BIOLIFE SOLUTIONS INC
Form 10-K
March 30, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

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FORM 10-K

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(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, 2009

¨ 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 ¨ No þ

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. þ

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 $2,822,210.

As of March 29, 2010, 69,679,854 shares of the registrant's common stock were outstanding.

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PART I

ITEM 1. BUSINESS

Note: The terms “the Company,” “us,” “we” and “our” refer to BioLife Solutions, Inc.

Overview

BioLife Solutions, Inc. ("BioLife” or the “Company”), a life sciences tools provider, was incorporated in 1998 in Delaware as a wholly owned subsidiary of Cryomedical Sciences, Inc. ("Cryomedical"), a company that was engaged in manufacturing and marketing cryosurgical products. In 2002, BioLife was merged into Cryomedical, which changed its name to BioLife Solutions, Inc. Our product and service offerings include:

- Patented hypothermic storage and cryopreservation media products for cells, tissues, and organs
- Generic formulations of blood stem cell freezing media products
- Custom product formulation and custom packaging services
- Contracted research and development and consulting services related to optimization of biopreservation processes and protocols.
- Contract aseptic manufacturing services

Our proprietary HypoThermosol®, CryoStor™, and generic BloodStor™ biopreservation media products are marketed to companies, laboratories, and academic institutions engaged in research and commercial clinical applications. Our product line of serum-free and protein-free biopreservation media products are fully defined and formulated to reduce preservation-induced, delayed-onset cell damage and death. This platform enabling technology provides academic and clinical researchers significant extension in biologic source material shelf life and also improved post-thaw cell, tissue, and organ viability and function.

Our Oprincipal executive offices are located at 3303 Monte Villa Parkway, Suite 310, Bothell, WA 98021 and the telephone number is (425) 402-1400.

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.

Technological Overview

Stability during transportation, 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. Modern therapies must be accomplished under time constraints if they are to be effective. This problem becomes especially critical in the field of cell and tissue therapy, where harvested cell culture and tissue, if maintained at body temperature (98.6ºF/37ºC), will lose viability over time. To slow the "metabolic engine" of harvested cells and tissues, chilling is required. However, chilling is of mixed benefit. Although cooling successfully reduces metabolism (i.e., lowers demand for oxygen), chilling, or hypothermia, is also damaging

to cells. To solve this problem, transplant surgeons, for example, will flush the donor tissue with a cold solution designed to provide short-term biopreservation support after removal of the organ from the donor and during transportation. Clinicians engaged in cell and gene therapy will also attempt to maintain the original and derived cellular material in a cold solution before and after application of the specific cell or gene therapy technique, and during necessary transportation. Traditional support solutions range from simple "balanced salt" (electrolyte) formulations to complex mixtures of electrolytes, energy substrates such as sugars, acid buffers, osmolytes and antibiotics. Clinically, there is not a great deal of protective difference between these various solutions that are often fifty year old formulas, and few offer long-term protection to biologic material.

Because of the cascading destructive cellular effects that begin with the reduction or arrest of metabolism as a result of cooling, and end with cell death through apoptosis and necrosis, development of new methods of cell and tissue preservation are important to ensure that cell-based and tissue-engineered products survive the trip from the factory to the operating room in good working order and do not die during transplantation. Improved post-thaw cell, tissue and organ viability, function, longer shelf life and transport time are the key unmet needs in the field of preservation of biologic material.

Our scientific research activities over the last 20 years enabled a detailed understanding of the molecular basis for the cryogenic destruction of cells through apoptosis. This research led directly to the development of our specifically formulated and patented HypoThermosol technology. Working from the HypoThermosol technology base, we developed a family of proprietary cell, tissue and organ specific hypothermic storage and cryopreservation media solutions to address the current unmet needs of academic and clinical researchers and transplant physicians. Our products are specifically formulated to:

- Minimize cell and tissue swelling
- Remove free radicals upon formation
- Maintain appropriate ion balances
- Provide regenerative, high energy substrates to stimulate recovery upon warming
- Avoid the creation of an acidic state (acidosis)
- Inhibit the onset of apoptosis

A key feature of our products is their fully "defined" nature. All of our products are serum-free, protein-free and packaged under sterile conditions using United States Pharmaopeia ("USP") grade or highest quality available synthetic components.

