officer on May 4, 2015, (3) which options vest to the extent of 1/4 of the underlying shares on May 4, 2016 and, thereafter, vest in monthly increments of 7,813 shares.

Amount is a result of options to purchase 229,837 shares at \$2.06 per share granted to officer on May 4, 2015, (4) which options vest to the extent of 1/4 of the underlying shares on May 4, 2016 and, thereafter, vest in monthly increments of 4,788 shares.

Amount is a result of options to purchase 10,000 shares at \$3.70 per share granted to officer on April 21, 2014, (5) which options vested to the extent of 1/4 of the underlying shares on April 21, 2015 and, thereafter, vest in monthly increments of 208 shares.

Amount is a result of options to purchase 174,510 shares at \$2.06 per share granted to officer on May 4, 2015, (6) which options vest to the extent of 1/4 of the underlying shares on May 4, 2016 and, thereafter, vest in monthly increments of 3,636 shares.

(7) Amounts represent company paid wellness benefits.

**Outstanding Equity Awards at Fiscal Year-End 2015**

The following table sets forth information concerning the outstanding equity awards as of December 31, 2015 granted to the named executive officers.

Name (a)	OPTION AWARDS		Equity	Option	Option
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#)	Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)		
	(b)	(c)	(d)	(e)	(f)
Michael Rice	107,142	—	—	0.98	8/7/2016(1)
Michael Rice	71,428	—	—	1.12	2/7/2017(2)
Michael Rice	54,642	—	—	1.26	2/2/2019(3)
Michael Rice	85,062	—	—	1.40	2/5/2020(4)
Michael Rice	28,571	—	—	1.12	2/25/2021(5)
Michael Rice	160,567	—	—	1.12	2/25/2021(6)
Michael Rice	—	375,000	—	2.06	5/4/2025(7)
Aby J. Mathew	7,142	—	—	0.98	10/12/2016(8)
Aby J. Mathew	35,714	—	—	1.12	2/7/2017(9)
Aby J. Mathew	24,285	—	—	1.40	8/7/2017(10)
Aby J. Mathew	7,142	—	—	0.70	2/11/2018(11)
Aby J. Mathew	7,142	—	—	0.56	11/5/2018(12)
Aby J. Mathew	37,966	—	—	1.40	2/5/2020(13)
Aby J. Mathew	55,451	—	—	1.12	2/11/2021(14)
Aby J. Mathew	17,113	744	—	1.40	2/15/2022(15)

Edgar Filing: BIOLIFE SOLUTIONS INC - Form 10-K/A

Aby J. Mathew	4,166	5,834	—	3.70	4/21/2024(16)
Aby J. Mathew	—	229,837	—	2.06	5/4/2025(17)
Daphne Taylor	17,857	—	—	1.40	3/1/2021(18)
Daphne Taylor	35,714	—	—	0.88	8/17/2021(19)
Daphne Taylor	17,113	744	—	1.40	2/15/2022(20)
Daphne Taylor	—	174,510	—	2.06	5/4/2025(21)

(1) This award vested 1/3 of the total underlying shares on each of August 7, 2007, 2008 and 2009.

(2) This award vested 1/3 of the total underlying shares on each of February 7, 2008, 2009 and 2010.

