BIOLIFE SOLUTIONS INC
Form 10-K/A
August 27, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K /A

(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, 2008

¨ 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 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 $1,648,894.

As of March 27, 2009, 69,639,854 shares of the registrant s common stock were outstanding.

Explanatory Note

This Amendment is being filed to amend (a) Item 9A to include required disclosure regarding the auditor attestation report of the registered public accounting firm and disclose that management s assessment of internal control of financial reporting concluded that its controls were effective, and (b) the contents of the certifications required pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended. All other items are identical in all respects to that contained in the Form 10-K filing filed on March 31, 2009.

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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. The Company develops and markets patented hypothermic storage and cryopreservation solutions for cells, tissues, and organs, and provides contracted research and development and consulting services related to optimization of biopreservation processes and protocols. Its proprietary HypoThermosol® and CryoStor™ biopreservation media products are marketed to companies, laboratories, and academic institutions engaged in research and commercial clinical applications. The Company s line of serum-free and protein-free biopreservation solutions 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 improvement in biologic source material shelf life and also post-thaw isolated cell, tissue, and organ viability and function.

In May 2002, Cryomedical implemented a restructuring and recapitalization program designed to shift its focus away from cryosurgery toward addressing the biopreservation needs of the life sciences, biotech and related markets. On June 25, 2002 the Company completed the sale of its cryosurgery product line and related intellectual property assets to Irvine, CA-based Endocare, Inc. (Endocare); (NASDAQ: ENDO). In the transaction, the Company transferred ownership of all of its cryosurgical installed base, inventory, and related intellectual property, in exchange for $2.2 million in cash and 120,022 shares of Endocare restricted common stock. In conjunction with the sale of Cryomedical s cryosurgical assets, Cryomedical s Board of Directors also approved merging BioLife into Cryomedical and changing its name to BioLife Solutions, Inc. In September 2002, Cryomedical changed its name to BioLife Solutions, Inc. and began to trade under the new ticker symbol, BLFS , on the OTCBB.

The Company s principal 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.

Guiding Values

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Our team members are our most important asset

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We only employ motivated, inspired people who thrive in a performance-based environment

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Honesty, integrity, and authentic communication are expected and required for continued employment

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We challenge every team member to continuously exceed customer expectations

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Our quality environment can and will be continuously improved

Critical Success Factors

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Building a world-class team dedicated to continually advancing the Preservation Sciences

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Promoting our products as the standard biopreservation tools for cells, tissues, and organs

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Achieving customer and industry recognition of our quality environment

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Producing a direct, measurable impact on biologic-based medicine

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Maintaining financial performance consistent with maximizing shareholder value

Quality Systems

We are committed to manufacturing our products in accordance with applicable current Good Manufacturing Practices and Quality System Regulations. Every team member in the organization is responsible for ensuring product quality during the performance of their duties and identifying opportunities for continuous quality improvement.

We will:

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Provide products and services of the highest possible standards to satisfy our customer needs and expectations of quality, safety, reliability and performance

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Encourage and promote a corporate culture of continuous quality improvement

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Maintain effective Quality Assurance Systems

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Invest to enhance the skills of all team members

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, 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 its 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:

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Minimize cell and tissue swelling

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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 its products are serum-free, protein-free and packaged under sterile conditions using USP grade or highest quality available synthetic components.

The results of independent testing demonstrate that our patented HypoThermosol solutions significantly 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 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 NIH 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 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™ D**Liteâ***

CryoStor D*Lite*, a member of the CryoStor series of solutions, addresses the molecular-biological properties of systems undergoing preservation processes. CryoStor D*Lite* 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.

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. The delivery systems serve to protect cells from arduous conditions during culture and distribution, and these delivery systems 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.

In the third and fourth quarters of 2006, we engaged the services of an industry-leading consulting firm to estimate the current and future worldwide demand for preservation media. An estimated demand model was created for both short-term hypothermic storage and long-term cryopreservation of cells, tissue, and whole organs. Based on the work done by the consulting firm, we believe the aggregate worldwide demand for the products in its target market segments could be $200 million in 2007, and growing to nearly $350 million by the end of 2011. The specific market segments used to create the aggregate total available market for its products include:

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Cell and tissue banks

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Cell suppliers

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Cord blood collection and storage

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Toxicity testing

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Hair transplantation

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Reproductive biology

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Tissue engineering

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Organ transplantation

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Cellular therapy

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Pharmaceutical drug discovery

We are unable to forecast its 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 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 Exclusive Private Label Distribution Agreement, executed by the parties on May 12, 2005, such notice being given due to VWR s failure to cure a breach of the agreement.

In addition to our direct sales activities, we are currently identifying and evaluating potential strategic distribution partners for our target market segments.

