BIOLIFE SOLUTIONS INC
Form 10-K
March 12, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)
þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the year ended December 31, 2014

o 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 incorporation or organization)	(IRS Employer 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 o No þ

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 oNo þ

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

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

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 þ No o

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. o

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 o Accelerated filer o Non-accelerated filer o Smaller reporting company þ

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

As of the registrant's most recently completed second fiscal quarter, the aggregate market value of common equity held by non-affiliates was $14,198,846.

As of January 31, 2015, 12,104,958 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of our definitive proxy statement to be filed with the Securities and Exchange Commission not later than April 30, 2015, in connection with our 2015 Annual Meeting of Stockholders, are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

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PART I

ITEM 1. BUSINESS

References in this Form 10-K to "BioLife", the "Company," "we," "us" or "our" refer to BioLife Solutions, Inc. The informati in this Annual Report on Form 10-K contains certain forward-looking statements, including statements related to our customers, regulatory approvals, markets for our products, capital requirements, intellectual property, suppliers, 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.

On January 29, 2014, we effected a 1-for-14 reverse stock split of our common stock. 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 indicated, all share and per share numbers set forth in this Annual Report on Form 10-K have, where applicable, been adjusted to give effect to the reverse stock split and are subject to the foregoing adjustments for fractional shares.

We develop, manufacture and market a portfolio of biopreservation tools and services for cells, tissues, and organs. Our product offerings include:

Patented biopreservation media products for cells, tissues, and organs
Generic formulations of blood stem cell freezing media products
Custom product formulation and custom packaging services
Precision thermal packaging products and related web applications
Cell thawing media products
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 biobanking, drug discovery, and regenerative medicine 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. 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, tissue, and organ viability and function. We believe that our products have been incorporated into the manufacturing, storage, shipping, freezing, and clinical delivery processes of over 175 cell-based clinical trial stage regenerative medicine applications.

The discoveries made by our scientists and consultants relate to how cells, tissues, and organs respond to the stress of hypothermic storage, cryopreservation, and the thawing process. These discoveries enabled the formulation of innovative biopreservation media products that protect biologic material from preservation-related cellular injury, much of which is not apparent immediately after return to normothermic body temperature. Our product formulations have demonstrated notable reduction in apoptotic (programmed) and necrotic (pathologic) cell death mechanisms and are enabling the clinical and commercial development of dozens of innovative regenerative medicine products.

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.

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.

biologistex Joint Venture

On September 29, 2014, we entered into a limited liability company agreement (the "LLC Agreement") with SAVSU Technologies, LLC, a Delaware limited liability company ("SAVSU") to create 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 (the "Products") based on SAVSU's next generation EVO smart container shipment platform (the "Smart Containers").

The joint venture vehicle, biologistex CCM, LLC, is structured as a Delaware limited liability company ("biologistex"). We will make a capital contribution of $2.4 million, and SAVSU contributed exclusive distribution rights to the Smart Containers under a separate Supply and Distribution Agreement (as defined below).

We will also pay SAVSU $1 million in consideration of SAVSU's participation in biologistex. If certain performance requirements are met, these payments to SAVSU will be made in monthly increments for twelve months and recorded as consulting expense in General and Administrative expenses on our Consolidated Statement of Operations, the first of which was made during the third quarter of 2014. During the year ended December 31, 2014, we recorded $0.3 million related to the participation fee, which represents four monthly fees.

The Company and SAVSU are the only members of biologistex, holding 52% and 48%, respectively, of the outstanding units of membership interests ("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 a supply and distribution agreement (the "Supply and Distribution Agreement") whereby biologistex became the exclusive, worldwide distributor of Smart Containers. Pursuant to the Supply and Distribution Agreement, biologistex agrees to purchase a minimum number of Smart Containers over a 24 month period 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 within 12 and 24 months of the date of the agreement. biologistex will pay us monthly for expenses incurred and certain overhead expenses. Until biologistex has achieved sufficient revenue to pay such expenses, it may be necessary for us to fund such reimbursements via inter-company loans to biologistex.

Mission

We strive to be the leading provider of biopreservation tools for cells, tissues, and organs; to facilitate basic and applied research on and commercialization of new therapies by maintaining the health and function of biologic source

material and finished products during the preservation process.

Technological Overview

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 (98.6ºF/37ºC), 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®, HypoThermosol® FRS and CryoStor® technologies. Our 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 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 HypoThermosol® FRS and CryoStor® 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.

Our proprietary HypoThermosol® FRS technology is optimized based on fundamental low temperature cellular and molecular biologic principles. Competing biopreservation media products are often formulated with simple isotonic media cocktails, animal serum, potentially a single sugar or human protein, and in the case of cryopreservation media, a single permeating cryoprotectant such as dimethyl sulfoxide (“DMSO”). A key differentiator of our proprietary formulations 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. Furthermore, 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.

Our research and intellectual property related to the cellular stress response to cold temperature also led to discoveries in the field of cryosurgery. Specifically, through contracted research and completion of the specific aims of two National Institutes of Health (“NIH”) Small Business Innovative Research (“SBIR”) grants awarded to Cryomedical Sciences, our predecessor, and to BioLife, we determined via in vitro experiments on cancer cells, that the combination of chemotherapy and cryosurgery was more effective than cryosurgery alone. This intellectual property was excluded from the asset sold to Endocare in 2002, and has been the subject of extensive publications.