- (3) This award vested 1/4 of the total underlying shares on February 2, 2010 and, thereafter, in 36 equal monthly increments.
- (4) This award vested 1/3 of the total underlying shares on each of February 5, 2012, 2013 and 2014.
- (5) This award vested on the date of grant.
- (6) This award vested at the end of the fourth quarter of 2012, when the Company achieved cash flow break even.
- (7) This award vests 1/4 of the total shares on May 4, 2016 and, thereafter, vests in 36 equal monthly increments.
- (8) This award vested 1/4 of the total underlying shares on each of October 12, 2007, 2008, 2009 and 2010.
- (9) This award vested 1/4 of the total underlying shares on each of February 7, 2008, 2009, 2010 and 2011.
- (10) This award vested 1/4 of the total underlying shares on each of August 7, 2008, 2009, 2010 and 2011.
- (11) This award vested 1/4 of the total underlying shares on each of February 11, 2009, 2010, 2011 and 2012.
- (12) This award vested 1/4 of the total underlying shares on each of November 5, 2009, 2010, 2011 and 2012.
- (13) This award vested 1/4 of the total underlying shares on each of February 5, 2011, 2012, 2013 and 2014.
- (14) This award vests 1/4 of the total underlying shares on each of February 11, 2012, 2013, 2014 and 2015.
- (15) This award vests 4,464 shares on February 15, 2013 and, thereafter, in 36 equal monthly increments.
- (16) This award vests 2,500 shares on April 21, 2015 and, thereafter, vests in 36 equal monthly increments.
- (17) This award vests 1/4 of the total shares on May 4, 2016 and, thereafter, vests in 36 equal monthly increments.
- (18) This award vests 1/4 of the total underlying shares on each of March 1, 2012, 2013, 2014 and 2015.
- (19) This award vests 1/4 of the total underlying shares on each of August 18, 2012, and, thereafter, vests in 36 equal monthly increments.
- (20) This award vests 1/4 of the total underlying shares on each of February 15, 2013, and, thereafter, vests in 36 equal monthly increments.
- (21) This award vests 1/4 of the total shares on May 4, 2016 and, thereafter, vests in 36 equal monthly increments.

## Employment Agreements

On February 19, 2015, we entered into new employment agreements with (i) Michael Rice, our President and Chief Executive Officer, (ii) Dr. Aby J. Mathew, Ph.D., our Senior Vice President and Chief Technology Officer, and (iii) Daphne Taylor, our Chief Financial Officer. None of the Employment Agreements is for a definite time period, but rather, each will continue until terminated in accordance with its terms.

The employment agreement with Michael Rice, our President and Chief Executive Officer, provides for a base salary of \$400,000 per year and the potential for an annual incentive bonus in the sole discretion of the Board. On February 19, 2015, the Board established Mr. Rice's bonus eligibility for 2015 at \$125,000. If Mr. Rice's employment is terminated without "Cause" (other than by reason of death or disability) or he resigns for "Good Reason," he will be entitled to a lump sum payment equal to 12 months' salary and a prorated portion of the current year's target bonus amount; provided that if Mr. Rice's employment is terminated without "Cause" upon or within 90 days following a "Change in Control," Mr. Rice is entitled to a lump sum payment equal to 24 months' salary, a prorated portion of the current year's target bonus amount and an amount equal to the cost of 24 months' medical insurance premiums at a monthly amount equal to the amount of COBRA coverage in effect as of the termination date, plus a tax gross-up amount with respect to such premiums.

The employment agreement with Dr. Aby J. Mathew, Ph.D., our Senior Vice President and Chief Technology Officer, provides for a base salary of \$345,000 per year. If Dr. Mathew's employment is terminated without "Cause" (other than by reason of death or disability), including upon or within 90 days of a "Change in Control," or if he resigns for "Good Reason," he will be entitled to a lump sum payment equal to 12 months' salary.

The employment agreement with Daphne Taylor, our Chief Financial Officer, provides for a salary of \$285,000 per year. If Mrs. Taylor's employment is terminated without "Cause" (other than by reason of death or disability) or if she resigns for "Good Reason," she will be entitled to a lump sum payment equal to six months' salary; provided that if Mrs. Taylor's employment is terminated without "Cause" upon or within 90 days following a "Change in Control," Mrs. Taylor is entitled to a lump sum payment equal to 12 months' salary and an amount equal to the cost of 12 months' medical insurance premiums at a monthly amount equal to the amount of COBRA coverage in effect as of the termination date, plus a tax gross-up amount with respect to such premiums.

