BIOLIFE SOLUTIONS INC
Form 10-K
March 29, 2013

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, 2012

¨ 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 ¨ 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 ¨ No 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 ¨

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 ¨

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

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ 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 $2,878,665.

As of February 28, 2013, 70,035,710 shares of the registrant's common stock were outstanding.

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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.

Overview

BioLife Solutions, Inc. ("BioLife” or the “Company”), was originally 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 its wholly-owned subsidiary, BioLife Solutions, Inc., which was engaged as a life sciences tools provider. Following the merger, the Company changed its name to BioLife Solutions, Inc.

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

Contract aseptic manufacturing formulation, fill, and finish services of liquid media products

Our proprietary HypoThermosol®, CryoStor®, and generic BloodStor® 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 products are serum-free and protein-free, fully defined, and are manufactured under current Good Manufacturing Practices (“cGMP”) using United States Pharmacopeia (“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 50 clinical trial stage regenerative medicine products and therapies.

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.

Our principal executive offices are located at 3303 Monte Villa Parkway, Suite 310, Bothell, WA 98021 and our telephone number is (425) 402-1400. Our cGMP manufacturing facility is located at 3301 Monte Villa Parkway, Suite 105, Bothell WA 98021.

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.

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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 tissue, if not maintained appropriately at normothermic body temperature (98.6ºF/37ºC), or stored 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 produces mixed results. Although cooling successfully reduces metabolism (i.e., lowers demand for energy), various levels of cellular damage and death occur when using suboptimal methods. To solve this problem, transplant surgeons, for example, flush the donor tissue with an engineered preservation solution designed to provide short-term biopreservation support after removal of the organ from the donor and during transportation. Companies and hospital cell transplantation centers engaged in regenerative medicine product development also maintain the original and derived cellular material in a solution before and after cell manipulation and processing, and during necessary transportation up to the point of infusion/injection into the patient. Traditional support solutions 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 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 engineered and patented HypoThermosol® 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” nature. All of our cGMP products are serum-free, protein-free and are formulated and filled using aseptic processing, utilizing United States Pharmaopeia (“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 manufacturing regulatory filings and patient delivery processes.

The results of independent testing demonstrate that our patented HypoThermosol 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 (iPS) 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 technology is optimized based on low temperature cellular and molecular biology 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 cryogenic protection and reduces the dependence on a single cryoprotectant.

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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®

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.

HypoThermosol® FRS

In addition to providing intracellular-like balance to cells and tissues at low temperatures, this solution has been formulated to decrease the free radical accumulation in cells undergoing prolonged hypothermic preservation. Numerous investigators have shown that an increase in free radicals can lead to either necrosis (pathological cell death) or apoptosis (programmed cell death) in clinical conditions. HypoThermosol FRS is very effective at extending the shelf life and improving the post-preservation viability and function of numerous cell and tissue types.

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 -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.

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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%.

CryoStor® CS2

Pre-formulated with 2% DMSO, in some cell types, CryoStor CS2 has demonstrated biopreservation efficacy at or above the levels of competing commercial and in-house formulated freeze media, even in the presence of significantly reduced levels of DMSO.

CryoStor® CS5

Pre-formulated with 5% DMSO, CryoStor CS5 routinely outperforms competing freeze media containing 10% DMSO and is recommended for cryopreservation of most cell types.

CryoStor® CS10

Pre-formulated with 10% DMSO, CryoStor CS10 has demonstrated remarkable biopreservation efficacy in numerous cell types, including sensitive cells such as hepatocytes. CryoStor CS10 has demonstrated improved post-thaw cell survival and function in specific cell systems that may be more sensitive to cryopreservation-induced cell damage and death. This variant has also been adopted by customers with cell processing methods that might entail some dilution of the cryopreservation media.

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.

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 Visiongain report "Translational Regenerative Medicine: Market Prospects 2012-2022" values the regenerative medicine market at $1.4 billion in 2012, and anticipates the market growing to $10 billion by 2020. More recently, in March 2013, TriMarkPublications forecasted that the regenerative medicine market will catapult to over $35 billion

by 2019. 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.

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Our target markets include:

Regenerative Medicine:

Our proprietary HypoThermosol® and CryoStor® biopreservation media products are used by customers to store, transport, and freeze biologic source material and cell-or tissue-based final 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.

This market is comprised of nearly 700 commercial companies and numerous other hospital-based transplant centers developing and delivering cellular therapies such as stem cells isolated from bone marrow, peripheral and umbilical cord blood as well as engineered tissue-based products.

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 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 50 regenerative medicine cell or tissue-based products in pre-clinical and clinical trial stages of development.

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 a typical regenerative medicine customer could reach $1 million per year within three to five years following their product approval. 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 labware 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. In April 2010, we filed an international patent application (PCT) to protect our intellectual property rights for our inventions which may for the first time, enable bulk freezing of cells in multiwell 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. Since the product launch in the third quarter of 2009, we continue to realize

increased sales of our BloodStor® 55-5, a GMP version of the traditional “home-brew” cord blood stem cell freeze media. Sales of CryoStor and HypoThermosol in this segment also continue to increase as we displace home-brew preservation media due to the quality and performance profile of our proprietary products. In the hair restoration segment, over fifty different physicians and centers now use HypoThermosol as an improved ex vivo holding solution for grafts during the procedure. We estimate that HypoThermosol 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 equity in BioLife Solutions as the brand that manufactures and delivers the best-in-class cGMP, serum-free, protein-free, biopreservation media products for cells, tissues, and organs. We provide premiere offerings to life science researchers and professionals applying biology in their work, such as commercial cell therapy and tissue engineering companies, hospital based stem cell transplant centers, university-based research labs, umbilical cord blood banks, adult stem cell banks, tissue banks, biorepositories, hair transplantation centers, pharmaceutical companies, cell suppliers, and toxicity testing labs.

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We are committed to being a partner of choice for our customers, which requires us to employ scientific personnel for our sales and service roles. Our sales team consists primarily of technical sales specialists, who are responsible for total customer account management. These individuals have an extensive background in biology or other scientific fields of study. Having a thorough understanding of biological techniques and the research process allows our team to act as advisors to our customers. If our customers have questions about their products, orders or other support areas, they have full access by phone or online, to our technical and customer service professionals.

We participate in numerous scientific conferences and industry trade events by exhibiting, presenting scientific and business lectures, and sponsoring industry association events. The Company is 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

Our initial internal production facility was validated and became operational during the second quarter of 2009. In December 2009, our quality and manufacturing systems became certified to ISO 13485:2003. The systems are organized according to 21 CFR Part 820 - Quality System Regulation for Good Manufacturing Practice (GMP) 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.

In 2012 we completed the design and build out of an additional cGMP clean room suite. This facility is validated and operational. We now have the capacity to meet the current and future demand for our proprietary products and also to serve select contract manufacturing customers.

In 2012, approximately 46% of total revenue was generated from an industry leading supplier in the field of transplant medicine. Management believes that the Company’s opportunity in the regenerative medicine market will start to 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. During the interim period until then, the Company is utilizing its manufacturing capacity to generate revenue from contract manufacturing customers.

Governmental Regulation

As an ancillary reagent or excipient used in the production, transportation, and patient administration of our customers’ regulated clinical products, HypoThermosol, CryoStor, and BloodStor are not subject to specific FDA or other non-US pre-market approval for drugs, devices, or biologics. In particular, 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 comply with Current Good Manufacturing Practice (“cGMP”).