Manufacturing

On October 26, 2007, we entered into the following non-exclusive 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:

1.

Manufacturing Services Agreement for the production of our products on a contracted basis, with a 12 month term. This agreement includes penalties BioLife would incur if certain order changes, cancellations, or postponement were required.

2.

Quality Agreement outlining the quality and regulatory requirements under which our products would be manufactured by Bioserv; to remain in effect so long as a Manufacturing Services Agreement exists between the parties.

3.

Storage Services Agreement with a 12 month term and cancellation provision for either party for convenience with 60 days prior written notice; except that if Bioserv cancels the agreement, the effective date of termination will not be less than 60 days following the completion of any production order scheduled or paid for by BioLife.

4.

Order Fulfillment Services Agreement, with a 12 month term, and cancellation provision for convenience for either party with 60 days prior written notice; except the Bioserv may not cancel the agreement prior to the effective termination of the Storage Services Agreement between the parties.

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 Bioserv as a contingency for additional production capacity. Our production facility is expected to be fully validated and operational in the second quarter of 2009.

Governmental Regulation

Governmental regulation in the United States and other countries is a significant factor affecting the research and development, manufacture and marketing of our products. In the United States, the Food and Drug Administration (FDA) has broad authority under the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to regulate the distribution, manufacture and sale of medical devices. Foreign sales of medical devices are subject to foreign governmental regulation and restrictions which vary from country to country.

The process of obtaining FDA and other required regulatory clearances or approvals is lengthy and expensive. There can be no assurance that, if needed, we will be able to obtain necessary clearances or approvals for clinical testing or for manufacturing or marketing of those of our products. Failure to comply with applicable regulatory approvals can, among other things, result in warning letters, fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. In addition, governmental regulations may be established which could prevent, delay, modify or rescind regulatory clearance or approval of our products.

Regulatory clearances or approvals, if granted, may include significant limitations on the indicated uses for which our products may be marketed. In addition, to obtain such clearances or approvals, the FDA and foreign regulatory authorities may impose numerous other requirements on us. FDA enforcement policy strictly prohibits the marketing of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory standards or the occurrence of unforeseen problems following initial marketing. There can be no assurance that we will be able to obtain regulatory clearances or approvals for our products on a timely basis or at all. Delays in receipt of, or failure to receive approvals, or the loss of previously obtained approvals, or the failure to comply with existing or future regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations.

As an excipient component of other developed technologies, HypoThermosol and CryoStor 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 2008, we submitted 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, two issued European patents, and several pending patent applications.

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

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HypoThermosol

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GelStor

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Powering the Preservation Sciences

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CryoStor D*Lite*

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BioPreservation Today

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CP-RXCUE

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

From our inception through March 2004, we conducted our internal research through Small Business Innovative Research (SBIR) grants, which were awarded to either our predecessor or to BioLife.

In 2004, we elected to discontinue engaging directly in the SBIR program to support our research and development activities. Accordingly, based upon numerous discussions with the Small Business Administration and a review of applicable SBIR rules and regulations, on March 15, 2004, we entered into a research agreement with Cell Preservation Services, Inc. (CPSI) to outsource to CPSI our research funded through SBIR grants. CPSI is owned by John M. Baust, a former employee of BioLife, and the son of John G. Baust, the past Chief Executive and then Chief Scientific Officer of BioLife. The research agreement was designed to comply with the rules and regulations applicable to the performance of research with respect to SBIR grants, and established a format pursuant to which CPSI would (a) take over the processing of the then existing applications for SBIR grants applied for by BioLife (Current Projects), (b) apply for additional SBIR grants for future research projects related to BioLife s core products (Future Projects), (c) perform a substantial portion of the principal work to be done, in terms of (i) time spent, and (ii) research, in connection with Current Projects and Future Projects (the Research), and (d) utilize BioLife personnel as consultants with respect to the Research. In conjunction therewith, BioLife granted to CPSI a non-exclusive, royalty free license (with no right to sublicense) to use BioLife s technology solely for the purpose of conducting the Research in connection with the Current Projects and Future Projects. Pursuant to the research agreement, (x) BioLife was to, among other things, provide CPSI with (i) suitable facilities in which to conduct the Research, including basic research equipment and office equipment (Facilities), and (ii) management services (Management Services), and (y) CPSI was to (i) accept assignment of Current Projects, (ii) be responsible for conducting the Research with respect to Current Projects and Future Projects, (iii) as mutually agreed to by the parties and within the confines of the rules and regulations applicable to the performance of the Research with respect to SBIR grants, utilize BioLife s personnel as consultants, (iv) provide suitable experienced personnel, including, without limitation, a principal investigator/program director, to conduct the Research, (v) comply with all federal laws, rules and regulations applicable to SBIR grants and file all necessary forms and reports with the federal agency awarding the SBIR grants, and (vi) utilize the Facilities and Management Services and pay BioLife fees with respect thereto. BioLife owns all right, title and interest in and to any technology, inventions, designs, ideas, and the like (whether or not patentable) that emanates from the Current Projects and Future Projects related to BioLife s core products and technology.