Products

HypoThermosol® FRS

HypoThermosol® biopreservation media is a novel, engineered, optimized hypothermic storage and shipping media product.

Serum-free, protein-free HypoThermosol® is designed to provide maximum storage and shipping stability for biologics at 2°-8°C.

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.

Similar to our companion freeze media CryoStor®, HypoThermosol® includes components that scavenge free radicals, provide pH buffering, oncotic/osmotic support, energy substrates, and ionic concentrations that balance the intracellular state at low temperatures.

Across a broad spectrum of cell and tissue types, intracellular-like HypoThermosol® has proven more effective in reducing post-preservation 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.

HypoThermosol is manufactured under cGMP and is tested to USP <71> Sterility and USP <85> Endotoxin standards.

PrepaStor®

PrepaStor®, formerly branded as HypoThermosol® PURGE 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.

CryoStor®

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) and are based upon the novel HypoThermosol® platform. 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.

Across a broad spectrum of cell types, CryoStor® products have proven more effective in reducing post-preservation necrosis and apoptosis as compared to commercial and home-brew isotonic and extracellular formulations without the addition of serum or protein. This enables improved post-thaw cell yield, viability, and recovery.

CryoStor® is manufactured under cGMP and is tested to USP <71> Sterility and USP <85> Endotoxin standards.

CryoStor® is offered in several packages and pre-formulated with DMSO in final concentrations of 2%, 5%, and 10%.

BloodStor®

BloodStor® freeze media is specifically designed for cryopreservation of 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® is manufactured under cGMP and tested to USP <71> Sterility and USP <85> Endotoxin standards.

Cell Thawing Media

In the first quarter of 2015, we introduced a family of cell thawing media products. These low molecular weight (LMD) Dextran solutions are used in thawing human cells after cryopreservation. We launched these new products in response to inquiries from numerous customers and clinicians who have been subjected to an extended worldwide shortage of dextran solutions that are used off-label to transition frozen cells to room temperature.

Precision Thermal Packaging Solutions

On a worldwide exclusive basis, we distribute a portfolio of precision thermal packaging products to the regenerative medicine and stem cell markets. We believe there is a significant unmet need for improved temperature stability during the transportation and shipping of cells and tissues, which is not currently met by the commercially available thermal shippers. Current commercial alternatives range from Styrofoam and EPS "beer cooler" type containers inside a cardboard box, up to and including vacuum panel insulation cartons. These alternatives suffer from reduced performance due to the form factor design and/or materials used. We believe that the design and super-insulating material used in our thermal shippers, along with the robustness of the products and reusability, represent a very favorable value proposition to the regenerative medicine and stem cell markets.

New EVO™ Smart Shipping Containers & biologistex Web Monitoring Service

The EVO™ line is our new line of "smart shippers" designed for the shipment of materials, which must be maintained frozen, at 2-8˚C and/or controlled room temperature (CRT) temperatures and where near real time monitoring of temperature, location, and payload status information is necessary. A sophisticated electronics package embedded in the EVO provides streaming data to the biologistex web-based application; where real time shipment status, history, and reports can be generated. Designed for small volume shipments; it fills a critical need in chain-of-custody scenarios for temperature sensitive shipments of cells, tissues, and other cell based products. We have commenced delivery of the new EVO and biologistex web monitoring service to beta customers.

PHD™ 2 – 8 C Shipper

The PHD™ line is designed for the shipment of materials, which must be maintained at 2-8˚C and or controlled room temperature (CRT) temperatures and is designed for small volume shipments from single dose to 3 liters in volume. Utilizing our antifreeze technology the PHD™ reduces the risk of freezing of 2-8˚C shipments. We believe the improved insulation performance of the PHD™ will also allow for extended shipping periods and thereby give greater product safety assurance. The packout process is completed in minutes, saving labor time.

CryoQ™ Dry Ice Shipper

The CryoQ™ line is designed for the shipment of small volumes of biomaterials, which need to be shipped at extremely stable deep-frozen temperatures when used with small volumes of dry ice. The CryoQ™ utilizes a Vial Rack system to deliver precision temperature management even after significant sublimation of dry ice has occurred. The Vial Rack system allows for reliable temperature stability even during rigorous shipping conditions. The unique benefit of the Vial Rack and CryoQ design is the ability to maintain uniform temperature around the entire payload volume, providing thermal protection for the biologic payload inside the shipper.

Market Opportunity

Recent advances in cord blood banking, adult stem cell banking, cell therapy, and tissue engineering have highlighted the significant and unmet need to maintain the stability and shelf life of biologics in the development and commercialization of new regenerative medicine products and therapies. Scarce and fragile source cells or tissues are extracted from a patient, transported to a cell processing and culture laboratory, and then transported back to the clinic for patient infusion or injection. Because this entire process can take months and may involve transportation over long distances, maintenance of cellular viability is of paramount importance.

The recently published Visiongain Translational Regenerative Medicine market research report forecasts that the regenerative medicine market comprised of cell and gene therapies and tissue-engineered products will grow to more

than $23 billion by 2024. BioLife's 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.

The December 2013 iMarc report forecasts the market for cold chain shippers and instruments growing to $5 billion by 2018.