To assist customers with regulatory applications, we have submitted Type II Master Files to the FDA for CryoStor and HypoThermosol, 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 who wish to notify the FDA of their intention to use our products in their product development and manufacturing process can now request 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 six issued U.S. patents, one issued European patent, one issued Japanese patent, and several pending US and international patent applications.

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

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

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, some 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 2012 and 2011, we spent approximately $463,600 and $516,500, 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. The current members are:

Shelly Heimfeld, Ph.D., Director of Heimfeld Research Laboratory, Scientific Director of Cellular Therapy Laboratory, Scientific Director of cGMP Therapeutic Manufacturing Facilities, 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.

Dayong Gao, Ph.D., 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, and has authored over 130 peer-reviewed journal articles on cryopreservation.

Andrew Hinson, Vice President of Clinical and Regulatory Affairs for Lone Star Heart, Inc. (formerly CardioPolymers, Inc.) since 2004. Lone Star Heart is a global developer of medical devices, small molecule, and cellular-based therapies for cardiovascular disease. Mr. Hinson is also a Director of the Company.

Scott R. Burger, M.D., Principal, 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.

Erik J. Woods, Ph.D., President and CEO at Cook General Biotechnology, and also Director of Genome Resources, an anonymous donor and client depositor sperm bank. Both laboratories are FDA registered and CLIA compliant.

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

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Colleen Delaney, MSc., M.D., 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.

John McMannis, Ph.D., is the Executive Vice President of Manufacturing at Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY). 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.

Jon Rowley, Entrepreneur and Independent Consultant at Entrepreneur and Independent Consultant, formerly the Innovation Director, Cell Processing Technologies at Lonza Biosciences. Jon has been responsible for driving technology development and innovation related to commercial scale bioprocessing of therapeutic cell-based products.

Edward LeCluyse, Ph.D., is 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.

Jerry Cooley, MD., Dr. Cooley 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 doctors. He has been performing hair transplants for almost 20 years.

Competition

The markets for our products are competitive and are characterized by the application of advanced technologies. Our competition comes from a wide array of competitors with a high degree of technical proficiency, ranging from in-house formulated biopreservation media, whereby the user purchases raw ingredients and manually mixes the ingredients, to larger manufacturers such as Life Technologies Corp. (formally Invitrogen), and distributors including STEMCELL Technologies, Sigma-Aldrich, VWR, Fisher, and smaller specialized companies, offering a broad array of biotechnology products and services that have significantly more financial, operational, sales and marketing and other resources than we do. 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. It is our belief 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.

The Company believes 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, the Company believes 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.

Workforce

At December 31, 2012, we had 28 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.

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Available Information

We maintain a website at 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.

ITEM1A. RISK FACTORS

Risks Related to Our Business

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 on Form 10-K, 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.

We derived approximately 60% of our product revenue in the third and fourth quarters of 2012 and approximately 46% of our product revenue in the fiscal year ended December 31, 2012 from our relationship with one contract manufacturing customer, which we commenced deliveries to in the second quarter of 2012. 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, the loss of our major contract manufacturing customer, 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, 2012 and December 31, 2011, we had net losses of $1,659,586 and $1,956,639, respectively. As of December 31, 2012, our accumulated deficit was approximately $56 million. Of this amount, approximately $18 million has accumulated since the merger of the Company 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.

Failure to comply with the covenants and conditions of our existing promissory notes could result in the acceleration of our outstanding indebtedness, and we may not have sufficient funds available to repay the amounts due.

We have outstanding $10.6 million principal amount of promissory notes due January 11, 2016 held by our two most significant stockholders, secured by all of the assets of the Company. An event of default, including from the failure to observe or comply with any material covenant or condition in the promissory notes or the Facilities, could, if not cured or waived, result in the acceleration of our outstanding indebtedness and the loss of some or all of our assets. If our operations are insufficiently profitable to permit us to pay such notes when due, and these stockholders are unable or unwilling to provide access to additional funds and/or amend the terms of the Facilities, we would need to find immediate additional sources of capital. There can be no assurance that such capital would be available on favorable terms, or at all. As such, we may have to cease operations and you could lose your investment.

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There is uncertainty surrounding our ability to successfully commercialize our HypoThermosol, CryoStor and BloodStor biopreservation media products and contract manufacturing services.

Our growth depends, in part, on our continued ability to successfully develop, commercialize and market our HypoThermosol, CryoStor, and BloodStor biopreservation media products and contract and 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 and CryoStor biopreservation media products is dependent, in part, on the commercial success of new regenerative medicine technologies.

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

We face significant competition.

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

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

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

Our 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.

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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 $6 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, the litigation could consume substantial time and attention of our management, and the resulting liability could exceed our total assets.

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

We currently manufacture our products ourselves. The manufacture of our products is difficult, complex and highly regulated. To support our current and prospective clinical customers, we intend to comply with Current Good Manufacturing Practice (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 Current Good Manufacturing Practices (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 the 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.

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.

As an ancillary or excipient reagent used in the production, transportation, and infusion of our customers' regulated clinical products, HypoThermosol, CryoStor, and BloodStor are not currently subject to specific FDA or other non-US pre-market approval for drugs, devices, or biologics. 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 controls over external financial reporting fail or are 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.

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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.

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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.

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

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

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

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

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

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

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

resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, if at all, which could seriously harm our business or financial condition.

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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 Over-the-Counter (OTC) 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:

- Future sales of our common stock or other fundraising events;
- 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, who have also provided us with our debt financing Facilities, and these stockholders therefore have significant influence on us and our corporate actions.

As of December 31, 2012, two of our existing stockholders beneficially owned, collectively, approximately 48% of our outstanding shares of common stock. We have also outstanding $10.6 million principal amount of promissory notes to such stockholders. One of those stockholders, Thomas Girschweiler, is also a member of our Board and of our Board’s Audit and Compensation committees. Accordingly, these shareholders 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. For more information regarding our principal stockholders, see "ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters”.

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Trading of our stock may be restricted by the SEC's "Penny Stock" regulations, which may limit a stockholder's ability to buy and sell our stock.

The SEC has adopted regulations that generally define "penny stock" to be any equity security that has a market price less than $5.00 per share. Our securities are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers or "accredited investors." The term "accredited investor "refers generally to institutions with assets in excess of $5,000,000 or individuals with a net worth in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 jointly with his or her spouse. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC, which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that, prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules may discourage investor interest in, and limit the marketability of, our common stock.

FINRA sales practice requirements may also limit a stockholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

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.

If we are unable to achieve and maintain positive cash flow, we will need to raise additional capital. In addition, we have issued to our two most significant stockholders $10.6 million principal amount of promissory notes due January 2016. If we are unable to achieve profitability sufficient to permit us to repay the notes, we may be required to raise additional capital to repay these notes, even if we are otherwise profitable. 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. In addition, if our significant stockholders agree to convert their debt securities into common stock, their ownership of our common stock and their control over our company will increase. New securities may contain certain rights, preferences or privileges that are senior to those of our common stock. Furthermore, any additional equity financing may be dilutive to stockholders, and 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 continue our operations.

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.