On January 8, 2007, we sent a written notice to Cell Preservation Services, Inc. (CPSI) that the Company elected not to renew the Research Agreement, which was set to expire on March 15, 2007, but automatically would be renewed for one-year periods unless notice of non-renewal was given by either party at least sixty (60) days prior to the expiration of the then current term. (See Item 3 Legal Proceedings).

We currently employ a team of research scientists, several who 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 2008, we spent $457,640 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. The current members are:

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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.

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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, having authored over 130 peer-reviewed journal articles on cryopreservation.

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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.

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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.

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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.

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

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

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. 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 it is involved as technical advances are made and become more widely known.

Employees

Our business is highly dependent upon our ability to attract and retain qualified scientific, technical and management personnel. We had ten full-time employees at December 31, 2008.

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.

The Company also makes its periodic and current reports available, free of charge, on its website, www.BioLifeSolutions.com, as soon as reasonably practicable after such material is electronically filed with the SEC.

Information available on its 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 the Company s 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. The Company s 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 similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. The Company undertakes 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 the Company 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 the Company competes 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.

The Company has 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, 2008 and December 31, 2007, we had net losses of $(2,775,117) and $(2,851,774), respectively. As of December 31, 2008, our accumulated deficit was $(47,442,870). 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 the Company s Common Stock is limited and its 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:

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Future sales of our common stock

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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 the Company s ability to successfully commercialize its biopreservative solutions.

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

The success of the Company s HypoThermosol and CryoStor biopreservative solutions 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 and CryoStor 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 and CryoStor biopreservative solutions in these markets, is expected to be limited for several years.

The Company faces 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 not able to compete successfully, there can be no assurance that we could do so in a profitable manner.

The Company s success will depend on its 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 the Company fails to protect its intellectual property rights, the Company s competitors may take advantage of its ideas and compete directly against it.

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 its 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, the Company 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 to 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 the Company fails to obtain or maintain necessary regulatory clearances or approvals for products, or if approvals are delayed or withdrawn, the Company will be unable to commercially distribute and market its products or any product modifications.

In the United States, the FDA has broad authority under the Federal Food, Drug and Cosmetic Act to regulate the distribution, manufacture and sale of medical devices. Foreign sales of drugs and medical devices are subject to foreign governmental regulation and restrictions, which vary from country to country. The process of obtaining FDA and other required regulatory clearances and approvals is lengthy and expensive. We may not be able to obtain or maintain necessary approvals for clinical testing or for the manufacturing or marketing of our products. Failure to comply with applicable regulatory approvals can, among other things, result in fines, suspension or withdrawal of regulatory approvals, product recalls, operating restrictions, and criminal prosecution. In addition, governmental regulations may be established which could prevent, delay, modify or rescind regulatory approval of our products. Any of these actions by the FDA, or change in FDA regulations, may adversely impact our business and financial condition.

As an excipient component of other developed technologies, HypoThermosol and CryoStor 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. 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.

The Company is dependent on outside suppliers for all of its 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.

The Company is transitioning to in-house manufacturing

We are completing the construction and validation of a new multi-class clean room manufacturing, research & development, and quality assurance and control suite. Production capacity will support our growth plan and also provide the ability to custom fill and finish our biopreservation media products to meet customer requests. Our facility

design, raw material qualification, and unidirectional process flow will be ISO14644 and 14971 compliant and were vetted by industry leading consultants to support cGMP compliance as called out in title 21 Code of Federal Regulations (CFR) part 820. Our production process will also be also compliant with 21 CFR parts 210 and 211 (for aseptic production). However, if we encounter contractor delays or a validation failure, we may experience a delay in our ability to meet customer demand for our products.

ITEM 1B.

UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2.

PROPERTIES

Rental expense for all of the Company s facilities for the year ended December 31, 2008 totaled approximately $111,955.

In March 2007, the Company signed a lease for 2,783 square feet of office and laboratory space in Bothell, WA at an initial rental rate of $3,500 per month. The Company terminated this lease in July 2007.

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

In November 2008, the Company signed an amended five-year lease to gain 5,798 square feet of additional clean room space for its manufacturing in a facility adjacent to its corporate office facility leased in Bothell, WA at an initial rental rate of $14,495 per month. Included in this amendment is the exercise of the renewal option for its 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 more recently, 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. This case is in discovery and depositions are in process. 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 (the Company s former Chief Executive Officer and President, and more recently, until January 8, 2007, the Chairman, Sr. Vice President and Chief Scientific Officer) 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. This case is in discovery and depositions are in process.