The results of independent testing demonstrate that our patented HypoThermosol solutions significantly extend shelf-life and improve cell and tissue post-thaw viability and function, which may, in turn, improve clinical outcomes for existing and new cell and tissue therapy applications. Our proprietary HypoThermosol technology is optimized based on low temperature molecular biology principles and genetic analysis. Competing biopreservation media products are often formulated with culture media, animal serum, a sugar, and in the case of cryopreservation media, a cryoprotectant such as Dimethyl Sufoxide ("DMSO"). A key differentiator of our proprietary formulations is the tuning and optimizing of the key ionic component concentrations for hypothermic environments, as opposed to normal body temperature around 37°C, as is found in culture media based formulas. 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.

BioLife Products

HypoThermosol®

HypoThermosol is a family of cell-specific, optimized hypothermic (2-8°C) biopreservation media that allows for improved and extended preservation of biologic source material and manufactured cell and tissue based clinical products. A full line of customized HypoThermosol biopreservation solutions are available to researchers and clinicians to preserve cells and tissue in low temperature environments for extended periods. The HypoThermosol family of biopreservation media for the hypothermic maintenance and cryopreservation of mammalian cell systems include:

HypoThermosol®-FRS

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 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.

HypoThermosol Purge

HypoThermosol-Purge is an acellular flush solution specifically designed for use during the transition from normothermic to mild hypothermic temperatures (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.

CryoStor™

Based on our proprietary HypoThermosol technology, we developed CryoStor, a family of optimized cryopreservation media designed for frozen (temperature of -196°C) storage of cells and tissues. CryoStor is uniquely formulated to address the molecular-biological aspects of cellular stress as a response to the biopreservation process thereby directly reducing the level of preservation-induced, delayed-onset cell damage and death.

CryoStor™ CS2

CryoStor CS2, a member of the CryoStor series of solutions, addresses the molecular-biological properties of systems undergoing preservation processes. CryoStor CS2 has been further formulated to provide reduced concentrations of cryoprotective agents (2% DMSO), for use in applications where a reduction in the levels of DMSO is preferred.

CryoStor™ CS5

CryoStor CS5 is a base cryopreservation solution which is designed to incorporate the principles which led to the successful development of the HypoThermosol series with the incorporation of agents to modulate the physical damaging effects associated with ice formation and cellular freezing such as dimethyl sulfoxide (“DMSO”). The proprietary formula of the CryoStor platform facilitates substantially improved post-thaw cell survival and function and allows for the maintenance of this enhanced recovery with substantially reduced levels of cryoprotective agents such as DMSO.

CryoStor™ CS10

CryoStor CS10, a member of the CryoStor series of solutions, addresses the molecular-biological properties of systems undergoing preservation processes. CryoStor CS10 contains 10% DMSO.

BloodStor™

BloodStor is a new family of generic blood cell freezing media products. BloodStor 55-5 is a GMP grade offering of the traditional 55% DMSO, 5% Dextran cord blood stem cell freezing media. This product is packaged in sterile, single-use vials and also custom bulk packaging.

Market Opportunity

Recent advances in cord blood banking, adult stem cell banking, cell therapy, and tissue engineering have highlighted the significant and unmet requirement to maintain the health and viability of biological material across time and space.

At the leading edge of biologic-based medicine is cell therapy, which involves a method of growing human cells that may be able to treat cancers and a variety of chronic disorders. Embryonic stem cells are the earliest precursor of human differentiated cells. Adult stem cells, as their name suggests, are derived from other sources, rather than from the blastocysts of embryos. Many researchers believe that cell therapy may revolutionize the treatment of chronic disorders by allowing scientists to utilize stem cells from these sources, as well as from umbilical cord blood, the

umbilical cord, placental tissue, the amniotic membrane, amniotic fluid, dental pulp from avulsed teeth, adipose tissue, bone marrow, and skeletal muscle to grow new cells that specifically replace and treat diseased tissue. Applications include the treatment of heart disease, Parkinson's, Alzheimer's, stroke, spinal cord injuries, burns and other wounds.