Our target markets include:

Regenerative Medicine

Our proprietary HypoThermosol® FRS and CryoStor® biopreservation media products are used by customers to store, transport, and freeze biologic source/starting material and cell-or tissue-based final manufactured products. Our scientific discoveries related to preservation-induced cell stress enabled the development and commercialization of a new class of patented biopreservation media formulations that have demonstrated broad and significant ability to extend shelf life/stability and improve post-preservation viability and function of numerous biologics. A number of regenerative medicine products may be non-frozen with shelf life less than 24 hours. This limited shelf life would constrain clinical distribution and create manufacturing limitations for the products. Our products specifically address this need by extending shelf life and stability long enough to enable the worldwide clinical distribution of temperature sensitive biologic-based products and therapies.

MedMarket Diligence, LLC, estimates that the current worldwide market for regenerative medicine products and services is growing at 20 percent annually. We expect pre-formulated biopreservation media products such as our HypoThermosol® FRS and CryoStor® to continue to displace “home-brew” cocktails due to increased regulatory and quality oversight, creating demand for high quality clinical grade preservation reagents that will grow at greater than the overall end market rate. We estimate that “home-brew” in-house formulated storage and freeze media comprise 80 percent of the market.

We have shipped our proprietary biopreservation media products to over 250 regenerative medicine customers. We estimate that our products are now incorporated in over 175 cell-based clinical trial stage regenerative medicine applications.

While this market is still in an early stage, we have secured a valuable position as a supplier of critical reagents to several commercial companies. Short-term revenue can be highly variable as customer therapies navigate the regulatory approval process, but we estimate that annual revenue from some of our regenerative medicine customers could reach $1 million per year within three to five years following their product approval, if approval is secured and large scale commercial manufacturing commences and is sustained. Our position as the leading provider of optimized clinical grade hypothermic storage and cryopreservation freeze media has also led to increased recognition of our scientific expertise.

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.

To leverage our scientific discoveries and presence in this market, we continue to develop a proprietary disposable lab-ware product that may address a significant workflow bottleneck in the drug screening market - insufficient supply of preserved cells required in high-throughput screening of new drug compounds. We have pending patent applications in the U.S., Australia, Canada, and Europe to protect our intellectual property rights for our inventions which may for the first time enable bulk freezing of cells in multi-well tissue culture plates.

Biobanking

Our customers in this segment include public and private cord blood banks, adult stem cell banks, tissue banks, hair transplant centers, and biorepositories. In the hair restoration segment, over sixty different physicians and centers now use HypoThermosol® FRS as an improved ex vivo holding solution for storing grafts during the procedure. We estimate that HypoThermosol® FRS is used in approximately 2% of the total worldwide procedures and have increased our marketing activities to capture additional share of this growing opportunity.

Sales and Marketing

Our sales and marketing strategy supports our objective of building brand equity in BioLife Solutions and establishing a position as the leading supplier of biopreservation tools for cells, tissues, and organs. We are committed to becoming and remaining a trusted, critical supplier to our customers. This requires us to employ scientific team members in sales and support roles. Our technical application support team consists of individuals with extensive experience in cell processing, biopreservation, and cryobiology.

We participate in numerous 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 AABB, the Alliance for Regenerative Medicine, the BEST Collaborative, and the International Society for Cellular Therapy. In addition to our direct sales activities, our products are marketed and distributed by STEMCELL Technologies, Sigma-Aldrich, and several other regional distributors under non-exclusive agreements.

Manufacturing

We maintain and operate two independent cGMP clean room production suites. 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.

Governmental 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® and HypoThermosol® FRS, 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.

Intellectual Property

Currently, we have five issued U.S. patents, two pending U.S. patent applications, one issued European patent, one issued Japanese patent, and several pending patent applications in foreign jurisdictions.

In addition to our corporate logo and name, we have registered the following marks:

HYPOTHERMOSOL
GELSTOR
POWERING THE PRESERVATION SCIENCES
BIOPRESERVATION TODAY
BLOODSTOR
CRYOSTOR
BIOLOGISTEX
PREPASTOR
PRESERVATION CHAIN

We have applied for trademark protection in the following marks:

KATA
CELLENERGY
GRAFTSTOR

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.

Research and Development

Currently, we employ a small team of researchers, three of whom hold Ph.D. degrees in molecular biology or related fields, who also engage in customer support and marketing activities. Also, we conduct collaborative research with several leading academic and commercial entities in our strategic markets.

During 2014 and 2013, we spent approximately $871,100 and $487,816, respectively, on research and development activities.

Our Scientific Advisory Board (SAB) is comprised of leaders in the fields of regenerative medicine, biopreservation, quality systems, and regulatory compliance. These members advise us on our product development, quality systems, and overall marketing strategies. Current SAB members include:

Jason Acker, Ph.D., a Senior Development Scientist with the Canadian Blood Services and a Professor in the Department of Laboratory Medicine and Pathology at the University of Alberta, Edmonton, Canada. He received his Bachelor of Science, Master of Science in Experimental Pathology and PhD in Medical Sciences degrees from the University of Alberta. Dr. Acker was a Canadian Institutes of Health Research Post-Doctoral Fellow at the Massachusetts General Hospital and Harvard Medical School. He completed his Master of Business Administration in Technology Commercialization program at the Alberta School of Business at the University of Alberta in 2009.

Scott M. Burger, MD, principal of Advanced Cell and Gene Therapy, a consulting firm specializing in cell, gene, and tissue-based therapies. Dr. Burger works with clients in industry and academic centers worldwide, providing assistance in process development and validation, GMP/GTP manufacturing, GMP facility design and operation, regulatory affairs, technology evaluation, and strategic analysis.

