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

_____

(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.