Time management in cell therapy becomes especially critical where very scarce and fragile source cells or tissues are extracted from a patient, transported to a culture laboratory, and then transported back to the patient to be inserted into the target tissue, organ, or blood stream. Because this entire process can take months and may involve transportation over long distances, cellular viability is of paramount importance.

Similar to techniques used in whole organ transplantation, clinicians engaged in cell therapy will attempt to maintain the original and derived cellular material in a cold solution to extend cell viability before and after application of the specific cell or gene therapy technique, and during necessary transportation.

Tissue engineering has led to the development of several artificial tissue substitutes for the therapeutic treatment of injury and disease. The process of preparing engineered tissue involves isolation of cells, manipulation and purification, expansion to larger quantities – often requiring appropriate media and support materials, some mechanism to control differentiation and longevity of the cells, and processes and conditions for maintaining viability during transportation and storage. The development of effective delivery systems for engineered tissue has been the subject of enormous investment for the last several years. These delivery systems serve to protect cells from arduous conditions during culture and distribution, and are often vital for protection of cells.

Areas such as vaccine and medicine development and toxicological testing for application in clinical, military, law enforcement, cosmetic, academic, environmental and pharmaceutical settings, also rely heavily on the utilization of biological components. Banking, distribution and storage of these biologics are critical components for successful practical application.

Common to each of these markets is the need for hypothermic preservation media that yields both extended survival time and superior post-preservation performance when contrasted with current processes and non-specific media solutions currently in use. For companies in these market segments, the therapeutic benefit they deliver to clinicians and patients is dependent on establishing a reasonable shelf-life and dosage potency and efficacy for the end product. Our products address this underlying and unmet need by providing an enabling technology – a platform of superior biopreservation media to the entire biotechnology industry.

Our target markets include:

- Cell and tissue banking
- Cell suppliers
- Cord blood collection and storage
- Toxicity testing
- Hair transplantation
- Reproductive biology
- Tissue engineering
- Organ transplantation
- Cellular therapy
- Pharmaceutical drug discovery

We are unable to forecast potential product sales in any of these markets because most of these markets are in their infancy, and it should be noted that in some of these segments we do not currently and may never participate as a result of a number of factors.

Sales and Marketing

On May 12, 2005, we signed an Exclusive Private Labeling and Distribution Agreement (“VWR Agreement”) with VWR International, Inc., a global leader in the distribution of scientific supplies, pursuant to which we manufactured our HypoThermosol and CryoStor product lines under the VWR label for sale by VWR to non-clinical customers in North America and Western Europe.

On February 25, 2008, we sent VWR International, Inc. a notice of termination, effective February 29, 2008, which discontinued the VWR Agreement, due to VWR's failure to cure a breach of the agreement.

In addition to our direct sales activities, we have STEMCELL Technologies, Sigma-Aldrich, and NexBio as distributors.

Manufacturing

In October 2007, we entered into non-exclusive master services, quality, and order fulfillment agreements with Bioserv Inc, a division of NextPharma Technologies, Inc., a leading contract manufacturing organization ("CMO") and provider of product development, contract manufacturing and distribution outsourcing services to the pharmaceutical, specialty pharmaceutical, generics and biotech industries.

In the third quarter of 2008, in order to lower our cost of product sales and increase our production flexibility, we decided to transition to internal manufacturing and maintain our relationship with our previous contract manufacturing organization as a contingency for additional production capacity. Our 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. We also adhere to 21 CFR Part 820 - Quality System Regulation for Good Manufacturing Practices (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 for Clean Rooms and Associated Controlled Environments. We expect to achieve CE Mark conformity for our products in 2010.

Governmental Regulation

As an ancillary or excipient reagent used in the production, transportation, and/or clinical delivery of other developed technologies, HypoThermosol, CryoStor, and BloodStor are not subject to specific FDA 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, it is highly likely that all potential customers would require that we comply with Current Good Manufacturing Procedures ("cGMP") as mandated by FDA. In 2008, we completed small animal safety studies on our products in collaboration with the Fred Hutchinson Cancer Research Center in Seattle.