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

Our certificate of incorporation and 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. In addition, our stockholders have, by non-unanimous written consent, also approved amended and restated bylaws (to become effective during April 2013) that authorize our Board 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.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 26,000 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 8 to the Financial Statements included in this Annual Report on Form 10-K.

ITEM 3. LEGAL PROCEEDINGS

On February 7, 2007, Kristi Snyder, a former employee of the Company filed a complaint in the New York State Supreme Court, County of Broome, against the Company alleging a breach of an employment agreement and seeking damages of up to $300,000 plus attorneys' fees. This case currently is in discovery. The Company is vigorously defending its position.

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

On June 15, 2007, the Company filed a lawsuit in the State of New York Supreme Court, County of Tioga against Cell Preservation Services, Inc. ("CPSI") and Coraegis Bioinnovations, Inc. ("Coraegis"), both of which are owned and/or controlled by John M. Baust, a former employee of the Company and the son of John G. Baust, both of whose employment with the Company was terminated on January 8, 2007.

On March 15, 2004, the Company had entered into a Research Agreement with CPSI, pursuant to which CPSI took over the processing of the Company's existing SBIR grants, on behalf of the Company was to apply for additional SBIR grants and, in each case, was to perform the research with respect to such grants. In connection therewith, the Company granted to CPSI a limited license to use the Company's technology ("BioLife's Technology"), including the Company's proprietary cryopreservation solutions (collectively, "Intellectual Property"), solely for the purpose of conducting the research pertaining to the SBIR grants, and CPSI agreed to keep confidential all Company confidential information disclosed to CPSI ("Confidential Information"). On January 8, 2007, the Company informed CPSI that the Research Agreement would not be extended and would terminate in accordance with its terms on March 15, 2007.

The lawsuit states various causes of action, including, (1) repeated violations of the Research Agreement by CPSI by improperly using BioLife's Technology, Intellectual Property and Confidential Information for its own purposes, (2) the unlawful misappropriation by CPSI and Coraegis of the Company's trade secrets, (3) unfair competition on the part of CPSI and Coraegis through their unlawful misappropriation and misuse of BioLife's Technology, Intellectual Property and Confidential Information, and (4) the conversion of BioLife's Technology, Intellectual Property and Confidential Information by CPSI and Coraegis to their own use without the Company's permission.

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The lawsuit seeks, among other things, (1) to enjoin CPSI from continuing to violate the Research Agreement, (2) damages as a result of CPSI's breaches of the Research Agreement, (3) to enjoin CPSI and Coraegis from any further use of the Company's trade secrets, (4) damages (including punitive damages) as a result of CPSI's and Coraegis' misappropriation of the Company's trade secrets, (5) to enjoin CPSI and Coraegis from any further use of BioLife's Technology, Intellectual Property and Confidential Information, (6) damages (including punitive damages) as a result of CPSI's and Coraegis' unfair competition against the Company, and (7) damages (including punitive damages) as a result of CPSI's and Coraegis' conversion of BioLife's Technology, Intellectual Property and Confidential Information to their own use. On September 30, 2008, Justice Jeffrey Tait issued a Letter Decision and Order which provides for a multi-phase process for discovery concerning contested discovery disclosures. The parties are awaiting Justice Tait's decision on the initial process to be used concerning these contested discovery issues. The parties have engaged in extensive motion practice. By decision of December 18, 2009, Justice Tait denied the attempt of the Defendants to dismiss Plaintiff's complaint. This case currently is in discovery. The Company is vigorously pursuing its position.

On December 4, 2007, John M. Baust, the son of John G. Baust, filed a complaint in the New York State Supreme Court, County of Tioga, against the Company and Michael Rice, the Company's Chairman and Chief Executive Officer, alleging, among other things, a breach of an employment agreement and defamation of character and seeking damages against the Company in excess of $300,000 plus attorneys fees. This case currently is in discovery. The Company is vigorously defending its position.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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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, par value $.001 per share, is traded on the OTC Bulletin Board under the symbol "BLFS". As of December 31, 2012, there were approximately 3,000 holders of record of its 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, for the periods indicated, the range of high and low quarterly closing sales prices of its common stock:

	High	Low
Year ended December 31, 2011		
4th Quarter	$0.10	$0.02
3rd Quarter	0.09	0.02
2nd Quarter	0.10	0.06
1st Quarter	0.11	0.06
Year ended December 31, 2012		
4th Quarter	$0.45	$0.14
3rd Quarter	0.17	0.07
2nd Quarter	0.12	0.07
1st Quarter	0.12	0.04

During the fourth quarter of 2012, we did not repurchase any of our securities.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Forward-Looking Statements

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. 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,” “could,” “plan,” “intend,” or similar e this Annual Report on Form 10-K or in documents incorporated by reference into 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 in Item 1A “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.

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 HypoThermosol®, CryoStor®, and generic BloodStor® 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 products are serum-free and protein-free, fully defined, and are manufactured under current Good Manufacturing Practices ("cGMP") using United States Pharmacopeia ("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 50 clinical trial stage regenerative medicine products and therapies.

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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 truly 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 remarkable 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.

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 broad direct sales and distribution network for our products which we utilize to expand sales to existing customers and to gain additional customers.

Highly technical sales team. Our sales 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 innovative new products. We are continuously seeking to utilize the unique nature of our technologies to create customer application-based solutions.

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.

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Results of Operations

Summary of 2012 Achievements

Revenue from our core products, CryoStor®, HypoThermosol®, and BloodStor® grew 23% over 2011 as we expanded our market share in the regenerative medicine, biobanking, and drug discovery segments and ended 2012 with over $3 million in revenue from core customers.

We executed a significant confidential multi-year contract manufacturing services agreement to perform aseptic media formulation, fill, and finish of several biopreservation solutions for a new multinational customer and delivered over $2.5 million in product to this customer in 2012.

We signed a lease amendment to increase the size of the corporate headquarters and manufacturing capacity by approximately 100% with the addition of a second Good Manufacturing Practice (cGMP) clean room suite.

We expanded our team from 12 people at the end of 2011 to 28 people at the end of 2012, to meet growing demand for our products and services. Team members were added to our production team and both direct and indirect sales professionals in the period.

We signed a new private-label distribution agreement to supply HypoThermosol® and CryoStor® to a leading life sciences cell culture tools provider.

We achieved positive cash flow from operations during the last quarter of the year for the first time in Company history.

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,		
	2012	2011	% Change
Revenue:	('000's)		
Product revenue			
Direct	$ 2,291	$ 1,893	21%
Indirect	728	565	29%
Core product sales	3,019	2,458	23%
Contract manufacturing services	2,624	281	834%
Total product sales	5,643	2,739	106%
Licensing revenue	20	20	—
Total revenue	5,663	2,759	105%
Cost of sales	3,371	1,356	149%
Gross profit	$ 2,292	$ 1,403	63%
Gross margin %	40.5%	50.9%	

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 direct customers in 2012 increased compared to 2011 due primarily to higher sales to existing customers, sales to new customers, higher selling prices in 2012 compared to 2011 for our family of core products, and the addition of three team members engaged in product sales.

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Contract Manufacturing Services. To leverage our capacity and the market opportunity for contract manufacturing services, we are manufacturing products for third parties pursuant to contractual arrangements. In 2012, contract manufacturing services primarily represented shipments to one significant customer, a public company engaged in the development and marketing of organ preservation solutions and devices. This customer accounted for 46% of total revenue in 2012 and $1.2 million, or 60% of total revenue in the fourth quarter of 2012.