On December 4, 2007, John M. Baust, the son of John G, Baust (the Company s former Chief Executive Officer and President, and more recently, until January 8, 2007, the Chairman, Sr. Vice President and Chief Scientific Officer) 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 M. Baust, the son of John G, Baust (the Company s former Chief Executive Officer and Chief Scientific Officer) filed a complaint 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 complaint on January 14, 2008. On March 5, 2008, the Company was notified by the Division that this complaint was ordered dismissed and the filed closed due to the Division s lack of jurisdiction in the matter, having determined that the civil suit filed by John M. Baust had precedence and precluded the Division from asserting jurisdiction. The determination was successfully appealed on October 23, 2008. As of the date of this filing, the New York Division of Human Rights and the Company are perfecting an appeal to reverse the summary judgment.

On December 27, 2007, John G. Baust (the Company s former Chief Executive Officer and President, and more recently, until January 8, 2007, the Chairman, Sr. Vice President and Chief Scientific Officer) filed a complaint with the State of New York, Division of Human Rights 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 complaint on January 22, 2008. On March 5, 2008, the Company was notified by the Division that this complaint was ordered dismissed and the filed closed due to the Division s lack of jurisdiction in the matter, having determined that the civil suit filed by John G. Baust had precedence and precluded the Division from asserting jurisdiction. The determination was successfully appealed on October 23, 2008. As of the date of this filing, the New York State Division of Human Rights and the Company are perfecting an appeal to reverse the summary judgment.

ITEM 4.

SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

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, 2008, there were approximately 585 holders of record of its common stock. The Company has never paid cash dividends on its common stock and does 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, 2007		
4th Quarter	$ 0.06	$ 0.05
3rd Quarter	0.11	0.10
2nd Quarter	0.11	0.09
1st Quarter	0.11	0.10
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

ITEM 6.

SELECTED FINANCIAL DATA

Not applicable.

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 the Company's audited financial statements and notes thereto that appear elsewhere in this report. This discussion contains forward-looking statements reflecting the Company s 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 the Company 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 st but the 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 its current expectations and beliefs concerning future developments and their potential effects on the Company. There can be no assurance that future developments affecting it will be those that the Company 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. The Company undertakes 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, its audited financial statements and accompanying footnotes thereto.

We develop and market patented biopreservation media products for cells, tissues, and organs. Our proprietary HypoThermosol and CryoStor 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 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 the Company s financial condition and results of operations is based on its financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires the Company to 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, the Company 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. The Company bases its estimates on historical experience and on other factors that it 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.

The Company s significant accounting policies are described in Note 1 to its audited financial statements for the year ended December 31, 2008. The most critical accounting policies of the Company are as follows:

Share-based Compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123(R) (revised 2004) "Share-Based Payment" (SFAS 123(R)). This statement replaces SFAS No. 123, "Accounting for Stock-Based Compensation," and supersedes Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees." This statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements. Pro forma disclosure is no longer an alternative. This statement establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair-value-based measurement method in accounting for share-based payment transactions with employees. This statement uses the terms compensation and payment in their broadest senses to refer to the consideration paid for goods or services, regardless of whether the supplier is an employee. The Company adopted SFAS No. 123(R) effective January 1, 2006 and is recognizing the cost of stock-based compensation, consisting primarily of stock options and warrants, using the Modified Prospective Application transition method whereby the cost of new awards and awards modified, repurchased or cancelled after January 1, 2006 and the portion of awards for which the requisite service has not been rendered (unvested awards) that are

outstanding as of January 1, 2006, is recognized as the requisite service is rendered on or after the effective date, January 1, 2006.

Income Taxes

Effective January 1, 2007, the Company adopted the provisions of FASB, Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109. The

first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than 50% likely of being realized upon ultimate settlement. The company considers many factors when evaluating and estimating its tax positions and tax benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes. Based on the implementation guidance set forth in the pronouncement and the Company s review of its tax positions leading up to and subsequent to adoption, FIN 48 did not have a material impact on its financial position, results of operations, or cash flows. As such, the Company has not recorded any liabilities for uncertain tax positions or any related interest and penalties. The Company s tax returns are open to audit for the years ending December 31, 2005 to 2008.