For purposes of each of these employment agreements, a "Change in Control" means (i) the consummation of a merger or consolidation of the Company with or into another entity, (ii) the dissolution, liquidation or winding up of the Company or (iii) the sale of all or substantially all of the Company's assets. The foregoing notwithstanding, a merger or consolidation of the Company shall not constitute a "Change in Control" if immediately after such merger or consolidation a majority of the voting power of the capital stock of the continuing or surviving entity, or any direct or indirect parent corporation of such continuing or surviving entity, will be owned by the persons who were the Company's stockholders immediately prior to such merger or consolidation in substantially the same proportions as their ownership of the voting power of the Company's capital stock immediately prior to such merger or consolidation.

Under each employment agreement, “Cause” means the Company’s belief that any of the following has occurred: (i) any breach of the employment agreement by the executive officer; (ii) any failure to perform assigned job responsibilities that continues unremedied for a period of 10 days after written notice to the executive officer by the Company; (iii) the executive officer’s malfeasance or misconduct in connection with the executive officer’s duties under the employment agreement or any act or omission of the executive officer which is materially injurious to the financial condition or business reputation of the Company or any of its subsidiaries or affiliates, (iv) commission of a felony or misdemeanor or failure to contest prosecution for a felony or misdemeanor; (v) the Company’s reasonable belief that the executive officer engaged in a violation of any statute, rule or regulation, any of which in the judgment of the Company is harmful to the business or to Company’s reputation; (vi) the Company’s reasonable belief that the executive officer engaged in unethical practices, dishonesty or disloyalty; or (vii) any reason that would constitute “cause” under the laws the State of Washington.

Under each employment agreement, “Good Reason” for the executive officer to terminate his or her employment means the following: (i) the Company’s material breach of the terms of the employment agreement or any other written agreement between the executive officer and Company; (ii) the assignment to the executive officer of any duties that are substantially inconsistent with or materially diminish the executive officer’s position prior to execution of the employment agreement; (iii) a material reduction of the executive officer’s salary, other than as a result of a general salary reduction affecting substantially all Company employees; (iv) any failure by the Company to obtain the assumption of the employment agreement by any successor or assign of the Company; or (v) a requirement that the executive officer be based at any office or location more than 50 miles from the executive officer’s primary work location prior to the effective date of the employment agreement.

Each of the employment agreements contains a covenant of the executive officer not to compete with the Company or solicit the Company’s employees, customers or suppliers for a period of one year after the date of termination.

### **Amended and Restated 2013 Performance Incentive Plan**

The Amended and Restated 2013 Performance Incentive Plan and the award agreements entered into thereunder include certain provisions that may result in a payment to, or acceleration of vesting of awards held by, a named executive officer in connection with a change in control. A change in control is defined as: (a) the acquisition, directly or indirectly, in one transaction or a series of related transactions, by any person or group (within the meaning of Section 13(d)(3) of the Exchange Act) of the beneficial ownership of securities of the Company possessing more than fifty percent (50%) of the total combined voting power of all outstanding securities of the Company; (b) a merger or consolidation of the Company with any other entity, whether or not the Company is the surviving entity in such transaction, except for a transaction in which the holders of the outstanding voting securities of the Company immediately prior to such merger or consolidation hold as a result of holding Company securities prior to such transaction, in the aggregate, securities possessing more than fifty percent (50%) of the total combined voting power of all outstanding voting securities of the Company or of the surviving entity (or the parent of the surviving entity) immediately after such merger or consolidation; (c) the sale, transfer or other disposition (in one transaction or a

series of related transactions) of all or substantially all of the assets of the Company; or (d) the approval by the stockholders of a plan or proposal for the liquidation or dissolution of the Company.

In the event of a change in control, the Administrator (as defined in the plan) has the discretion to provide in each award agreement for (i) the vesting of options to accelerate automatically upon a change in control of the Company (as defined in the plan) and (ii) the assumption of awards by the acquiring or successor entity (or parent thereof) or replacement by such entity with new options or other incentives upon a change in control of the Company. The terms of the Company's outstanding option agreements under the plan provide for accelerated vesting upon the occurrence of the change in control transaction, provided, that the Administrator in its sole discretion may provide for the purchase or exchange of each option for an amount of cash or other property having a value equal to the difference between (x) the value of the cash or other property that you would have received pursuant to the change in control transaction in exchange for the shares issuable upon exercise of the option had the option been exercised immediately prior to the change in control transaction, and (y) the exercise price of the option. Outstanding options shall terminate and cease to be exercisable upon consummation of a change in control except to the extent that such awards are assumed by the successor entity pursuant to the terms of the change in control transaction. The Administrator shall give written notice of a proposed change in control transaction to the holder not less than fifteen (15) days prior to the anticipated effective date of the proposed transaction.