Cost of Product Sales. Cost of sales consists of raw materials, labor and overhead expenses. Cost of sales in 2012 increased compared to 2011 due to the significant increase in sales of both core and contract manufacturing products.

Gross Profit and Gross Margin. Gross profit increased in 2012 compared to 2011 due to the significant increase in sales of both core and contract manufacturing products. Gross margin as a percentage of revenue decreased significantly in 2012 compared to 2011 due primarily to the increase in contract manufacturing product sales, which has a higher cost of sales, compared to core product sales. Additionally, gross margin declined due to additional personnel and other costs included in cost of goods sold related to the expansion of our production operations.

Licensing Revenue. We have entered into license agreements with one customer that provides this customer with limited access to our intellectual property under certain conditions. This customer paid upfront fees for the specific rights and we recognize license revenue ratably over the term of the agreements.

Revenue Concentration. In 2012, we derived approximately 46% of our product revenue from our relationship with one contract manufacturing customer, which we commenced deliveries to in the second quarter of 2012. Either party may terminate the agreement with this contract manufacturing customer for any reason on six months' notice. No other customer accounted for more than 10% of revenue in 2012. In 2011, no individual customer accounted for more than 10% of sales. Revenue from customers located in foreign countries represented 11% and 13% of total revenue during the years ended December 31, 2012 and 2011, respectively.

Operating Expenses

Our operating expenses for the years ended December 31, 2012 and 2011 were:

(dollars in 000's)	Year Ended December 31, 2012	2011
Research and development	$ 464	$ 516
% of revenue	8%	19%
Sales and marketing	619	267
% of revenue	11%	10%
General and administrative	2,152	1,829
% of revenue	38%	66%
Total operating expenses	3,235	2,613
% of revenue	57%	95%

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 decreased in 2012 compared to 2011 due primarily to reduced spending with contract research organizations, which accounted for approximately $25,000 of the variance and lower spending on patent related legal expenses, which accounted for $45,000 of the difference. This was offset slightly by an increase in personnel related costs.

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 2012 compared to 2011 was primarily due to increased personnel costs which resulted from the additional team members on this team which were added in the second quarter of 2012. The additional team members were added to focus on our sales of our core products through both direct sales to customers and through our indirect distribution network.

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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. General and administrative expenses were higher in 2012 compared to 2011 due to higher personnel costs in 2012, offset somewhat by a reduction in consulting expenses due to the termination of one consulting agreement in the third quarter of 2011.

Other Income (Expenses)

Interest Expense. The increase in interest expense in 2012 compared to 2011 was due to a higher average debt balance.

Amortization of Deferred Financing Costs. Amortization of deferred financing costs represents the cost of warrants issued which are being amortized over the life of the warrants.

Liquidity and Capital Resources

We have been unable to generate sufficient income from operations in order to meet our operating needs and have an accumulated deficit of approximately $56 million at December 31, 2012. Of this amount, approximately $18 million has accumulated since the merger of the Company in 2002.

We believe our current cash and cash provided by operations will satisfy our working capital requirements, debt obligations and capital expenditures for the foreseeable future. Our future capital requirements and the adequacy of our available funds will depend on many factors, including future profitable operations, debt repayment, and competing technological and market developments.

Our working capital factors, such as inventory turnover and days sales outstanding, fluctuate on a quarterly basis and, on an interim basis during the year, may require an influx of short-term working capital. The Company will continuously assess the most appropriate method of financing the Company’s short and long term operations. While conditions of the credit market at any given time may impact our ability to obtain credit, the Company believes that it has the ability to raise funding, if needed, through public and private markets.

Future debt repayment or future acquisitions may be financed by a combination of cash on hand, our positive cash flow generation, a revolving credit facility, or an issuance of new debt or stock.

We have outstanding $10.6 million principal amount of promissory notes due January 11, 2016 under the facilities held by our two most significant stockholders, secured by all of the assets of the Company. An event of default, including from the failure to observe or comply with any material covenant or condition in the promissory notes could, if not cured or waived, result in the acceleration of our outstanding indebtedness.

At December 31, 2012, we had cash and cash equivalents of $196,478 compared to cash and cash equivalents of $16,864 at December 31, 2011. At December 31, 2012, we had working capital of $262,421, compared to working capital of $581,159 at December 31, 2011. The decline in our working capital is due primarily to an increase in our accounts payable related to purchases of materials, which has significantly increased in 2012.

Net Cash Provided by (Used in) Operating Activities

During the year ended December 31, 2012, net cash provided by operating activities was $854,934 compared to net cash used by operating activities of $989,917 for the year ended December 31, 2011. Cash used in operating activities

relates primarily to funding net losses and changes in operating assets and liabilities, offset by non-cash compensation related to stock options and depreciation. In 2012, cash provided by operating activities included an increase in deferred rent of $901,000 related to lease incentives received from our landlord.

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Net Cash Used in Investing Activities

Net cash used in investing activities totaled $1,150,320 during the year ended December 31, 2012, and $91,430 during the year ended December 31, 2011. Cash used in investing activities was due primarily to the increase in tenant improvements related to our expanded manufacturing facility and the purchase of equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $475,000 and $1,095,000 during the years ended December 31, 2012 and 2011, respectively. Cash provided by financing activities resulted from funding from two existing shareholders under the existing Facilities.

At December 31, 2012, the unused portion of the Facilities was approximately $900,000.

Outlook

In 2013, BioLife management expects revenue to be in the range of $6.5 million to $7.0 million. This increase will be driven by continued increases in sales to existing customers, the addition of new customers in the regenerative medicine market as our customers continue to move their cell and tissue based therapies and products through the clinical trial and regulatory approval processes, and continued focus on sales through our existing distribution network.

We expect gross margin as a percentage of revenue of approximately 38% - $41% in 2013 with fluctuation occurring as a result of changes in the mix of core product sales and contract manufacturing services revenue.

We expect operating expenses in 2013 to increase 10% - 20% over 2012, with increases expected in all areas primarily in personnel related costs.

We will continue to focus on generating positive operating income in 2013, and expect the results for the full year to increase over 2012. We believe cash generated from customer collections will provide sufficient funds to operate our business.

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.

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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, 2009 to 2012.

Off-Balance Sheet Arrangements

As of December 31, 2012, we did not have any off-balance sheet financing arrangements.

Contractual Obligations

In November of 2012 we signed an amended lease agreement, which expanded the premises leased by us from the landlord to approximately 26,000 rentable square feet. The term of the lease was extended to July 31, 2021. The amendment includes two (2) options to extend the term of the lease, each option is for an additional period of five (5) years, with the first extension term commencing, if at all, on August 1, 2021, and the second extension term commencing, if at all, immediately following the expiration of the first extension term. In accordance with the amended lease agreement, our monthly base rent increased to approximately $35,000 effective January 1, 2013, and will increase to approximately $46,000 estimated to be effective in May 2013, upon the completion of leasehold improvement, with scheduled annual increases each August. We will be required to pay an amount equal to our proportionate share of certain taxes and operating expenses.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

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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 balance sheets of BioLife Solutions, Inc. ("the Company") as of December 31, 2012 and 2011, and the related statements of operations, shareholders' equity (deficiency), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the 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 financial statements referred to above present fairly, in all material respects, the financial position of BioLife Solutions, Inc. as of December 31, 2012 and 2011, and the results of its operations and its 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 29, 2013

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BioLife Solutions, Inc.