Recent Accounting Pronouncements

In May 2008, the FASB, issued FASB Staff Position (FSP) Accounting Principles Board (APB) (FSP APB 14-1) Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement). FSP APB 14-1 applies to convertible debt instruments that, by their stated terms, may be settled in cash (or other assets) upon conversion, including partial cash settlement of the conversion option. FSP APB 14-1 requires bifurcation of the instrument into a debt component that is initially recorded at fair value and an equity component. The difference between the fair value of the debt component and the initial proceeds from issuance of the instrument is recorded as a component of equity. The liability component of the debt instrument is accreted to par using the effective yield method; accretion is reported as a component of interest expense. The equity component is not subsequently re-valued as long as it continues to qualify for equity treatment. FSP APB 14-1 must be applied retrospectively to previously issued cash-settleable convertible instruments as well as prospectively to newly issued instruments. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Though the Company does not believe FSP APB 14-1 will have an effect on its current financial position, the Company is currently evaluating the requirements of FSP APB 14-1 with respect to its recent convertible debt financing and has not yet determined the impact on the Company s financial statements.

In February 2008, the FASB issued FSP, 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2. FSP 157-2 delays the effective date of *Fair Value Measurements*, or SFAS No. 157 for nonfinancial assets and nonfinancial liabilities, except for certain items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The Company has applied the provisions of SFAS 157 to financial assets and liabilities prospectively as of January 1, 2008. The Company will be required to apply the provisions of SFAS 157 to these nonfinancial assets and nonfinancial liabilities as of January 1, 2009 and is currently evaluating the impact of the application of SFAS 157 as it pertains to these items.

In November 2007, the Emerging Issues Task Force of the FASB, or EITF, ratified a consensus of EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF 07-1, which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 is effective beginning in the first quarter of 2009. The Company does not expect the adoption of EITF 07-1 to have a material impact on its results of operations, financial condition and disclosures.

Results of Operations for the Years Ended December 31, 2008 and 2007

Revenue

Revenue for the year ended December 31, 2008 increased $350,235 or 36%, to $1,322,497, compared to $972,262 for the year ended December 31, 2007. In 2008, we had product sales of $1,277,497, an increase of $331,902 or 35%, as compared to $945,595 in 2007. We had licensing revenue of $45,000 for the year ended December 31, 2008,

compared to $26,667 for the year ended December 31, 2007. The increase in product sales resulted from a combination of increased use of our products by existing customers and the acquisition of new customers in the cell therapy, drug discovery, cell supplier, and cord blood banking markets.

Cost of Product Sales

For the year ended December 31, 2008, the cost of product sales totaled $770,646 as compared to $463,106 for the year ended December 31, 2007, resulting in a gross margin as a percentage of product revenue of 39.7% as compared to 51.0% for the same period in 2007. The increase in cost of product sales as a percentage of revenue primarily is attributable to the higher production costs at our Contract Manufacturing Organization (CMO) compared to the prior periods when our products were manufactured internally. To reduce cost of product sales, and enhance production flexibility, we decided to transition to internal manufacturing and intend to maintain our relationship with our contract manufacturer as a contingency for additional production capacity.

Research and Development

Expenses relating to research and development for the year ended December 31, 2008 increased 11% to $457,640, compared to $413,376 for the year ended December 31, 2007. This increase was primarily due to an increase in headcount, offset by a decrease in contracted research and legal expenses.

Sales and Marketing

For the year ended December 31, 2008, sales and marketing expenses decreased $336,337, or 47%, to $372,324, compared to $708,661 for the year ended December 31, 2007. The decrease in 2008 was due to a lower headcount in sales, which resulted in lower costs in sales commissions, tradeshow activities and travel related expenses.

General and Administrative Expenses

For the year ended December 31, 2008, general and administrative expenses increased $23,528, or 1% to $1,925,654, compared to $1,902,126 for the year ended December 31, 2007. The increase in general and administrative expenses was primarily due to higher legal fees related to litigation filed by and against the Company in 2007, increased financial and IT related consulting fees, and higher headcount expense due to bringing the controllership in-house and pay increases. These were offset by a decrease in professional accounting fees, stock-based compensation and travel expenses.

Manufacturing Start-up Costs

For the year ended December 31, 2008, manufacturing start-up costs were $259,687, compared to $198,490 for the year ended December 31, 2007. During the third quarter of 2007, as a result of relocating the Company from Owego, NY to Bothell, WA, we decided to outsource manufacturing and entered into a contract with a CMO. One-time start-up costs related to the outsourcing of its manufacturing were expensed as incurred. In the third quarter of 2008, to reduce cost of product sales and enhance its production flexibility, we decided to transition to internal manufacturing and maintain our relationship with our CMO as a contingency for additional production capacity.

Interest Expense

For year ended December 31, 2008, interest expense was $284,762. For the year ended December 31, 2007, interest expense was $113,400. The increase is due to a higher average debt balance.

Operating Expenses and Net Loss

For the year ended December 31, 2008, operating expenses decreased $207,348, or 6% to $3,015,305, compared to $3,222,653 for the year ended December 31, 2007. We reported a net loss of $(2,775,117) for the year ended December 31, 2008, compared to a net loss of $(2,851,774) for the year ended December 31, 2007.