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

The following table sets forth, as of February 25, 2016, certain information regarding the beneficial ownership of common stock by (i) each stockholder known by the Company to be the beneficial owner of more than 5% of the outstanding shares thereof; (ii) each director and nominee of the Company; (iii) each named executive officer of the Company; and (iv) all of the Company's current directors and executive officers as a group.

Name and Address of Beneficial Owner	Common Stock	Percentage of Class	
<b>Directors and Executive Officers</b>			
Thomas Girschweiler (Director) (1)	4,392,427	30.9	%
Michael Rice (Officer and Director) (2)	528,180	4.1	%
Aby J. Mathew (Officer) (3)	242,088	1.9	%
Raymond Cohen (Director) (4)	104,893	0.8	%
Daphne Taylor (Officer) (5)	71,428	0.6	%
Andrew Hinson (Director) (6)	60,713	0.5	%
Rick Stewart (Director) (7)	13,690	0.1	%
Joseph Schick (Director) (8)	8,928	0.1	%
Total shares owned by Executive Officers and Directors (10 persons) (9)	5,433,894	35.9	%
<b>5% Stockholders</b>			
Walter Villiger (10)	5,524,714	38.5	%
WAVI Holding AG (11)	5,381,857	37.8	%
Taurus4757 GmbH (12)	4,188,857	29.9	%

Shares of common stock subject to options and warrants that are exercisable or will be exercisable within 60 days of February 25, 2016 are deemed outstanding for computing the number of shares beneficially owned. The percentage of the outstanding shares held by a person holding such options or warrants includes those currently exercisable or exercisable within 60 days of February 25, 2016, but such options and warrants are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and subject to community property laws where applicable, we believe that the persons named in the table have sole voting and investment power with respect to all shares shown as beneficially owned by them. Unless otherwise indicated, the business address of each person listed is in care of 3303 Monte Villa Parkway, #310, Bothell, WA 98021.

(1) Includes 142,857 shares of common stock issuable upon exercise of warrants held by Mr. Girschweiler, options to purchase 60,713 shares of common stock issuable upon stock options exercisable within 60 days from February 25, 2016, 2,644,663 shares of common stock held indirectly through Mr. Girschweiler's wholly-owned entity named Taurus4757 GmbH and 1,544,194 shares of common stock issuable upon exercise of warrants held by Taurus4757



GmbH.

- (2) Includes options to purchase 507,413 shares of common stock issuable under stock options exercisable within 60 days from February 25, 2016.
- (3) Includes options to purchase 197,699 shares of common stock issuable under stock options exercisable within 60 days from February 25, 2016.
- (4) Includes options to purchase 96,427 shares of common stock issuable under stock options exercisable within 60 days from February 25, 2016.
- (5) Includes options to purchase 71,428 shares of common stock issuable under stock options exercisable within 60 days from February 25, 2016.
- (6) Includes options to purchase 60,713 shares of common stock issuable under stock options exercisable within 60 days from February 25, 2016.

- (7) Includes options to purchase 8,928 shares of common stock issuable under stock options exercisable within 60 days from February 25, 2016.
- (8) Includes options to purchase 8,928 shares of common stock issuable under stock options exercisable within 60 days from February 25, 2016.
- (9) Includes the securities listed in footnotes 1-8, in addition to options to purchase 9,166 shares of common stock issuable under stock options exercisable within 60 days from February 25, 2016.  
Includes 3,604,646 shares of common stock held indirectly through Mr. Villiger's wholly-owned entity named
- (10) WAVI Holding AG, 142,857 shares of common stock issuable upon exercise of warrants held by Mr. Villiger and 1,777,211 shares of common stock issuable upon exercise of warrants held by WAVI Holding AG.
- (11) Includes 1,777,211 shares of common stock issuable upon exercise of warrants.
- (12) Includes 1,544,194 shares of common stock issuable upon exercise of warrants.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