Balance Sheets

	December 31, 2012	December 31, 2011
Assets		
Current assets		
Cash and cash equivalents	$ 196,478	$ 16,864
Accounts receivable, trade, net of allowance for doubtful accounts of $1,100 at December 31, 2012 and 2011	600,153	547,143
Inventories	656,397	505,956
Prepaid expenses and other current assets	174,731	90,444
Total current assets	1,627,759	1,160,407
Property and equipment		
Leasehold improvements	919,035	—
Furniture and computer equipment	288,725	177,013
Manufacturing and other equipment	741,771	623,782
Subtotal	1,949,531	800,795
Less: Accumulated depreciation	(615,085)	(447,393)
Net property and equipment	1,334,446	353,402
Long term deposits	36,166	36,166
Deferred financing costs	171,458	112,042
Total assets	$ 3,169,829	$ 1,662,017
Liabilities and Shareholders' Equity (Deficiency)		
Current liabilities		
Accounts payable	$ 862,492	$ 403,103
Accrued expenses and other current liabilities	8,495	57,315
Accrued compensation	363,101	86,563
Deferred rent	111,250	12,267
Deferred revenue	20,000	20,000
Total current liabilities	1,365,338	579,248
Long term liabilities		
Promissory notes payable, related parties	10,603,127	10,128,127
Accrued interest, related parties	2,759,391	2,025,961
Deferred rent, long term	838,829	—
Deferred revenue, long term	89,167	109,167
Total liabilities	15,655,852	12,842,503
Commitments and Contingencies (Note 8)		
Shareholders' equity (deficiency)		
Common stock, $0.001 par value; 100,000,000 shares authorized, 69,679,854 shares issued and outstanding at December 31, 2012 and 2011	69,680	69,680
Additional paid-in capital	43,255,374	42,901,325
Accumulated deficit	(55,811,077)	(54,151,491)
Total shareholders' equity (deficiency)	(12,486,023)	(11,180,486)

Total liabilities and shareholders' equity (deficiency)	$ 3,169,829	$ 1,662,017

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

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BioLife Solutions, Inc.

Statements of Operations

	Years Ended December 31, 2012	2011
Revenue		
Product sales	$ 5,642,990	$ 2,738,729
Licensing revenue	20,000	20,000
Total revenue	5,662,990	2,758,729
Cost of product sales	3,370,571	1,355,571
Gross profit	2,292,419	1,403,158
Operating expenses		
Research and development	463,638	516,454
Sales and marketing	619,202	267,080
General and administrative	2,151,817	1,829,307
Total operating expenses	3,234,657	2,612,841
Operating loss	(942,238)	(1,209,683)
Other income (expenses)		
Other income	94,253	46
Interest expense	(733,430)	(670,986)
Amortization of deferred financing costs	(78,539)	(74,403)
Gain (loss) on disposal of property and equipment	368	(1,613)
Total other income (expenses)	(717,348)	(746,956)
Net Loss	$ (1,659,586)	$ (1,956,639)
Basic and diluted net loss per common share	$ (0.02)	$ (0.03)
Basic and diluted weighted average common shares used to calculate net loss per common share	69,679,854	69,679,854

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

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BioLife Solutions, Inc.

Statements of Shareholders' Equity (Deficiency)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity (Deficiency)
Balance, December 31, 2010	69,679,854	$ 69,680	$ 42,576,260	$ (52,194,852)	$ (9,548,912)
Stock-based compensation	—	—	235,840	—	235,840
Warrants issued as consideration for deferred financing costs	—	—	89,225	—	89,225
Net loss	—	—	—	(1,956,639)	(1,956,639)
Balance, December 31, 2011	69,679,854	$ 69,680	$ 42,901,325	$ (54,151,491)	$ (11,180,486)
Stock-based compensation	—	—	216,094	—	216,094
Warrants issued as consideration for deferred financing costs	—	—	137,955	—	137,955
Net loss	—	—	—	(1,659,586)	(1,656,586)
Balance, December 31, 2012	69,679,854	$ 69,680	$ 43,255,374	$ (55,811,077)	$ (12,486,023)

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

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BioLife Solutions, Inc.

Statements of Cash Flows

	Years Ended December 31, 2012	2011
Cash flows from operating activities		
Net loss	$ (1,659,586)	$ (1,956,639)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation	169,644	97,115
Loss (gain) on disposal of property and equipment	(368)	1,613
Stock-based compensation expense	216,094	235,840
Amortization of deferred financing costs	78,539	74,403
Lease incentive received from landlord, net of amortization	861,802	—
Change in operating assets and liabilities		
(Increase) Decrease in		
Accounts receivable, trade	(53,010)	(208,244)
Inventories	(150,441)	(95,470)
Prepaid expenses and other current assets and long-term deposits	(84,287)	(28,067)
Increase (Decrease) in		
Accounts payable	459,389	286,035
Accrued compensation and other expenses and other current liabilities	227,718	(59,756)
Accrued interest, related parties	733,430	670,986
Deferred rent	76,010	12,267
Deferred revenue	(20,000)	(20,000)
Net cash provided by (used in) operating activities	854,934	(989,917)
Cash flows from investing activities		
Cash received from sale of property and equipment	1,400	2,100
Purchase of property and equipment	(1,151,720)	(93,530)
Net cash used in investing activities	(1,150,320)	(91,430)
Cash flows from financing activity		
Proceeds from notes payable	475,000	1,095,000
Net increase in cash and cash equivalents	179,614	13,653
Cash and cash equivalents - beginning of year	16,864	3,211
Cash and cash equivalents - end of year	$ 196,478	$ 16,864
Non-cash financing activities		
Deferred financing costs from issuance of warrants (see note 6)	$ 137,955	$ 89,225

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

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NOTES TO FINANCIAL STATEMENTS

1. Organization and Significant Accounting Policies

Business

BioLife Solutions, Inc. ("BioLife," “us,” “we,” “our,” or the “Company”) develops, manufactures and markets patente hypothermic storage and cryopreservation solutions for cells and tissues. The Company’s proprietary HypoThermosol® and CryoStor® platform of solutions are marketed to academic and commercial organizations involved in the biobanking, drug discovery, and regenerative medicine markets. BioLife’s products are serum-free and protein-free, fully defined, and are formulated to reduce preservation-induced, delayed-onset cell damage and death. BioLife’s enabling technology provides academic and clinical researchers significant improvements in post-thaw cell, tissue, and organ viability and function. Additionally, for our direct, distributor, and contract customers, we perform custom formulation, fill, and finish services.

Use of estimates

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

Net loss per share

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated using the weighted average number of common shares outstanding plus dilutive common stock equivalents outstanding during the period. Common stock equivalents are excluded for the years ending December 31, 2012 and 2011 since the effect is anti-dilutive due to the Company’s net losses. Common stock equivalents include stock options and warrants.