Liquidity and Capital Resources

Cash and Cash Equivalents

At December 31, 2008, we had cash and cash equivalents of $98,724, compared to cash and cash equivalents of $56,497 at December 31, 2007. At December 31, 2008, we had working capital of $113,378, compared to working capital $123,770 at December 31, 2007.

Net Cash Used in Operating Activities

During the year ended December 31, 2008, net cash used in operating activities was $(2,113,418) as compared to net cash used by operating activities of $(2,708,979) for the year ended December 31, 2007.

Net Cash Provided by and Used in Investing Activities

Net cash used in investing activities totaled $(46,688) during the year ended December 31, 2008 which resulted from the purchase of property and equipment. Net cash used in investing activities totaled $(105,546) during the year ended December 31, 2007 resulting from the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled $2,202,333 for the year ended December 31, 2008, which resulted primarily from the issuance of promissory notes to two shareholders (see below). Net cash provided by financing activities totaled $2,752,348 for the year ended December 31, 2007 resulting from the issuance of promissory notes to two shareholders (see below).

In February 2007, in order to secure capital necessary to continue its operations, we borrowed $750,000 in equal amounts, from Thomas Girschweiler, a director and stockholder of the Company, and Walter Villiger, an affiliate of the Company, each a non-U.S. Person (as defined in Regulation S of the Securities Act of 1933, as amended) (collectively, the Investors). Each loan was evidenced by a Promissory Note (February Notes). Each February Note, together with interest accrued thereon at the rate of 7% per annum (collectively, the Conversion Amount), was due and payable in one lump sum on the earlier of (a) the second anniversary of the date of the February Note, (b) an Event of Default (as defined in the February Notes) or (c) sale, merger or change in control of the Company, as defined. In addition, if the February Note was outstanding at the time of any bona fide equity financing of the Company of at least $1,000,000 (excluding conversion of the February Notes) (a Financing), then the February Note holder was able to convert the February Note into that number of shares or units of the equity securities of the Company sold in the Financing (New Equity Securities) as is equal to the Conversion Amount divided by 85% of the per share or per unit purchase price of the New Equity Securities.

In June 2007, we borrowed an additional $1,000,000, in equal amounts, from the Investors. Each loan was represented by a Promissory Note (June Note). Each June Note, together with interest accrued thereon at the rate of 7% per annum (collectively, the Conversion Amount), was due and payable in one lump sum on the earlier of (a) June 30, 2008 or (b) an Event of Default (as defined in the June Notes). In addition, if the June Note was outstanding at the time of any bona fide equity financing of the Company of at least $1,000,000 (excluding conversion of the June Notes) (a Financing), then the June Note holder was able to convert the June Note into that number of shares or units of the equity securities of the Company sold in the Financing (New Equity Securities) as is equal to the Conversion Amount divided by 100% of the per share or per unit purchase price of the New Equity Securities.

In September 2007, we borrowed an additional $1,000,000, in equal amounts, from the Investors. Each loan was represented by a Promissory Note (September Note). Each September Note, together with interest accrued thereon at the rate of 7% per annum (collectively, the Conversion Amount), was due and payable in one lump sum on the earlier of (a) September 30, 2008 or (b) an Event of Default (as defined in the September Notes). In addition, if the September Note was outstanding at the time of any bona fide equity financing of the Company of at least $1,000,000 (excluding conversion of the February Notes, June Notes and September Notes) (a Financing), then the September Note holder was able to convert the September Note into that number of shares or units of the equity securities of the Company sold in the Financing (New Equity Securities) as is equal to the Conversion Amount divided by 100% of the per share or per unit purchase price of the New Equity Securities.

In January 2008, we entered into a Secured Convertible Multi-Draw Term Loan Facility Agreement with each of the Investors, pursuant to which each Investor extended to the Company a secured convertible multi-draw term loan facility (the Facility) of $2,500,000, which Facility (a) incorporates (i) a refinancing of the existing indebtedness of the Company to the Investor, represented by the February Notes, June Notes and September Notes, and accrued interest thereon, in the aggregate amount of $1,431,563.30, (ii) a current advance of $300,000, and (iii) a commitment to advance to the Company, from time to time, additional amounts up to a maximum of $768,436.70, (b) bears interest at the rate of 7% per annum on the principal balance outstanding from time to time, (c) is evidenced by a secured convertible multi-draw term loan note (the Multi-Draw Term Loan Note), due and

payable, together with accrued interest thereon, the earlier of (i) January 11, 2010, or (ii) an Event of Default (as defined in the Multi-Draw Term Loan Note), (d) if outstanding at the time of any bona fide equity financing of the Company of at least Two Million Dollars ($2,000,000) (a Financing), at the option of the Investor, may be converted into that number of fully paid and non-assessable shares or units of the equity security(ies) of the Company sold in the Financing (New Equity Securities) as is equal to the quotient obtained by dividing the principal amount of the Facility outstanding at the time of the conversion plus accrued interest thereon by 85% of the per share or per unit purchase price of the New Equity Securities, and (e) is secured by all of the Company s assets.