Since January 1, 2014, there has not been, nor has there been proposed, any transaction, arrangement or relationship or series of similar transactions, arrangements or relationships, including those involving indebtedness not in the ordinary course of business, to which we or our subsidiaries were or are a party, or in which we or our subsidiaries were or are a participant, in which the amount involved exceeded or exceeds the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which any of our directors, nominees for director, executive officers, beneficial owners of more than 5% of any class of our voting securities, or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than as described above under the headings "Executive Compensation" and "Board of Directors—Director Compensation" and other than the transactions described below. Each of the transactions described below was reviewed and approved or ratified by the Audit Committee of the Board. It is anticipated that any future transactions between us and our officers, directors, principal stockholders and affiliates will be on terms no less favorable to us than could be obtained from unaffiliated third parties. In accordance with our Audit Committee's charter, all such transactions will be reviewed and approved by our Audit Committee and a majority of the independent and disinterested members of the Board.

#### *Facility Agreements*

On January 11, 2008, we entered into the facility agreements with each of Thomas Girschweiler, an affiliate and director of the Company, and Walter Villiger, an affiliate of the Company, pursuant to which each noteholder extended to the Company a secured convertible multi-draw term loan facility of \$2,500,000, which facility (a) incorporated (i) a refinancing of then existing indebtedness of the Company to the Investor, and accrued interest thereon, in the aggregate amount of \$1,431,563.30, (ii) a then current advance of \$300,000, and (iii) a commitment to advance to us, from time to time, additional amounts up to a maximum of \$768,436.70, (b) bears interest at the rate of 7% per annum on the principal balance outstanding from time to time, (c) is evidenced by a secured convertible multi-draw term loan, which was due and payable, together with accrued interest thereon, the earlier of (i) January 11, 2010, or (ii) a certain events of default, and (d) is secured by all of our assets.

In May and July 2008, we received \$1,000,000 in total from the noteholders pursuant to the facility agreements. On October 20, 2008, the amounts available under each of the facility agreements was increased by \$2,000,000 to \$4,500,000 (an aggregate of \$9,000,000), and, on October 24, 2008, we received \$600,000 in total from the noteholders pursuant to the amended facility agreements. In 2009, we received an additional \$2,825,000 in total from the noteholders pursuant to the amended facility agreements. In December 2009, the noteholders extended the repayment date to January 11, 2011. On November 16, 2010, the amount available under each of the facility agreements was increased by \$250,000 to \$4,750,000 (an aggregate of \$9,500,000) and the noteholders granted an extension of the repayment date to January 11, 2013. In 2010, we received \$1,145,000 in total from the noteholders pursuant to the amended facility agreements. In 2011, we received \$1,095,000 in total from the noteholders pursuant to the amended facility agreements. In August 2011 we entered into an amendment to each of the facility agreements pursuant to which the amount of each facility agreement was increased to \$5,250,000. The multi-draw term loan notes previously delivered to each of the noteholders also was amended to reflect the changes to the facility agreements. In consideration of such amendments, we issued to each of the noteholders a five-year warrant to purchase 1,000,000 shares of our common stock at a price of \$0.063 per share, which share amount and price was adjusted to 71,429 and \$0.88, to reflect the reverse stock split effective January 29, 2014. On May 30, 2012, the amounts available under each of the facility agreements were increased to \$5,750,000 (an aggregate of \$11,500,000) and the noteholders granted an extension of the repayment date to January 11, 2016. The multi-draw term loan notes previously delivered to each of the noteholders also was amended to reflect the changes to the facility agreements. In consideration of such amendments, we issued to each of the noteholders a five-year warrant to purchase 1,000,000 shares, at a price of \$0.08 per share, which share amount and price was adjusted to 71,429 and \$1.12 respectively, to reflect the reverse stock split effective January 29, 2014.