Basic weighted average common shares outstanding, and the potentially dilutive securities excluded from loss per share computations because they are antidilutive, are as follows for the years ended December 31, 2012 and 2011:

	2012	2011
Basic and diluted weighted average common stock shares outstanding	69,679,854	69,679,854
Potentially dilutive securities excluded from loss per share computations:		
Common stock options	20,379,602	17,873,277
Common stock purchase warrants	7,718,750	6,218,750

Cash and cash equivalents

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

Inventories

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

Accounts receivable

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

Property and equipment

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

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Deferred Financing Costs

Deferred financing costs consist of fees associated with obtaining or restructuring existing debt. These fees are amortized over the term of the related debt using the effective interest method.

Deferred Rent

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

Revenue recognition

We recognize product revenue, including shipping and handling charges billed to customers, upon shipment of product when title and risk of loss pass to customers. Shipping and handling costs are classified as part of cost of product sales. Generally, revenue related to licensing agreement activity is recognized ratably over the estimated term of the service period. Payments received in advance of the related licensing agreement period are recorded as deferred revenue and recognized when earned.

Income taxes

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

We have not recorded any liabilities for uncertain tax positions or any related interest and penalties. Our tax returns are open to audit for years ending December 31, 2009 to 2012.

Advertising

Advertising costs are expensed as incurred and totaled $15,607 and $16,521 for the years ended December 31, 2012 and 2011, respectively.

Fair value of financial instruments

We generally have the following financial instruments: cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and notes payable. The carrying value of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair value based on the short-term nature of these financial instruments. The carrying values of notes payable approximate their fair value because interest rates of notes payable approximate market interest rates.

Operating segments

As described above, our activities are directed in the life sciences field of biopreservation products and services. As of December 31, 2012 and 2011 this is the Company's only operating unit and segment.

Concentrations of credit risk and business risk

In 2012, we derived approximately 46% of our product revenue from our relationship with one contract manufacturing customer, which we commenced deliveries to in the second quarter of 2012. No other customer accounted for more than 10% of revenue in 2012. At December 31, 2012, our contract manufacturing customer accounted for 36% of gross accounts receivable and one other customer accounted for 11% of gross accounts receivable. Either party may terminate the agreement with our contract manufacturing customer for any reason on six months' notice. In 2011, no individual customer made up more than 10% of sales. At December 31, 2011, two customers accounted for approximately 29% of total gross accounts receivable.

Revenue from customers located in foreign countries represented 11% and 13% of total revenue during the years ended December 31, 2012 and 2011, respectively.

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Research and development

Research and development costs are expensed as incurred.

Stock-based compensation

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

The fair value of options at the date of grant is determined under the Black-Scholes option pricing model. During the years ended December 31, 2012 and 2011, the following weighted-average assumptions were used:

Assumptions	2012	2011
Risk-free rate	0.77%	2.12%
Annual rate of dividends	—	—
Historical volatility	103.02%	92.91%
Expected life	6.7 years	6.0 years

The risk-free interest rate was based on the U.S. Treasury yield curve in effect at the time of grant. We do not anticipate declaring dividends in the foreseeable future. Volatility was based on historical data. We utilize the simplified method as allowed by SEC Staff Accounting Bulletin No. 107 and 110 in determining option lives. The simplified method is used due to the fact that we have had significant structural changes in our business such that our historical exercise data may not provide a reasonable basis to estimate option lives.

We recognize compensation expense for only the portion of options that are expected to vest. Therefore, management applies an estimated forfeiture rate that is derived from historical employee termination data. The estimated forfeiture rate applied for the years ended December 31, 2012 and 2011 was 8.15% and 9.37%, respectively. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods. Our stock price volatility, option lives and expected forfeiture rates involve management's best estimates at the time of such determination, all of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option.

Recent accounting pronouncements

There have been no new accounting pronouncements made effective during the year ended December 31, 2012 or not yet effective, that are of significance, or potential significance, to us.

Liquidity

We have incurred annual operating losses since inception, and may continue to incur operating losses. For the fiscal years ended December 31, 2012 and December 31, 2011, we had net losses of $1,659,586 and $1,956,639, respectively. As of December 31, 2012, our accumulated deficit was $55,811,077. 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.

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2. Inventories

Inventories consist of the following at December 31, 2012 and 2011:

	2012	2011
Raw materials	$ 398,510	$ 173,510
Work in progress	116,319	11,768
Finished goods	141,568	320,678
Total	$ 656,397	$ 505,956

3. Deferred Rent

Deferred rent consists of the following at December 31, 2012 and 2011:

	2012	2011
Landlord-funded leasehold improvements	$ 900,989	$ —
Less accumulated amortization	(39,187)	—
Total (current portion $111,250)	861,802	—
Straight line rent adjustment	88,277	12,267
Total deferred rent	$ 950,079	$ 12,267

During the year ended December 31, 2012, the Company recorded $900,989 in deferred rent relating to leasehold improvements funded by the Company's landlord as incentives under the facility lease, which was amended in March 2012 and November 2012. The deferred rent related to the leasehold improvements will be amortized over the life of the lease. Amortization commenced in the third quarter of 2012. During the year ended December 31, 2012 the Company recorded $39,187 in deferred rent amortization of these landlord funded leasehold improvements.

In addition, during the year ended December 31, 2012, the Company recorded deferred rent of $88,277 which represented the difference between cash rent payments and the recognition of rent expense on a straight-line basis over the terms of the lease.

4. Promissory Notes Payable

On May 30, 2012, each of our two most significant investors agreed to (i) increase the amount of their credit facilities to $5,750,000 (total of $11,500,000), and (ii) extend the date their note becomes due and payable, together with accrued interest thereon, to January 11, 2016. The notes are secured by all assets of the Company and accrue interest at the rate of 7% per annum.

5. Income Taxes

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

	2012	2011
Federal tax (benefit) at statutory rate	$ (564,259)	$ (665,257)
Expiration of net operating loss carryforwards	533,950	1,794,072
Expiration of tax credits	—	33,000
Change in valuation allowance	30,403	(1,162,821)
Other	(94)	1,006
Provision for income taxes, net	$ —	$ —

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At December 31, 2012 and 2011, the components of the Company's deferred taxes are as follows:

	2012	2011
Deferred tax assets (liabilities)		
Net operating loss carryforwards	$ 7,824,444	$ 8,209,728
Accrued compensation	105,767	29,431
Depreciation	4,253	173
Stock-based compensation	350,401	276,929
Accrued related party interest	938,193	688,827
Other	20,082	7,649
Total	9,243,140	9,212,737
Less: Valuation allowance	(9,243,140)	(9,212,737)
Net deferred tax asset	$ —	$ —

The Company has the following net operating loss tax carryforwards available at December 31, 2012:

Year of Expiration	Net Operating Losses
2013	$ 1,425,000
2014	1,234,000
2020	2,849,000
2021	4,168,000
2023	1,217,000
2024	646,000
2025	589,000
2026	873,000
2027	2,607,000
2028	2,512,000
2029	2,196,000
2030	1,232,000
2031	1,028,000
2032	437,000
Total	$ 23,013,000

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

6. Shareholders' Equity (Deficiency)

Warrants

The following table summarizes warrant activity for the years ended December 31, 2012 and 2011:

	Year Ended December 31, 2012		Year Ended December 31, 2011	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price

Outstanding at beginning of year	6,218,750	$ 0.08	4,218,750	$ 0.10
Granted	2,000,000	0.08	2,000,000	0.06
Exercised	—	—	—	—
Forfeited/Expired	(500,000)	0.25	—	—
Outstanding and exercisable at end of year	7,718,750	$ 0.07	6,218,750	$ 0.08

During the years ended December 31, 2012 and December 31, 2011, the Company issued a total of 2,000,000 warrants each year to the current note holders in consideration for financing fees related to the restructuring of the existing promissory notes. The warrants were valued using the Black-Scholes option pricing model resulting in a total value of $137,955 in 2012 and $89,225 in 2011, which was recorded as deferred financing costs and is being amortized to expense over the term of the notes.