In May and July 2008, the Company received an additional $1,000,000 in total from the Investors pursuant to the Multi-Draw Term Loan Facility.

On October 20, 2008, each Facility was increased by $2,000,000 to $4,500,000 (an aggregate of $9,000,000), and, on October 24, 2008, the Company received an additional $600,000 in total from the Investors pursuant to the amended Multi-Draw Term Loan Facility.

In January 2009, the Company received an additional $1,400,000 in total from the Investors pursuant to the amended Multi-Draw Term Loan Facility, which brought the Company s total principal balance owed under the Multi-Draw Term Loan Notes to $6,463,127, which leaves $2,536,873 left to draw from the Facility.

Operating Capital and Capital Expenditure Requirements

We believe that continued access to the amended Multi-Draw Term Loan Note, in combination with cash generated from operations, will provide sufficient funds through at least the next twelve months. However, we would require additional capital in the immediate short term if our ability to draw on the amended Multi-Draw Term Loan Note was to be restricted or terminated. Other factors that would negatively impact our ability to finance our operations include (i) significant reductions in revenue (ii) increased capital expenditures (iii) significant increases in cost of goods and operating expenses or; (iv) an adverse outcome resulting from current litigation. We expect that we may need additional capital to reach a sustainable level of positive cash flow. Although the Investors who have provided the amended Multi-Draw Term Loan Note have historically demonstrated a willingness to grant access to the Facility, there is no assurance they will continue to do so in the future. If the Investors were to become unwilling to provide access to additional funds through the amended Multi-Draw Term Loan Note, we will need to find immediate additional sources of capital and there can be no assurance that such capital would be available at all, or if available, that the terms of such financing would not be dilutive to other stockholders. If we are unable to secure additional capital as circumstances require, we may not be able to continue our operations.

Off-Balance Sheet Arrangements

As of December 31, 2008, we did not have any off-balance sheet financing arrangements.

Contract Obligations

In March 2007, we signed a lease for 2,783 square feet of office and laboratory space in Bothell, WA at an initial rental rate of $3,500 per month. We terminated this lease in July 2007.

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, WA 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, WA 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 7A.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8.

FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements included in Item 15 (a)1 of this Form 10-K Annual Report.

ITEM 9.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A.

CONTROLS AND PROCEDURES

Management s Report on Internal Control Over Financial Reporting

The Company s management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Its internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of the financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. This process includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

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

The Company s management conducted an evaluation of the design effectiveness of its internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), as of December 31, 2008. This design review of the control environment consisted of a top-down approach to risk assessment according to principles as provided for by SEC guidance and did not identify any material weaknesses. The Company evaluated the effectiveness of its internal controls over financial reporting based primarily on management s daily interaction with its control environment. Based on our assessment, we conclude that as of December 31, 2008 our internal control over financial reporting was effective.

This annual report does not include an attestation report of the Company s registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by the Company s registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit

the Company to provide only management s report in this annual report.

Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to ensure that material information required to be disclosed in its periodic reports filed under the Securities Exchange Act of 1934, as amended, or 1934 Act, is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms and to ensure that such information is accumulated and communicated to its management, including its chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding required disclosure. During the quarter ended December 31, 2008 it carried out an evaluation, under the supervision and with the participation of its management, including the chief executive officer and chief financial officer, as required by the rules and regulations under the 1934 Act, of the effectiveness of the design and operation of its disclosure controls and procedures, as defined in Rule 13a-15(e) under the 1934 Act. Based on this evaluation, the Company s chief executive officer and chief financial officer concluded that, as of December 31, 2008, that its disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There were no changes that materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting during the quarter ended December 31, 2008.

Limitations on Controls

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

ITEM 9B.

OTHER INFORMATION

None.

PART III

ITEM 10.

DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The following table and text set forth the names and ages of all directors and executive officers of the Company as of March 31, 2009. The Board of Directors is comprised of only one class. All of the directors will serve until the next annual meeting of shareholders, and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. There are no family relationships among directors and executive officers. Also provided herein are brief descriptions of the business experience of each director and executive officer during the past five years (based on information supplied by them) and an indication of directorships held by each director in other companies subject to the reporting requirements under the Federal securities laws.