Lizabeth J. Cardwell, MT (ASCP), MBA, RAC, Principal, Compliance Consulting, LLC, a private consulting business offering quality and regulatory consulting services to cell therapy, medical device, and pharmaceutical companies.

Jerry E. Cooley, MD, is a board certified dermatologist and diplomate of the American Board of Hair Restoration Surgery (ABHRS). He has served in leadership positions including President of the International Society of Hair Restoration Surgery (ISHRS) and co-editor of the Hair Transplant Forum, the main journal for hair transplant physicians. He has been performing hair transplants for almost 20 years.

Colleen Delaney, MD, is the Director of the Cord Blood Research and Transplant Program at Fred Hutchinson Cancer Research Center (FHCRC) and Seattle Cancer Care Alliance (SCCA). She is an attending physician at Seattle Children's Hospital, Assistant Member of the Clinical Research Division of FHCRC and Assistant Professor at the University of Washington School of Medicine.

Anthony Davies, PhD, Dr. Davies is President of Dark Horse Consulting, a boutique practice focused on CMC and product development issues in cell and gene therapy. After training as a biochemist, chemical engineer and molecular biologist, Dr. Davies has worked in the cell and gene therapy field for some 20 years. He brings with him an extensive track record in manufacturing, operational management and commercial development, most recently as Chief Technology Officer for Capricor, Inc. and Vice President, Product Development for Geron Corporation's cell therapy programs.

Dayong Gao, PhD, professor of biomedical engineering at the University of Washington in Seattle. Dr. Gao has been actively engaged in cryopreservation research for more than 20 years, having authored over 130 peer-reviewed journal articles on cryopreservation.

Shelly Heimfeld, PhD, is the Director, Heimfeld Research Laboratory, Scientific Director, Cellular Therapy Laboratory, and Scientific Director, cGMP Therapeutic Manufacturing Facilities at the Fred Hutchinson Cancer Research Center, and former President of the International Society of Cellular Therapy. Dr. Heimfeld is internationally recognized for research in hematopoietic-derived stem cells and the development of cell processing technologies for improved cancer therapy.

Andrew Hinson, Vice President for Clinical and Regulatory Affairs for LoneStar Heart, Inc., a developer of proprietary biopolymer, small molecule and cellular-based therapies to effectively treat heart failure and other cardiac conditions. Mr. Hinson has diverse experience in the cell and gene therapy markets and extensive experience with regulatory and clinical trial issues for new therapies for cardiac, neurologic, and gastrointestinal applications. Mr. Hinson also serves on our Board of Directors.

Edward LeCluyse, PhD, Senior Research Investigator at The Hamner Institutes for Health Sciences. Dr. LeCluyse pioneered the use of HypoThermosol® and CryoStor® in improving preservation of research designated livers and derived commercial hepatocytes marketed to the pharmaceutical industry.

John McMannis, PhD, Executive Vice President of Manufacturing at Mesoblast Limited. Dr. McMannis was previously the Director, Cellular Therapy Laboratory, Department of Stem Cell Transplantation, Division of Cancer Medicine, University of Texas MD Anderson Cancer Center, Houston, Texas.

Robert (Bob) A. Preti, PhD, President & Chief Scientific Officer at PCT, a NeoStem Company. Dr. Preti is the co-founder and visionary behind PCT's successful growth and development strategy over much of the last two decades. As Chief Scientific Officer of NeoStem, Bob is involved in directing the development and expansion of NeoStem's cell therapy pipeline, as well as participating in setting NeoStem's strategic direction. Bob holds a Bachelor of Science degree in biology from Fordham University, and a Master of Science degree and Doctorate, both in biology, from New York University

Jon Rowley, PhD, Chief Executive & Technology Officer at RoosterBio, Inc. Dr. Rowley founded RoosterBio as part of his personal quest to significantly improve commercial translation of technologies that incorporate living cells, including cellular therapies, engineered tissues, and tomorrow's medical devices. Jon holds a PhD from the University of Michigan in Biomedical Engineering and has authored over 30 peer reviewed manuscripts and 15 issued or pending patents related to biomaterials development, tissue engineering, and cellular therapy. Prior to RoosterBio, Jon created innovative products at BD, Aastrom

Bioscience, and most recently, was Director of Innovation and Process Development at Lonza's Cell Therapy CMO business.

Erik J. Woods, PhD, Co-Founder, CEO of General Biotechnology, LLC, now Cook General BioTechnology, a subsidiary of Cook Group. Dr. Woods is the current President of the Society for Cryobiology.

Competition

For our biopreservation media products, 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 technical advances are made and become more widely known.
For our precision thermal shipping products, formidable competition currently exists from traditional freight and "cold chain" shipper companies such as Sonoco Thermosafe, Cryopak, Pelican Technologies, and others. These competitors 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.

Employees

As of February 1, 2015, we had 38 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.

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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 2014 and 2013, we derived approximately 18% and 49%, respectively, 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. In 2014 we derived approximately 11% of our revenue from one other customer and in 2013, we derived approximately 14% of our revenue from one other customer, which included license revenue and core product revenue. No other customer accounted for more than 10% of revenue in 2014 or 2013. 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 operating losses since inception, and may continue to incur operating losses. For the fiscal years ended December 31, 2014 and December 31, 2013, we had net losses of $3,217,750 and $1,084,160, respectively. As of December 31, 2014, our accumulated deficit was approximately $60.1 million. Of this amount, approximately $21 million has accumulated since our merger in 2002. 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.