There can be no assurance that we will not be required to obtain approval from the FDA prior to marketing any of our products in the future. We do not market our products for use in embryo and gamete preservation or for tissue or organ transplants, and expect that we will need to obtain pre market approval from the FDA before we do so. This would entail substantial financial and other resources and could take several years before the products are approved, if at all. During 2009, we submitted updated Type II Master Files to the FDA for CryoStor and HypoThermosol. These enhanced regulatory submissions provide the FDA with information regarding the quality of components used in the formulation of our products, the manufacturing process, our quality system, and stability testing that we have 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.

Intellectual Property

We currently have six issued U.S. patents, one issued European patents, one issued Japanese patents, and several pending patent applications.

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

- HypoThermosol
- GelStor
- Powering the Preservation Sciences
- CryoStor CS2
- BioPreservation Today
- CP-RXCUE
- BloodStor
- CryoStor

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, know-how 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 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

We currently employ a team of one FTE (“full time equivalent”) and several partial FTE research scientists some of whom hold Ph.D. degrees in molecular biology or related fields. We also conduct collaborative research with several leading academic and commercial entities in our strategic markets.

During 2009 and 2008, we spent approximately $414,500 and $457,600, respectively, on research and development activities. In 2007, we established a Scientific Advisory Board (SAB) comprised of external members including leaders in the fields of cellular therapy, preservation of biologic material, and regulatory compliance. These members advise us on our product development and overall marketing strategies. The current members are:

- Shelly Heimfeld, Ph.D., Director of the Cellular Therapy Laboratory at the Fred Hutchinson Cancer Research Center in Seattle, and 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.

- Darin Weber, Ph.D., a leading regulatory expert for cellular and tissue based products, and former FDA cellular therapy reviewer. Dr. Weber’s knowledge of the regulatory landscape for cell and gene therapy is extensive and directly relevant to our business since our biopreservation solutions are a critical process component in several active clinical trials for new cellular therapy products.

- Andrew Hinson, Vice President for Clinical and Regulatory Affairs for CardioPolymers, Inc. (formerly Symphony Medical, Inc.) since 2004. CardioPolymers is a venture capital backed privately-held developer of therapeutic biopolymer therapies for the treatment of heart failure and other cardiac abnormalities.

- 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., Co-founder, CEO and Laboratory Director of The Genesis Bank, a private cord blood bank, 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.

- 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.

Competition

The life sciences industry is highly competitive. Most of our potential competitors have considerably greater financial, technical, marketing, and other resources than we do.

Our competitors include Life Technologies Corp. (formally Invitrogen), Lonza, Sigma Aldrich, and less than 5 other much smaller companies. However, 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 demand thereof. 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 expect competition to intensify with respect to the areas in which we are involved as technical advances are made and become more widely known.

Employees

At December 31, 2009, we had 10 employees, of whom two were engaged in aseptic production; two were engaged in quality assurance; one in research and development; two were engaged in sales and marketing; and three were engaged in finance and administration. Our employees are not covered by any collective bargaining agreement. We consider relations with our employees to be good.

Reports to Security Holders

This annual report on Form 10-K, including the exhibits and schedules filed as part of the annual report, may be inspected at the public reference facility maintained by the Securities and Exchange Commission ("SEC") at its public reference room at 450 Fifth Street NW, Washington, DC 20549 and copies of all or any part thereof may be obtained from that office upon payment of the prescribed fees. One may call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference room and request copies of the documents upon payment of a duplicating fee, by writing to the SEC. In addition, the SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants, including the Company, that file electronically with the SEC which can be accessed at www.sec.gov.

We also make our periodic and current reports available, free of charge, on our website, www.BioLifeSolutions.com, as soon as reasonably practicable after such material is electronically filed with the SEC. Information available on our website is not a part of, and is not incorporated into, this annual report on Form 10-K.