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The outstanding warrants have expiration dates between November 2013 and May 2017.

Stock compensation plans

During 1998, we adopted the 1998 Stock Option Plan ("the Plan"). An aggregate of 4,000,000 shares of common stock were reserved for issuance upon the exercise of options granted under the Plan. In September 2005, the shareholders approved an increase in the number of shares available for issuance to 10,000,000 shares. The Plan expired on August 31, 2008. The options are exercisable for up to ten years from the grant date. As of December 31, 2012, there were outstanding options to purchase 6,150,000 share of Company common stock under the Plan.

Subsequent to the expiration of the Plan, the Company issued, outside of the Plan, non-incentive stock options for an aggregate of 14,229,602 (net of cancellations) shares of Company common stock. All non-incentive stock options issued in 2012 and 2011 were issued outside of the Plan.

Certain options awarded during 2012 and 2011 contain provisions which allow for the automatic proportionate adjustment of the number of shares covered and the exercise price of each share in the event that the Company changes its shares of common stock by a stock dividend, stock split, combination, reclassification, exchange, merger or consolidation.

The following is a summary of stock option activity under the Plan and outside of the Plan for 2012 and 2011, and the status of stock options outstanding at December 31, 2012 and 2011:

	Year Ended December 31, 2012		Year Ended December 31, 2011	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price
Outstanding at beginning of year	17,873,227	$ 0.08	14,564,815	$ 0.09
Granted	3,150,000	0.12	6,220,873	0.08
Exercised	-	-	-	-
Forfeited	(643,625)	(0.12)	(2,912,461)	(0.08)
Outstanding at end of year	20,379,602	$ 0.09	17,873,227	$ 0.08
Stock options exercisable at year end	14,105,066	$ 0.08	9,667,990	$ 0.08

Weighted average fair value of options granted was $0.10 and $0.06 per share for the years ended December 31, 2012 and 2011, respectively.

As of December 31, 2012, there was $5,124,147 of aggregate intrinsic value of outstanding stock options, including $3,657,911 of aggregate intrinsic value of exercisable stock options. Intrinsic value is the total pretax intrinsic value for all "in-the-money" options (i.e., the difference between the Company's closing stock price on the last trading day of 2012 and the exercise price, multiplied by the number of shares) that would have been received by the option holders had all option holders exercised their options as of December 31, 2012. This amount will change based on the fair market value of the Company's stock.

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The following table summarizes information about stock options outstanding at December 31, 2012:

Range of Exercise Prices	Number Outstanding at December 31, 2012	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$ 0.04-$0.07	2,725,000	5.11	$ 0.06
$ 0.08-$0.09	11,522,114	6.47	$ 0.08
$ 0.10-$0.31	6,132,488	7.75	$ 0.11
	20,379,602	6.67	$ 0.09

Total unrecognized compensation cost at December 31, 2012 of $376,977 is expected to be recognized over a weighted average period of 2.7 years.

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

7. Related Party Transactions

We incurred $18,636 and $52,132 in legal fees during the years ended December 31, 2012 and 2011, respectively, for services provided by Breslow & Walker, LLP in which Howard S. Breslow, who was a director of the Company until February 4, 2013 and is a current stockholder of the Company, is a partner. At December 31, 2012 and 2011, accounts payable included $0 and $22,631, respectively, due to Breslow & Walker, LLP for services rendered.

We incurred $56,000 in consulting fees during the year ended December 31, 2011 to Roderick de Greef, a director of the Company, for the task of overseeing the Company's financing activities, internal accounting functions and SEC reporting, and assisting in the search for, and reviewing, strategic alternatives, on a part-time basis. At December 31, 2011, accounts payable included $2,500 due to Mr. de Greef for services rendered. The agreement with Mr. De Greef was terminated in August of 2011 and no costs were incurred in 2012 related to his consulting services.

8. Commitments and Contingencies

Leases

In November of 2012 we signed an amended lease agreement, which expanded the premises leased by the Company from the landlord to approximately 26,000 rentable square feet. The term of the lease was extended to July 31, 2021. The amendment includes two (2) options to extend the term of the lease, each option is for an additional period of five (5) years, with the first extension term commencing, if at all, on August 1, 2021, and the second extension term commencing, if at all, immediately following the expiration of the first extension term. In accordance with the amended lease agreement, the Company's monthly base rent will increase to approximately $35,000 effective January 1, 2013, and will increase to approximately $46,000 estimated to be effective in May 2013, upon the completion of leasehold improvement, with scheduled annual increases each August. The Company will be required to pay an amount equal to the Company's proportionate share of certain taxes and operating expenses.

The following is a schedule of future minimum lease payments required under the facility leases as of December 31, 2012:

Year Ending December 31

2013	512,000
2014	568,000
2015	581,000
2016	593,000
2017	604,000
Thereafter	2,265,000
Total	$ 5,123,000

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Rental expense for this facility lease for the years ended December 31, 2012 and 2011 totaled $486,425 and $368,273, respectively. These amounts include the Company's proportionate share of property taxes and other operating expenses as defined by the lease.

Employment agreements

We have employment agreements with the Chief Executive Officer, Chief Financial Officer, Chief Technology Officer, Chief Quality Officer, and Vice President of Manufacturing which automatically renew for successive one year periods in the event either party does not send the other a "termination notice" not less than 90 days prior to the expiration of the initial term or any subsequent term. The agreements provide for certain minimum compensation per month and incentive bonuses at the discretion of the Board of Directors. Under certain conditions, we may be required to continue to pay the base salary under the agreement for a period of up to two years.

Litigation

We are a party in a number of legal matters filed in the state of New York by the Company or John G. Baust, the Company's former Chief Executive Officer, and members of his extended family related to damages sought due to breaches of employment and other agreements. We cannot reasonably estimate the potential loss related to these matters and therefore no accrual has been made as of December 31, 2012 or 2011.

9. Supplemental Cash Flow Disclosures

Actual cash payments

No cash was paid for either interest expense or income taxes for the years ended December 31, 2012 and 2011.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to ensure that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding required disclosure. During the year ended December 31, 2012 we carried out an evaluation, under the supervision and with the participation of our management, including the chief executive officer and chief financial officer, as required by the rules and regulations under the Exchange Act, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2012, our disclosure controls and procedures were effective.

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Management's Report on Internal Control Over Financial Reporting

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

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

Our management, including our chief executive officer and chief financial officer, conducted an evaluation of the design effectiveness of our internal control over financial reporting based on the framework in "Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), as of December 31, 2012. Based on our assessment, we conclude that as of December 31, 2012 our internal control over financial reporting was effective.

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

Changes in Internal Control Over Financial Reporting

There were no changes that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the three months ended December 31, 2012.