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, biopreservation thermal packaging products and contract manufacturing services.

Our growth depends, in part, on our continued ability to successfully develop, commercialize and market our HypoThermosol® FRS, CryoStor®, and BloodStor® biopreservation media products, precision thermal packaging products and contract manufacturing services. 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 industry is highly competitive. We anticipate that we will continue to face increased competition as existing companies develop new or improved products and as new companies enter the market with new technologies. Many of our competitors are significantly larger than us and have greater financial, technical, research, marketing, sales, distribution and other resources than us. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more effective or commercially attractive than any that are being developed or marketed by us, or that such competitors will not succeed in obtaining regulatory approval, or introducing or commercializing any such products, prior to us. Such developments could have a material adverse effect on our business, financial condition and results of operations. Also, even if we are able to compete successfully, there can be no assurance that we could do so in a profitable manner.

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

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

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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. 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.

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 within 12 and 24 months of the date of the agreement. If we are not able 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 or operations, 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. These risks are inherent in the development of life sciences industry products. We currently maintain commercial general and umbrella liability policies with combined limits of $7 million per occurrence and in the aggregate, in addition to a $5 million per claim and annual aggregate product liability insurance policy consistent with industry standards. 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 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 the majority of our products.. The manufacture of our 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 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 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

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 appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

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

Filing, prosecuting and defending patents on all of our products in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to

develop their own products. These products may compete with our products, and may not be covered by any patent claims or other intellectual property rights.

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

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

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

The patent protection for our products may expire before we are able to maximize their commercial value, which 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.

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 unenforceability 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.

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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, 2014, two of our existing stockholders, Thomas Girschweiler and Walter Villiger, beneficially owned, collectively, approximately 50.5% of our outstanding shares. Messrs. Girschweiler and Villiger were previously secured lenders to our Company, and Mr. Girschweiler is a former 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 exerciseable 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.

ITEMLEGAL PROCEEDINGS
3.

There are no material legal proceedings to which the Company or any of its subsidiaries is a party or of which any of their property is the subject.

ITEMMINE SAFETY DISCLOSURES
4.

Not applicable.

PART II

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

Price Range of Common Stock

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

As of March 6, 2015, there were approximately 450 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, 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
Year ended December 31, 2013		
4th Quarter	$19.60	$7.84
3rd Quarter	12.18	5.04
2nd Quarter	5.74	4.06
1st Quarter	5.88	3.50

Recent Sales of Unregistered Securities

As previously disclosed by the Company, we were party to an agreement with Life Sci Advisors, in which we agreed to issue the consultant shares of our common stock as partial compensation for services. The agreement has been modified to eliminate the compensation in company stock. On October 22, 2014, we issued 28,573 common shares pursuant to this agreement. This issuance was exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, since, among other things, the transaction did not involve a public offering and the common shares were acquired for investment purposes only and not with a view to any resale, distribution or other disposition of the common shares in violation of U.S. securities laws.

Issuer Repurchases of Equity Securities

During 2014, we did not repurchase any of our securities.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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ITEMMANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF
7. 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, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, business strategies, cost savings, objectives of management 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,” “plan,” “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. Examples of these forward-looking statements include, but are not limited to:

anticipated regulatory filings and requirements;
timing and amount of future contractual payments, product revenue and operating expenses;
market acceptance of our products and the estimated potential size of these markets; and
our anticipated future capital requirements and the terms of any capital financing agreements.

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. 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.

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 the LLC Agreement with SAVSU to create 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 Containers.

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, and SAVSU contributed exclusive distribution rights to the Smart Containers under a separate Supply and Distribution Agreement.

We will also pay SAVSU $1 million in consideration of SAVSU's participation in biologistex. If certain performance requirements are met, these payments to SAVSU will be made in monthly increments for twelve months and recorded as consulting expense in General and Administrative expenses on our Consolidated Statement of Operations, the first of which was made during the third quarter of 2014. During the year ended December 31, 2014, we recorded $0.3 million related to the participation fee, which represents four monthly fees. At December 31, 2014, the Company had $0.2 million in outstanding accounts payable related to the monthly fees.

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 Containers. Pursuant to the Supply and Distribution Agreement, biologistex agrees to purchase a minimum number of Smart Containers over a 24 month period 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 within 12 and 24 months of the date of the agreement. biologistex will pay us monthly for expenses incurred and certain overhead expenses. Until biologistex has achieved sufficient revenue to pay such expenses, it may be necessary for us to fund such reimbursements via inter-company loans to biologistex.

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.

Our proprietary, clinical grade HypoThermosol® FRS and CryoStor® biopreservation media products are marketed to the biobanking, drug discovery, and regenerative medicine 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. 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, tissue, and organ viability and function. We believe that our products have been incorporated into the manufacturing, storage, shipping, freezing, and clinical delivery processes of over 175 cell-based clinical trial stage regenerative medicine applications.

The discoveries made by our scientists and consultants relate to how cells, tissues, and organs respond to the stress of hypothermic storage, cryopreservation, and the thawing process. These discoveries enabled the formulation of innovative biopreservation media products that protect biologic material from preservation-related cellular injury, much of which is not apparent immediately after return to normothermic body temperature. Our product formulations have demonstrated notable reduction in apoptotic (programmed) and necrotic (pathologic) cell death mechanisms and are enabling the clinical and commercial development of dozens of innovative regenerative medicine products.