Safe Harbor for Forward-Looking Statements Under the Securities Litigation Reform Act of 1995; Risk Factors

This Annual Report on Form 10-K and other reports, releases, and statements (both written and oral) issued by the Company and its officers from time to time may contain statements concerning our future results, future performance, intentions, objectives, plans, and expectations that are deemed to be “forward-looking statements.” Such statements are made in reliance upon safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results, performance, and achievements may differ significantly from those discussed or implied in the forward-looking statements as a result of a number of known and unknown risks and uncertainties including, without limitation, those discussed below and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In light of the significant uncertainties inherent in such forward-looking statements, the inclusion of such statements should not be regarded as a representation by the Company or any other person that the Company’s objectives and plans will be achieved. Words such as “believes,” “anticipates,” “expects,” “intends,” “may,” and simi expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. We undertake no obligation to revise any of these forward-looking statements.

ITEM 1A. RISK FACTORS

The risks presented below may not be all of the risks we may face. These are the factors that we believe could cause actual results to be different from expected and historical results. Other sections of this report include additional factors that could have an effect on our business and financial performance. The industry in which we compete is very competitive and changes rapidly. Sometimes new risks emerge and management may not be able to predict all of them or how they may cause actual results to be different from those contained in any forward-looking statements. One should not rely upon forward-looking statements as a prediction of future results.

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 because new products will require substantial development, clinical, regulatory, manufacturing, marketing, and other expenditures. For the fiscal years ended December 31, 2009 and December 31, 2008, we had net losses of $(2,768,352) and $(2,775,117), respectively. As of December 31, 2009, our accumulated deficit was $(50,211,221). We may not be able to successfully commercialize our current or future products, achieve significant revenues from sales, or achieve or sustain profitability. Successful completion of our commercialization program and our transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure.

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The market for our Common Stock is limited and our stock price is volatile.

Our common stock, traded on the OTC Bulletin Board, 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 health care 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
- 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
- Other factors outside of our control

There is uncertainty surrounding our ability to successfully commercialize our biopreservative solutions.

Our growth depends, in part, on our continued ability to successfully develop, commercialize and market our HypoThermosol, CryoStor, and BloodStor biopreservation media products. Even in markets that do not require us to undergo clinical trials and obtain regulatory approvals, our products will not be used unless they present an attractive alternative to competitive products and if the benefits and cost savings achieved through their use outweigh the cost of the solutions.

The success of our HypoThermosol, CryoStor, and BloodStor biopreservation media products is dependant, in part, on the commercial success of new cell and gene therapy technology.

We are developing biopreservative media for, and marketing our HypoThermosol, CryoStor, and BloodStor biopreservative solutions to, biotechnology companies and research institutions engaged in research and development of cell, gene and tissue engineering therapy. Although we, as a component supplier, may not be subject to the same formal prospective, controlled clinical-trials to establish safety and efficacy, and to substantial regulatory oversight by the FDA and other regulatory bodies, with respect to the commercialized end-products or therapies developed by these biotechnology companies and research institutions, the development of these therapies are years away from commercialization, and demand, if any, for the HypoThermosol, CryoStor, and BloodStor biopreservative solutions in these markets, is expected to be limited for several years.

We face significant competition.

The life sciences industry is highly competitive. Many of our competitors are significantly larger than we are and have greater financial, technical, research, marketing, sales, distribution and other resources than we do. Additionally, we believe there will be intense price competition with respect to our products. 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.

Further, even if we are able to compete successfully, there can be no assurance that we could do so in a profitable manner.

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, technical and sales personnel. If we fail to attract and retain skilled scientific and sales personnel, our research and development and sales efforts will be hindered. Our future success depends to a significant degree upon the continued services of key scientific and technical personnel. If we do not attract and retain qualified personnel we will not be able to achieve our growth objectives.

If we 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 proprietary 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.

Because the life sciences industry is litigious, we may be sued for allegedly violating the intellectual property rights of others.