On December 16, 2013, we entered into note conversion agreements with the noteholders. Pursuant to the note conversion agreements, we agreed to issue units pursuant to a private placement on substantially similar terms as the offering to each of the noteholders in exchange for the conversion of the \$10.6 million principal amount outstanding under the promissory notes and accrued and unpaid interest of approximately \$3.7 million through March 25, 2014.

On February 11, 2014, Mr. Girschweiler transferred to Taurus4757 GmbH, an entity wholly-owned by Mr. Girschweiler, and Mr. Villiger transferred to WAVI Holding AG, an entity wholly-owned by Mr. Villiger, pursuant to an assignment and amendment agreement between the Company and each respective noteholder and transferee, all of their rights and obligations under the noteholder's respective note, the facility agreement and respective note conversion agreement (collectively, we refer to these documents as the note documents. The noteholders have advised us that the transfers were effected for tax structuring purposes. The assignment and amendment agreements did not change the noteholders' beneficial ownership of the notes and the other note documents, nor did they affect the terms of conversion set forth in the note conversion agreements.

On March 25, 2014, pursuant to the note conversion agreements, we issued 3,321,405 shares and 3,321,405 warrants to the noteholders in exchange for the notes, all unpaid interest and the release of all security interests. In addition, on March 25, 2014, the facility agreements were terminated.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

### Principal Accountant Fees and Services

#### *Audit and Audit-Related Fees*

Fees for audit and audit-related services by Peterson Sullivan, LLP our independent registered public accounting firm, for the years ended December 31, 2015 and 2014 were as follows:

	2015	2014
Audit fees	\$75,000	\$71,500
Audit related fees (1)	1,200	20,287
Total audit and audit related fees	\$76,200	\$91,787

Audit-related fees consist of assurance and related services that are reasonably related to the performance of the (1) audit or review of our financial statements. In the years ended December 31, 2015 and 2014, we incurred audit-related fees in connection with our registration statements and related comfort letter procedures.

*Tax Fees; All Other Fees*

We were not billed for any tax fees or for any other fees from our principal accountants in 2015 or 2014.

**Audit Committee Pre-Approval Policies and Procedures**

It is the policy of our Audit Committee to pre-approve all audit and permissible non-audit services to be performed by Peterson Sullivan, our independent registered public accounting firm. All audit fees and audit-related fees provided by Peterson Sullivan during 2015 and 2014 were pre-approved by the Audit Committee.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

(1) Financial Statements (Included Under Item 8): The Index to the Financial Statements is included on page 28 of this Annual Report on Form 10-K and is incorporated herein by reference.

(2) Financial Statement Schedules:

None.

*(b) Exhibits*

Reference is made to the Index of Exhibits beginning on page 67, which is incorporated herein by reference.

*(c) Excluded financial statements:*

None.

## SIGNATURES

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

Date: December 9, 2016 BIOLIFE SOLUTIONS, INC.

/s/ Michael Rice  
Michael Rice  
Chief Executive Officer and President  
(principal executive officer) and Director

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

Date: December 9, 2016 /s/ Michael Rice  
Michael Rice  
Chief Executive Officer and President  
(principal executive officer) and Director

Date: December 9, 2016 /s/ Roderick de Greef  
Roderick de Greef  
Chief Financial Officer (principal financial  
officer and principal accounting officer)

Date: December 9, 2016 /s/ Raymond Cohen  
Raymond Cohen  
Chairman of the Board of Directors