Limitations on Controls

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

ITEM 9B. OTHER INFORMATION

None.

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PART III

Certain information required by Part III is omitted from this Form 10-K in that we will file a definitive proxy statement pursuant to Regulation 14A with respect to our 2013 Annual Meeting (the "Proxy Statement") no later than 120 days after the end of the fiscal year covered by this Form 10-K, and certain information included therein is incorporated herein by reference. Only those sections of the Proxy Statement which specifically address the items set forth herein are incorporated by reference. In addition, we have adopted a code of ethics which can be reviewed and printed from our website www.biolifesolutions.com.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to the Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the Proxy Statement.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this annual report on Form 10-K:

(1) Financial Statements (Included Under Item 8): The Index to the Financial Statements is included on page 19 of this annual report on Form 10-K and is incorporated herein by reference.

(2) Financial Statement Schedules:

None.

(b) Exhibits

Reference is made to the Index of Exhibits beginning on page 50 which is incorporated herein by reference.

(c) Excluded financial statements:

None.

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SIGNATURES

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

Date: March 29, 2013	BIOLIFE SOLUTIONS, INC.
	/s/Michael Rice Michael Rice Chief Executive Officer
March 29, 2013	/s/Daphne Taylor Daphne Taylor Chief Financial Officer

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

Date: March 29, 2013	/s/Michael Rice Michael Rice Director
Date: March 29, 2013	/s/Roderick de Greef Roderick de Greef Director
Date: March 29, 2013	/s/Richard Stewart Richard Stewart Director
Date: March 29, 2013	/s/Thomas Girschweiler Thomas Girschweiler Director
Date: March 29, 2013	/s/Raymond Cohen Raymond Cohen Director
Date: March 29, 2013	/s/Andrew Hinson Andrew Hinson Director

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Index of Exhibits

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

Exhibit Number	Document
3.1	Certificate of Incorporation, as amended. (1)
3.2	By-Laws, and amendment, dated March 19, 1990, thereto. (1)
4.1	Specimen of Common Stock Certificate. (1)
10.1	1998 Stock Option Plan (2)
10.2	Employment Agreement dated July 26, 2006 between the Company and Michael Rice (3) ^
10.3	Amendment to Employment Agreement dated February 7, 2007 between the Company and Michael Rice (4) ^
10.4	Manufacturing Service Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (5)
10.5	Quality Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (5)
10.6	Storage Services Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (5)
10.7	Order Fulfillment Services Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (5)
10.8	Lease Agreement dated August 1, 2007 for facility space 3303 Monte Villa Parkway, Bothell, WA 98021 (6)
10.9	Consulting Agreement dated August 7, 2007 between the Company and Roderick de Greef (7)
10.10	Secured Convertible Multi-Draw Term Loan Facility Agreement dated January 11, 2008, between the Company and Thomas Girschweiler (8)
10.11	Secured Convertible Multi-Draw Term Loan Facility Agreement dated January 11, 2008, between the Company and Walter Villiger (8)
10.12	First Amendment to the Secured Convertible Multi-Draw Term Loan Facility Agreement dated October 20, 2008, between the Company, Thomas Girschweiler, and Walter Villiger (9)
10.13	Promissory Note dated October 20, 2008 issued by the Company to Thomas Girschweiler (9)
10.14	Promissory Note dated October 20, 2008 issued by the Company to Walter Villiger (9)

10.15	First Amendment to the Lease, dated the November 4, 2008, between the Company and Monte Villa Farms, LLC (9)
10.16*	Employment Agreement Addendum dated December 31, 2008 between the Company and Michael Rice^
10.17	Second Amendment to the Secured Convertible Multi-Draw Term Loan Facility Agreement dated December 16, 2009, between the Company, Thomas Girschweiler and Walter Villiger (10)

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10.18	Promissory Note dated December 16, 2009 issued by the Company to Thomas Girschweiler (10)
10.19	Promissory Note dated December 16, 2009 issued by the Company to Walter Villiger (10)
10.20	Third Amendment to the Secured Multi-Draw Term Loan Facility Agreement dated November 29, 2010, between the Company, Thomas Girschweiler and Walter Villiger (11)
10.21	Promissory Note dated November 29, 2010 issued by the Company to Thomas Girschweiler (11)
10.22	Promissory Note dated November 29, 2010 issued by the Company to Walter Villiger (11)
10.23	Warrant to purchase 1,000,000 shares of the Company's Common Stock, at $0.07 per share, issued to Thomas Girschweiler (11)
10.24	Warrant to purchase 1,000,000 shares of the Company's Common Stock, at $0.07 per share, issued to Walter Villiger (11)
10.25	Fourth Amendment to the Secured Multi-Draw Term Loan Facility Agreement dated August 10, 2011, between the Company, Thomas Girschweiler and Walter Villiger (12)
10.26	Promissory Note dated August 10, 2011 issued by the Company to Thomas Girschweiler (12)
10.27	Promissory Note dated August 10, 2011 issued by the Company to Walter Villiger (12)
10.28	Warrant to purchase 1,000,000 shares of the Company's Common Stock, at $0.063 per share, issued to Thomas Girschweiler (12)
10.29	Warrant to purchase 1,000,000 shares of the Company's Common Stock, at $0.063 per share, issued to Walter Villiger (12)
10.30	Employment Agreement dated August 17, 2011 between the Company and Daphne Taylor^ (12)
10.31	Second Amendment to the Lease, dated the March 2, 2012, between the Company and Monte Villa Farms, LLC (13)
10.32*	Fifth Amendment to the Secured Multi-Draw Term Loan Facility Agreement dated May 30, 2012, between the Company, Thomas Girschweiler and Walter Villiger
10.33*	Promissory Note dated May 30, 2012 issued by the Company to Thomas Girschweiler
10.34*	Promissory Note dated May 30, 2012 issued by the Company to Walter Villiger
10.35*	Warrant to purchase 1,000,000 shares of the Company's Common Stock, at $0.08 per share, issued to Thomas Girschweiler
10.36*	Warrant to purchase 1,000,000 shares of the Company's Common Stock, at $0.08 per share, issued to Walter Villiger
10.37*	

	Third Amendment to the Lease, dated the June 15, 2012, between the Company and Monte Villa Farms, LLC
10.38*	Employment Agreement dated September 1, 2012 between the Company and Aby J. Mathew^
10.39*	Employment Agreement dated September 1, 2012 between the Company and Mark Sandifer^

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10.40*	Employment Agreement dated September 1, 2012 between the Company and Joseph Annicchiarico^
10.41*	Fourth Amendment to the Lease, dated the November 26, 2012, between the Company and Monte Villa Farms, LLC
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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(1) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2000.

(2) Incorporated by reference to the Company's Definitive Proxy Statement for the special meeting of shareholders held on December 16, 1998.

(3) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006.

(4) Incorporated by reference to the Company's current report on Form 8-K filed February 12, 2007.

(5) Incorporated by reference to the Company's current report on Form 8-K filed October 30, 2007.

(6) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007.

(7) Incorporated by reference to the Company's current report on Form 8-K filed November 19, 2007.

(8) Incorporated by reference to the Company's current report on Form 8-K filed January 14, 2008.

(9) Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

(10) Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

(11) Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

(12) Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

(13) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the fiscal year ended March 31, 2012.

* Filed herewith

^ Compensatory plan or arrangement