In the past, the life sciences industry has been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. In addition, many life science companies have used litigation against emerging growth companies as a means of gaining a competitive advantage. Should third parties file patent applications or be issued patents claiming technology claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine the relative priorities of our inventions and the third parties' inventions. We could also be required to participate in interference proceedings involving our issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require that we cease using the technology or license rights from prevailing third parties. Third parties may claim that we are using their patented inventions and may go to court to stop us from engaging in our normal operations and activities. These lawsuits are expensive to defend and conduct and would also consume and divert the time and attention of our management. A court may decide that we are infringing on a third party's patents and may order us to cease the infringing activity. The court could also order us to pay damages for the infringement. These damages could be substantial and could harm our business, financial condition and operating results. If we are unable to obtain any necessary license following an adverse determination in litigation or in interference or other administrative proceedings, we would have to redesign our products to avoid infringing a third party's patent and temporarily or permanently discontinue manufacturing and selling some of our products. If this were to occur, it would negatively impact future sales.

If we fail to obtain or maintain future regulatory clearances or approvals for our products, or if approvals are delayed or withdrawn, we will be unable to commercially distribute and market our products or any product modifications.

As an ancillary or excipient reagent used in the manufacturing, transportation, or clinical delivery of other developed technologies, HypoThermosol, CryoStor, and BloodStor are not currently subject to specific FDA 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, it is highly likely that all potential customers would require that we comply with Current Good Manufacturing Procedures ("cGMP") as mandated by FDA. In 2008, we completed small animal safety studies on our products in collaboration with the Fred Hutchinson Cancer Research

Center in Seattle. Regulatory approvals, if granted, may include significant limitations on the indicated uses for which our products may be marketed. In addition, to obtain such approvals, the FDA and foreign regulatory authorities may impose numerous other requirements on us. FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses. Furthermore, product approvals can be withdrawn for failure to comply with regulatory standards or unforeseen problems following initial marketing. We may not be able to obtain or maintain regulatory approvals for our products on a timely basis, or at all, and delays in receipt of or failure to receive such approvals, the loss of previously obtained approvals, or failure to comply with existing or future regulatory requirements would have a significant negative effect on our financial condition.

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 would increase costs to us and/or have a material adverse effect on manufacturing schedules, products performance and market acceptance.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

In July 2007, we signed a four-year lease, commencing August 1, 2007, for 4,366 square feet of office and laboratory space in Bothell, Washington at an initial rental rate of $6,367 per month. We are also responsible for paying our proportionate share of property taxes and other operating expenses as defined in the lease.

In November 2008, we signed an amended five-year lease to gain 5,798 square feet of additional clean room space for manufacturing in a facility adjacent to our corporate office facility leased in Bothell, Washington at an initial rental rate of $14,495 per month. Included in this amendment is the exercise of the renewal option for our current office and laboratory space to make the lease for such space coterminous with the new facility five-year lease period.

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 continues in pre-trial discovery. The Company is defending the lawsuit vigorously.

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, and, on behalf of the Company, was to apply for additional SBIR grants; 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.

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 is in pre-trial discovery. The Company is prosecuting the lawsuit vigorously.

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. The case currently is in discovery. The Company is defending the lawsuit vigorously.

On December 27, 2007, John G. Baust and John M. Baust, each separately, filed complaints with the State of New York, Division of Human Rights ("the Division") alleging unlawful discrimination practices against the Company based on wrongful termination due to retaliation for bringing complaints of sexual harassment on the part of Michael Rice, the Company's Chairman and Chief Executive Officer. The Company responded to the complaints, filed by John G. Baust on January 22, 2008, and by John M. Baust on January 14, 2008. On March 5, 2008, the Company was notified by the Division that these complaints were ordered dismissed and the files were closed due to the Division's lack of jurisdiction in the matter, the Division having determined that the civil suits filed by John G. Baust and John M. Baust had precedence and precluded the Division from asserting jurisdiction. The determination was successfully appealed and overturned by Justice Tait on October 23, 2008. On February 4, 2010, the Appellate Division of the Supreme Court of New York, Third Department affirmed Justice Tait's opinion that John G. Baust and John M. Baust could pursue a complaint in the Division. On March 15, 2010, the Division delivered to the Supreme Court, Appellate Division, a Notice of Motion and Motion for Reargument or Leave to Appeal. The motion is returnable April 5, 2010. In the event the Division's motion is denied or, if granted, the Division is unsuccessful in its reargument or appeal, the Company retains all of its rights to oppose the complaint of Messrs. Baust before the Division. In such

event, the Company would vigorously oppose any attempt at a recovery.