Date: December 9, 2016 /s/ Thomas Girschweiler  
Thomas Girschweiler  
Director

Date: December 9, 2016 /s/ Andrew Hinson  
Andrew Hinson  
Director

Date: December 9, 2016 /s/ Joseph Schick  
Joseph Schick  
Director





**Index of Exhibits –**

See Exhibit Index below for exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Document
3.1	Amended and Restated Certificate of Incorporation of BioLife Solutions, Inc. (included as Exhibit 4.1 to the Registration Statement on Form S-8 filed on June 24, 2013)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of BioLife Solutions, Inc. (included as Exhibit 3.1 to the Current Report on Form 8-K filed on January 30, 2014)
3.3	Amended and Restated Bylaws of BioLife Solutions, Inc., effective April 25, 2013 (included as Exhibit A to the Registrant’s Definitive Information Statement on Schedule 14C filed March 27, 2013)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Annual Report on Form 10-K filed on February 12, 2014)
10.1**	1998 Stock Option Plan, as amended through September 28, 2005 (included as Exhibit 4.3 to the Registration Statement on Form S-8 filed on June 24, 2013)
10.2**	Amended and Restated 2013 Performance Incentive Plan (included as Appendix A to the Registrant’s Definitive Proxy Statement filed on March 24, 2015)
10.3**	BioLife Solutions, Inc. Form of Non-Plan Stock Option Agreement (included as Exhibit 4.4 to the Registration Statement on Form S-8 filed on June 24, 2013)
10.4	Lease Agreement dated August 1, 2007 for facility space 3303 Monte Villa Parkway, Bothell, WA 98021 (included as Exhibit 10.27 and Exhibit 10.29 to the Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007 filed April 1, 2008)
10.5	First Amendment to the Lease, dated November 4, 2008, between the Company and Monte Villa Farms, LLC (included as Exhibit 10.16 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2008 filed March 31, 2009)
10.6	Second Amendment to the Lease, dated March 2, 2012, between the Company and Monte Villa Farms, LLC (included as Exhibit 10.30 to the Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 filed May 14, 2012)
10.7	Third Amendment to the Lease, dated June 15, 2012, between the Company and Monte Villa Farms, LLC (included as Exhibit 10.37 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed March 29, 2013)
10.8	Fourth Amendment to the Lease, dated November 26, 2012, between the Company and Monte Villa Farms, LLC (included as Exhibit 10.41 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed March 29, 2013)
10.9	Fifth Amendment to Lease, dated August 19, 2014, by and between the Company and Monte Villa Farms LLC (included as Exhibit 10.1 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 6, 2014)
10.10	Manufacturing Service Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (included as Exhibit 10.26 to the Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007 filed April 1, 2008)
10.11	Storage Services Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (included as Exhibit 10.25 to the Annual Report on Form 10-KSB for the

fiscal year ended December 31, 2007 filed April 1, 2008)

10.12 Order Fulfillment Services Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (included as Exhibit 10.23 to the Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007 filed April 1, 2008)

