BIOLIFE SOLUTIONS INC
Form 10-K
March 28, 2011

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, 2010

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE

ACT OF 1934

For the transition period from to

Commission File Number 0-18170

BioLife Solutions, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	94-3076866
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

3303 MONTE VILLA PARKWAY, SUITE 310, BOTHELL, WASHINGTON, 98021
(Address of registrant's principal executive offices, Zip Code)

(425) 402-1400
(Telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
COMMON STOCK, $0.001 PAR VALUE

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ 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 $3,191,442.

As of February 28, 2011, 69,679,854 shares of the registrant's common stock were outstanding.

Table of Contents

PART I

ITEMBUSINESS
1.

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 biopreservation 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 fill and finish services

Our proprietary HypoThermosol®, CryoStor®, and generic BloodStor® biopreservation media products are marketed to regenerative medicine companies, hospital-based stem cell transplant centers, pharmaceutical companies, cord blood and adult stem cell banks, hair transplant surgeons, and suppliers of cells to the 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 using United States Pharmacopeia (“USP”) 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.

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 normal 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 a number of innovative regenerative medicine products.

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 (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 cell culture and tissue, if not maintained at 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 oxygen), various levels of cellular damage and death occur. To solve this problem, transplant surgeons, for example, 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 regenerative medicine product development also maintain the original and derived cellular material in a cold 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, acid buffers, osmolytes and antibiotics. The limited stability which results from 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 cryogenic (hypothermia induced) destruction of cells through apoptosis and necrosis. 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 formulations. Our products are specifically formulated to:

·Minimize cell and tissue swelling
·Remove free radicals 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 products are serum-free, protein-free and packaged under aseptic processing using United States Pharmaopeia (“USP”) 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 and patient delivery processes and regulatory filings.

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 Sulfoxide (“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 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.

Products

HypoThermosol®

HypoThermosol is a family of optimized hypothermic (2-8°C) temperature biopreservation media products that enable improved and extended preservation of biologic source material and manufactured cell and tissue based products. The HypoThermosol product line includes:

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 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.

HypoThermosol PURGE

HypoThermosol PURGE is a flush solution specifically designed for use during the transitions from normothermic to mild hypothermic (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. HypoThermosol PURGE is also used to support the transition from hypothermic to normothermic temperatures following the preservation interval.

CryoStor®

Based on our proprietary HypoThermosol technology, we developed the CryoStor family of optimized cryopreservation media products designed for frozen storage of cells and tissues. CryoStor is uniquely formulated to address the molecular-biological aspects of cellular stress as a response to the freezing and thawing processes, by 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 level 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 contains 10% DMSO and has been adopted by numerous academic and clinical customers throughout the world.

BloodStor®

BloodStor is a family of generic blood cell freezing media products. BloodStor 55-5 is our GMP grade version 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 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 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, cellular viability is of paramount importance.

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.

- 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 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 200 regenerative medicine customers. We estimate that our products are now incorporated into 30 to 40 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.

Drug Screening:

- 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. Key customers include 8 of the 10 largest cell suppliers and numerous pharmaceutical companies.

- 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. Of note, 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 standard “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.

Sales and Marketing

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 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 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 for Clean Rooms and

Associated Controlled Environments.

Governmental Regulation

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 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").

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.

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

We currently have six issued U.S. patents, one issued European patent, one issued Japanese patent, and several pending US and international 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 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 2010 and 2009, we spent approximately $318,900 and $414,500, 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 regenerative medicine, biopreservation mechanics, 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 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 Lone Star Heart, Inc. (formerly CardioPolymers, Inc.) since 2004. Lone Star Heart is a venture capital backed privately-held developer of therapeutic biopolymer therapies for the treatment of heart failure and other cardiac abnormalities. 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., 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.

7

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 10 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 worldwide demand. 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, 2010, we had 11 employees, of whom three were engaged in manufacturing; 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.

ITEMRISK FACTORS
1A.

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, 2010 and December 31, 2009, we had net losses of $(1,983,630) and $(2,768,352), respectively. As of December 31, 2010, our accumulated deficit was $(52,194,852). 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.

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 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
·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