PART II

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

Price Range of Common Stock

The common stock, par value $.001 per share, of the Company ("Common Stock") is traded on the OTC Bulletin Board under the symbol "BLFS". As of December 31, 2009, there were approximately 3,000 holders of record of its common stock. The Company has 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, 2008		
4th Quarter	$0.04	$0.03
3rd Quarter	0.04	0.04
2nd Quarter	0.05	0.05
1st Quarter	0.08	0.08
Year ended December 31, 2009		
4th Quarter	$0.11	$0.10
3rd Quarter	0.13	0.13
2nd Quarter	0.22	0.17
1st Quarter	0.07	0.05

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

The following discussion and analysis should be read in conjunction with our audited financial statements and notes thereto that appear elsewhere in this report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this report.

The statements contained in this Annual Report on Form 10-K, including statements under this section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding our management's expectations, hopes, beliefs, intentions or strategies regarding the future. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar expressions may identify forward-looking statements, but t absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this Annual Report on Form 10-K is based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we anticipated. These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include those factors described in greater detail in Item 1A of Part I, "Risk Factors". Should one or more of these risks or uncertainties materialize, or should any of our

assumptions prove incorrect, actual results may vary in material respects from those anticipated in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Overview

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

We develop and market patented biopreservation media products for cells, tissues, and organs. Our proprietary HypoThermosol, CryoStor, and BloodStor platform of hypothermic storage, transport, and cryopreservation media products are marketed to cell therapy companies, pharmaceutical companies, cord blood banks, hair transplant surgeons, and suppliers of cells to the toxicology testing and diagnostics markets. All of our products are serum-free and protein-free, fully defined, and are manufactured under current Good Manufacturing Practices using USP or the highest available grade components.

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, and enables the formulation of truly innovative biopreservation media products that protect biologic material from preservation related cellular injury, much of which is not apparent immediately post-thaw. Our enabling technology provides significant improvement in post-preservation viability and function of biologic material. This yield improvement can reduce research, development, and commercialization costs of new cell and tissue based clinical therapies.

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 evaluates estimates, including, but not limited to those related to accounts receivable allowances, determination of fair value of share-based compensation, contingencies, income taxes, and expense accruals. We base our estimates on historical experience and on other factors that we believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Share-based Compensation

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

Income Taxes

We follow the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and on the expected future tax benefits to be derived from net operating loss carryforwards measured using current tax rates. A valuation allowance is established if it is more likely than not that some portion or all of the deferred tax assets will not be realized. We have not recorded any liabilities for uncertain tax positions or any related interest and penalties. Our tax returns are open to audit for the years ending December 31, 2006 to 2009.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board ("FASB") issued authoritative guidance on revenue arrangements with multiple deliverables that are outside the scope of the software revenue recognition guidance (which does not have impact on our accounting). Under the new guidance, when vendor specific objective evidence or third party evidence for deliverables in an arrangement cannot be determined, a best estimate of a selling price is required to separate deliverables and allocate arrangement consideration using the relative selling price method. The new guidance includes new disclosure requirements on how the application of the relative selling price method affects the timing and amount of revenue recognition. We believe adoption of this new guidance will not have a material effect on our financial statements.

Comparison of Annual Results of Operations

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

	Years Ended December 31,			
	2009	2008	$ Change	% Change
Revenue				
Product sales	$ 1,556,600	$ 1,277,497	$ 279,103	22 %
Licensing revenue	25,000	45,000	(20,000)	-20 %
Total revenue	1,581,600	1,322,497	259,103	20 %
Cost of product sales	1,007,022	770,646	236,376	31 %
Gross profit	574,578	551,851	22,727	4 %
Operating expenses				
Research and development	414,465	457,640	(43,175)	-9 %
Sales and marketing	558,721	372,324	186,397	50 %
General and administrative	1,503,552	1,925,654	(422,102)	-22 %
Manufacturing start-up costs	385,205	259,687	125,518	48 %