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.

Our Mission

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 the preservation process.

Our strategies to achieve this objective include:

Utilize Existing Sales, Distribution and Manufacturing Infrastructure.

Extensive network. 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.

Highly technical applications support team. Our technical applications team is highly trained and are considered thought leaders in the area of biopreservation. We are able to provide highly relevant data and assist our customers with a consultative selling approach.

High degree of customer satisfaction. Our sales, marketing, customer service and technical support and service teams aspire to provide our customers exceptional service and have been highly rated in customer satisfaction surveys.

Highly accessible product. We have the ability to ship product on a same-day or next-day basis. We use this ability to provide convenient service to our customers and to generate additional product revenues.

Contract-manufacturing. We utilize excess capacity in our manufacturing operations to perform contract manufacturing in both small and large lot sizes. With our extensive knowledge in cGMP media manufacturing, we are able to assist our customers and optimize their formulation processes to improve the manufactured yield and margin.

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.

Invest in Regenerative Medicine. We are the leading supplier of pre-formulated, clinical grade biopreservation media products for advancing the field of regenerative medicine. Fragile, live cells from source materials such as blood, tissue, and organs are enabling the development of biologic-based therapies and treatments for the leading causes of death and disability. These cells must be transported from the processing lab to the bedside in a refrigerated or frozen state to preserve viability, quality, and potency. We will continue to invest in adding to our suite of biopreservation product offerings to the commercial cell therapy and tissue engineering companies, hospital based stem cell transplant centers, university-based research labs engaged in this field.

Results of Operations

Summary of 2014 Achievements

We grew our core business 25% over 2013, with a substantial increase in the number of clinical trials incorporating our products. In January 2014, management estimated that BioLife products were incorporated into the storage, shipping, freezing, and/or clinical administration processes and protocols of 100 regenerative medicine clinical trials. For the calendar year 2014, management estimates that an additional 75 cell-based regenerative medicine clinical trials using BioLife products were confirmed, bringing the total to 175.

We focused on bringing new products to the market to round out our platform of biopreservation tools by:

ºForming the biologistex CCM, LLC joint venture to offer logistics tools and cloud-based data used to monitor and manage the movement of biologic materials such as vaccines, cells, tissues, and organs across time and space. We anticipate commercial launch of the biologistex service during the first half of 2015.

ºLaunching two new improved packaging options for our BloodStor® and CryoStor® cryopreservation freeze media products, the single-use syringes and bulk dispensing bags with sterile dockable tubing, both of which were created to improve our customers' aseptic processing of clinical cells and tissues

We announced the execution of a long-term contract manufacturing services agreement with Somahlution LLC, a Jupiter, Florida-based biotechnology company in July 2014. We will manufacture DuraGraft™, a tissue preservation solution for storage of harvested veins used in coronary artery bypass graft (CABG) and other vascular access surgeries. In the fourth quarter, we completed process engineering work for this customer.

Our business was recognized for our growth and was named to the Deloitte 2014 Technology Fast 500™, a ranking of the 500 fastest growing technology, media, telecommunications, life sciences and clean technology companies in North America. This was the second consecutive year BioLife received this recognition for our high growth.

We received the Frost & Sullivan 2014 Technology Innovation Leadership Award for Biopreservation Media, recognizing our position as a market leader.

We were issued a new US patent number 8642255 B2, titled "Materials and methods for hypothermic collection of whole blood", which includes claims related to hypothermic preservation and storage of whole blood and blood components using the Company's HypoThermosol cell and tissue storage/shipping medium.

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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,			
	2014	2013	% Change	
Revenue:	(‘000’s)			
Product revenue				
Core product sales	$4,913	$3,924	25	%
Contract manufacturing services	1,278	4,416	(71	%)
Licensing revenue	—	609		
Total revenue	6,191	8,949	(31	%)
Cost of sales	3,155	5,187	(39	%)
Gross profit	$3,036	$3,762	(19	%)
Gross margin %	49.0 %	42.0 %		

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 2014 increased compared to 2013 due to a 31% increase in volume sold offset by a slight decrease in our average selling price per liter in 2014. The increase was primarily in the area of sales through our distributors, which more than doubled in 2014 compared to 2013. Sales to our core customers tend to be uneven due to the pace of product evaluation, adoption, and clinical trials. Our products are incorporated in over 175 clinical trials in the regenerative medicine segment. Revenue from this market will become fully realized 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.To leverage our capacity and the market opportunity for contract manufacturing services, we manufacture products for third parties pursuant to contractual arrangements. In 2014, we recorded revenue from sales to Organ Recovery Services of $1.1 million, compared to $4.4 million in 2013. The contract with this customer was terminated in May 2014. In 2014, we also recorded $0.2 million associated with a new contract manufacturing customer.

Licensing Revenue. During the first quarter of 2013, we negotiated a new intellectual property license agreement that provides Janssen Research & Development, LLC with limited access to our intellectual property under certain conditions. This customer paid upfront fees for the specific rights and there are no future performance obligations. The upfront fee of $500,000 was recognized as revenue during the quarter and $109,167 in deferred revenue associated with this customer was recognized as all future performance obligations associated with the previous license agreements were cancelled with the agreement signed in the first quarter of 2013.