67

- 10.13 Warrant to purchase Common Stock issued to Thomas Girschweiler (included as Exhibit 10.23 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed March 28, 2011)
- 10.14 Warrant to purchase Common Stock issued to Walter Villiger (included as Exhibit 10.24 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed March 28, 2011)
- 10.15 Warrant to purchase Common Stock issued to Thomas Girschweiler (included as Exhibit 10.27 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed March 29, 2012)
- 10.16 Warrant to purchase Common Stock issued to Walter Villiger (included as Exhibit 10.28 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed March 29, 2012)
- 10.17 Warrant to purchase Common Stock issued to Thomas Girschweiler (included as Exhibit 10.35 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed March 29, 2013)
- 10.18 Warrant to purchase Common Stock issued to Walter Villiger (included as Exhibit 10.36 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed March 29, 2013)
- 10.19 Note Conversion Agreement, dated December 16, 2013, by and among the Company and Walter Villiger (included as Exhibit 10.1 to the Current Report on Form 8-K filed on December 16, 2013)
- 10.20 Note Conversion Agreement, dated December 16, 2013, by and among the Company and Thomas Girschweiler (included as Exhibit 10.2 to the Current Report on Form 8-K filed on December 16, 2013)
- 10.21\* Manufacturing Services Agreement with Organ Recovery Systems, Inc., effective as of December 22, 2011 (included as Exhibit 10.44 to Amendment No. 1 to the Registration Statement on Form S-1 filed on January 23, 2014)
- 10.22 Form of Warrant issued to Taurus4757 GmbH and WAVI Holding AG pursuant to conversion of outstanding notes (incorporated by reference to Exhibit 10.1 to the Company's report on Form 8-K filed March 25, 2014)
- 10.23 Form of Warrant issued to purchasers in the March 25, 2014 public offering (incorporated by reference to Exhibit 4.1 to the Company's report on Form 8-K filed March 20, 2014)
- 10.24 Assignment and Amendment of Note Conversion Agreement, dated February 11, 2014, by and among the Company, Walter Villiger and WAVI Holding AG (included as Exhibit 10.1 to the Current Report on Form 8-K filed on February 12, 2014)
- 10.25 Assignment and Amendment of Note Conversion Agreement, dated February 11, 2014, by and among the Company, Thomas Girschweiler and Taurus4757 GmbH (included as Exhibit 10.2 to the Current Report on Form 8-K filed on February 12, 2014)
- 10.26 biologistex CCM, LLC Limited Liability Company Agreement dated September 29, 2014 (included as Exhibit 10.2 to the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 6, 2014)
- 10.27\* Supply and Distribution Agreement between SAVSU Technologies, LLC and biologistex CCM dated September 29, 2014 (included as Exhibit 10.3 to the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 6, 2014)
- 10.28\* Services Agreement between BioLife Solutions, Inc. and biologistex CCM dated September 29, 2014 (included as Exhibit 10.4 to the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 6, 2014)
- 10.29\*\* Employment Agreement dated February 19, 2015 between the Company and Michael Rice (included as Exhibit 10.29 to the Annual Report on Form 10-K for the year ended December 31, 2014 filed on March 12, 2015)
- 10.30\*\* Employment Agreement dated February 19, 2015 between the Company and Aby Mathew (included as Exhibit 10.30 to the Annual Report on Form 10-K for the year ended December 31, 2014 filed on March 12, 2015)

- 10.31\*\* Employment Agreement dated February 19, 2015 between the Company and Daphne Taylor (included as Exhibit 10.31 to the Annual Report on Form 10-K for the year ended December 31, 2014 filed on March 12, 2015)
- 10.32\*\* Employment Agreement dated February 19, 2015 between the Company and Joseph Annicchiarico (included as Exhibit 10.32 to the Annual Report on Form 10-K for the year ended December 31, 2014 filed on March 12, 2015)
- 10.33\*\* Employment Agreement dated February 19, 2015 between the Company and Matthew Snyder (included as Exhibit 10.33 to the Annual Report on Form 10-K for the year ended December 31, 2014 filed on March 12, 2015)
- 10.34\*\* Employment Agreement dated February 19, 2015 between the Company and Todd Berard (included as Exhibit 10.34 to the Annual Report on Form 10-K for the year ended December 31, 2014 filed on March 12, 2015)
- 10.35 Board of Directors Services Agreement entered into May 4, 2015 by and between the Company and Raymond Cohen (included as Exhibit 10.1 to the Current Report on Form 8-K filed on May 5, 2015)
- 10.36 Board of Directors Services Agreement entered into May 4, 2015 by and between the Company and Thomas Girschweiler (included as Exhibit 10.2 to the Current Report on Form 8-K filed on May 5, 2015)
- 10.37 Board of Directors Services Agreement entered into May 4, 2015 by and between the Company and Other Non-Employee Directors (included as Exhibit 10.3 to the Current Report on Form 8-K filed on May 5, 2015)
- 21.1 Subsidiaries of the Company
- 23.1 Consent of Peterson Sullivan LLP
- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101.INS\*\*\* XBRL Instance Document
- 101.SCH\*\*\* XBRL Taxonomy Extension Schema
- 101.CAL\*\*\* XBRL Taxonomy Extension Calculation Linkbase
- 101.DEF\*\*\* XBRL Taxonomy Extension Definition Linkbase
- 101.LAB\*\*\* XBRL Taxonomy Extension Label Linkbase
- 101.PRE\*\*\* XBRL Taxonomy Extension Presentation Linkbase

\* Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to an order granted by the SEC.

\*\* Management contract or compensatory plan or arrangement.

\*\*\* Previously filed