Cost of Sales. Cost of sales consists of raw materials, labor and overhead expenses. Cost of sales in 2014 decreased compared to 2013 due primarily to the significant reduction in volume in our contract manufacturing services revenue and costs related to the manufacture of this product.

Gross Margin. Gross margin as a percentage of revenue increased to 49.0% in 2014 compared to 42.0% in 2013. Gross margin as a percentage of revenue increased in 2014, 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. Gross margin as a percentage of

revenue in 2013 included the impact of recognition of $609,167 in license revenue during the quarter with no associated costs, which resulted in a significant improvement in gross margin as a percentage of revenue in 2013. Excluding that revenue, the gross margin in 2013 would have been 37.8%.

Revenue Concentration. In 2014 and 2013, we derived approximately 18% and 49%, respectively, of our revenue from our relationship with one contract-manufacturing customer. In 2014 we derived approximately 11% of our revenue from one other customer and in 2013, we derived approximately 14% of our revenue from one other customer which included license revenue and core product revenue. No other customer accounted for more than 10% of revenue in 2014 or 2013. At December 31, 2014, two customers accounted for 25% of gross accounts receivable. Revenue from customers located in foreign countries represented 16% and 9% of total revenue during the years ended December 31, 2014 and 2013, respectively.

Operating Expenses

Our operating expenses for the years ended December 31, 2014 and 2013 were:

	Year Ended December 31,					
	2014		2013		% Change	
	('000's)					
Operating Expenses:						
Research and development	$871		$488		79	%
Sales and marketing	1,330		841		58	%
General and administrative	3,970		2,719		46	%
Operating Expenses	6,171		4,048		52	%
% of revenue	99.7	%	45.2	%		

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. Research and development expenses for 2014 increased compared to 2013 due to $0.3 million in higher salaries and bonuses related to additional personnel in the department and additional contract research costs of $0.1 million.

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 2014 compared to 2013 was primarily due to our ramp-up in sales and marketing personnel of $0.3 million and higher trade show and sponsorship related costs of $0.1 million.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries, bonuses and other personnel-related expenses, non-cash stock-based compensation for administrative personnel and non-employee members of the board of directors, professional fees, such as accounting and legal, corporate insurance and facilities costs. The increase in 2014 compared to 2013 included $0.3 million in SAVSU participation fees, which represents the first four of twelve monthly payments to SAVSU related to the biologistex joint venture. Also included in the increase are higher personnel costs of $0.2 million and higher corporate costs of $0.7 million. Corporate costs include legal costs related to formation of the joint venture, investor relations consulting, shareholder communications, director compensation and D&O insurance.

Other Income (Expenses)

Interest Expense. The reduction in interest expense in 2014 compared to 2013 was due to the conversion of the notes and interest into stock as of March 25, 2014, and did not include a full quarter of interest. See above, "—Recent Developments—Conversion of Notes and Interest to Equity."

Amortization of Deferred Financing Costs. Amortization of deferred financing costs represents the cost of warrants issued which were amortized over the life of the debt. In connection with the termination of the note facility agreements, we recorded $101,852, the remaining unamortized costs, as an adjustment to additional paid in capital. See above, "—Recent Developments—Conversion of Notes and Interest to Equity."

2015 Expectations:

We expect to see continued growth in adoption and use of our proprietary biopreservation media products, resulting in the goal of an increase in our proprietary product revenue of 20% to 30% over 2014.

We expect gross margins to be in the range of 50% to 60% for the year and we anticipate that our use of cash and operating loss will increase by as much as 30% based primarily on sales, marketing and G&A investments in biologistex.

Achieving these results will depend on a number of factors, including: the level and pace of market adoption of our products; the clinical and commercial success of our customers; competition; and the risks set forth in this Annual Report on Form 10-K under the heading “Risk Factors”.

Liquidity and Capital Resources

We believe that our current level of cash and cash equivalents will be sufficient to meet our liquidity needs for the foreseeable future. We expect to have ongoing cash requirements which we plan to fund through total available liquidity and cash flows generated from operations. 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 and infrastructure scaling for biologistex, and continuing to strengthen our balance sheet and competitive position.

On December 31, 2014, we had $9,938,394 in cash, cash equivalents and short term investments, compared to cash and cash equivalents of $156,273 at December 31, 2013.

Net Cash Provided/(Used) by Operating Activities

During the year ended December 31, 2014, we used $3,162,316 in cash from operations, compared to providing cash from operations of $146,007 for the year ended December 31, 2013. During 2014, operating cash was primarily used to fund the 2014 net loss.

Net Cash Used in Investing Activities

Net cash used in investing activities totaled $8,135,023 in 2014 and $236,670 in 2013. 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 2014 and 2013, we used $589,680 and $236,670, respectively, 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 $13,679,824 in 2014, which included gross proceeds of $15,432,175 received in the registered public stock offering completed on March 25, 2014, net of placement agent fees of $1,211,735 and offering costs of $624,211 and $83,594 from the exercise of stock options. Net cash provided by financing activities of $50,458 during 2014 was the result of proceeds received from warrant and employee stock option exercises.

Upon conversion of all of our outstanding notes and interest to equity on March 25, 2014, we terminated the facility agreements.

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 believes 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, 2011 to 2014.

Off-Balance Sheet Arrangements

As of December 31, 2014, 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.

ITEMQUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK
7A.

Not applicable.

ITEMFINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
8.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders
BioLife Solutions, Inc.
Bothell, Washington

We have audited the accompanying consolidated balance sheets of BioLife Solutions, Inc. and Subsidiary ("the Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive loss, shareholders' equity (deficiency), 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 financial statements are free of 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 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, 2014 and 2013, 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
March 12, 2015

BioLife Solutions, Inc.
Consolidated Balance Sheets

	December 31, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$2,538,758	$156,273
Short term investments	7,399,636	—
Accounts receivable, trade, net of allowance for doubtful accounts of $0 at December 31, 2014 and $1,100 at December 31, 2013	901,623	1,009,316
Inventories	965,224	420,924
Prepaid expenses and other current assets	360,521	291,745
Total current assets	12,165,762	1,878,258
Property and equipment		
Leasehold improvements	1,284,491	1,121,362
Furniture and computer equipment	476,788	300,581
Manufacturing and other equipment	972,386	764,258
Subtotal	2,733,665	2,186,201
Less: Accumulated depreciation	(1,078,060)	(862,157)
Net property and equipment	1,655,605	1,324,044
Intangible asset	2,215,385	—
Long term deposits	36,166	36,166
Deferred financing costs, net	—	114,874
Total assets	$16,072,918	$3,353,342
Liabilities and Shareholders' Equity (Deficiency)		
Current liabilities		
Accounts payable	$474,662	$867,070
Accrued expenses and other current liabilities	121,869	146,626
Accrued compensation	535,029	503,194
Deferred rent	130,216	111,250
Total current liabilities	1,261,776	1,628,140
Long term liabilities		
Promissory notes payable, related parties	—	10,603,127
Accrued interest, related parties	—	3,501,610
Deferred rent, long term	874,825	891,986
Total liabilities	2,136,601	16,624,863
Commitments and Contingencies (Note 10)		
Shareholders' equity (deficiency)		
Common stock, $0.001 par value; 150,000,000 shares authorized, 12,084,859 and 5,031,336 shares issued and outstanding at December 31, 2014 and 2013	12,084	5,030
Additional paid-in capital	71,911,328	43,618,686
Accumulated other comprehensive loss	(6,448)	—
Accumulated deficit	(60,112,987)	(56,895,237)

Total BioLife Solutions, Inc. shareholders' equity (deficiency)	11,803,977	(13,271,521)
Total non-controlling interest equity (deficiency)	2,132,340	—
Total shareholders' equity (deficiency)	13,936,317	(13,271,521)
Total liabilities and shareholders' equity (deficiency)	$16,072,918	$3,353,342

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,	
	2014	2013
Revenue		
Product sales	$ 6,190,698	$ 8,340,234
Licensing revenue	—	609,167
Total revenue	6,190,698	8,949,401
Cost of product sales	3,155,288	5,186,514
Gross profit	3,035,410	3,762,887
Operating expenses		
Research and development	871,100	487,816
Sales and marketing	1,329,746	841,451
General and administrative	3,970,254	2,718,977
Total operating expenses	6,171,100	4,048,244
Operating loss	(3,135,690)	(285,357)
Other income (expenses)		
Interest income	20,825	—
Interest expense	(177,308)	(742,219)
Amortization of deferred financing costs	(13,022)	(56,584)
Gain on disposal of property and equipment	4,400	—
Total other income (expenses)	(165,105)	(798,803)
Net Loss	(3,300,795)	(1,084,160)
Net loss attributable to non-controlling interest	83,045	—
Net Loss attributable to BioLife Solutions, Inc.	$ (3,217,750)	$ (1,084,160)
Basic and diluted net loss per common share attributable to BioLife Solutions, Inc.	$ (0.31)	$ (0.22)
Basic and diluted weighted average common shares used to calculate net loss per common share	10,447,030	5,007,999

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,	
	2014	2013
Net Loss	$ (3,300,795)	$ (1,084,160)
Other comprehensive loss		
Unrealized loss on available-for-sale investments	(6,448)	—
Total other comprehensive loss	(6,448)	—
Comprehensive Loss	$ (3,307,243)	$ (1,084,160)
Comprehensive loss attributable to non-controlling interest	83,045	—
Comprehensive Loss attributable to BioLife Solutions, Inc.	$ (3,224,198)	$ (1,084,160)

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

BioLife Solutions, Inc.
Consolidated Statements of Shareholders' Equity (Deficiency)

	BioLife Solutions, Inc. Shareholders' Equity (Deficiency)							
	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total BioLife Solutions, Inc. Shareholders' Equity/Deficiency	Non-Controlling Interest Equity/Deficiency	Total Shareholders' Equity/Deficiency
Balance, December 31, 2012	4,978,834	$4,977	$43,320,077	$-	$(55,811,077)	$(12,486,023)	$	$(12,486,023)
Stock-based compensation			248,204			248,204		248,204
Stock options/warrant exercises	47,740	48	50,410			50,458		50,458
Issuance of stock upon vesting of restricted stock units	4,762	5	(5)			-		-
Net loss					(1,084,160)	(1,084,160)		(1,084,160)
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	3,321,405	3,321	14,176,872			14,180,193		14,180,193

unamortized deferred financing costs of $101,852						
Other comprehensive loss		(6,448)		(6,448)		(6,448)
Capital contribution of non-controlling interest in biologistex CCM, LLC joint venture				-	2,215,385	2,215,385
Net loss			(3,217,750)	(3,217,750)	(83,045)	(3,300,795)
Balance, December 31, 2014	12,084,859					