Name	Age	Position and Offices With the Company
Michael Rice	46	Chief Executive Officer, President, and Director
Howard S. Breslow	69	Director, Secretary
Roderick de Greef	48	Director
Thomas Girschweiler	51	Director
Raymond Cohen	49	Director
Andrew Hinson	43	Director

Michael Rice has been President and Chief Executive Officer and a director of the Company since August 2006. From October 2004 to August 2006, Mr. Rice served as Sr. Business Development Manager for the Medical & Wireless Products Group at AMI Semiconductor, Inc. (NASDAQ: AMIS). Prior thereto, from October 2000 to October 2004 he served as Director of Marketing & Business Development, Western Region Sales Manager, and Director, Commercial Sales at Cardiac Science, Inc. (NASDAQ: CSCX); from May 1998 to October 2000 as Vice President, Sales and Marketing at TEGRIS Corporation; and from May 1986 to May 1998 in several sales and marketing roles at Physio Control Corporation.

Howard S. Breslow has served as a director of the Company since July 1988. He has been a practicing attorney in New York City for more than 40 years and is a member of the law firm of Breslow & Walker, LLP, New York, NY, which firm serves as general counsel to the Company.

Roderick de Greef has served on the Company s Board of Directors since June 19, 2000. Effective July 1, 2007, Mr. de Greef was retained by the Company as an outside consultant to provide oversight of the Company s financing activities, internal accounting functions and SEC reporting, and assist in the search for, and reviewing, strategic alternatives. Mr. de Greef currently serves as the Chairman of the Board of Cambridge Heart, Inc. (NASDAQ: CAMH), a manufacturer of diagnostic cardiology products. Mr. de Greef also serves on the board of directors of Endologix, Inc. (NASDAQ: ELGX), a medical device company and Elephant Talk Communications, Inc., a publicly traded telecommunications company. Previously, Mr. de Greef served as the Chief Financial Officer of Cambridge Heart from October 2005 to July 2007. From 2001 to 2005, Mr. de Greef served as the Executive Vice President, Chief Financial Officer and Secretary of Cardiac Science, Inc. (NASDAQ: CSCX).

Thomas Girschweiler joined the Board in 2003. Mr. Girschweiler has been engaged in corporate financing activities on his own behalf since 1996. From 1981 to 1996 he was an investment banker with Union Bank of Switzerland. Mr. Girschweiler is a graduate of the Swiss Banking School.

Raymond W. Cohen joined the Board in May 2006. Mr. Cohen currently serves as Chief Executive Officer of Laguna Hills, CA-based Symphony Medical, Inc., a venture capital backed privately-held developer of therapeutic biopolymer therapies for the treatment of heart failure and other cardiac abnormalities. Mr. Cohen is also a director of Bothell, WA-based Cardiac Science Corporation (NASDAQ: CSCX), a global leader in advanced cardiac monitoring and defibrillation products formed by the merger of Quinton Cardiology Systems, Inc., and Cardiac Science, Inc., where he served as Chief Executive Officer for nine years. Mr. Cohen also serves as a member of the Board of Directors of Cardiogenesis Corp. (OTC: CGCP), manufacturer of cardiac revascularization lasers, Biogenix, Inc., a privately-held manufacturer of diagnostic lab equipment and Syncroness, Inc., a privately-held contract engineering and product development firm based in Westminster, CO.

Andrew Hinson joined the Board in February 2007. He currently is the Vice President for Clinical and Regulatory Affairs for Symphony Medical, Inc., a venture capital backed privately-held developer of therapeutic biopolymer therapies for the treatment of heart failure and other cardiac abnormalities. Mr. Hinson has diverse experience in the

cell and gene therapy markets and extensive experience managing clinical trials for new biologic based therapies for cardiac, neurologic, and gastrointestinal applications.

Committee Membership, Meetings and Attendance

During the fiscal year ended December 31, 2008, there were:

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Three meetings of the Board of Directors

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Three meetings of the Audit Committee

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No meetings of the Compensation Committee

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No meetings of the Nominating and Corporate Governance Committee

Each director attended or participated in at least 75% of the meetings of the Board of Directors held during the fiscal year ended December 31, 2008.

Board Committees

In February 2008 the Company s Board of Directors established three standing committees: Audit, Compensation, and Nominating and Corporate Governance.

Audit Committee and Audit Committee Financial Expert

On February 11, 2008, the Company formed a separately designated standing Audit Committee. The Audit Committee is currently composed of Messrs. Girschweiler, Cohen and de Greef. The Board of Directors has determined that Mr. de Greef is an audit committee financial expert as defined in Item 407(d)(5)(ii) of Regulation S-K. The Audit Committee has the sole authority and responsibility to select, evaluate and replace our independent registered public accounting firm or nominate the independent auditors for stockholder approval. The Audit Committee must pre-approve all audit engagement fees and terms and all non-audit engagements with the independent auditors. The Audit Committee consults with management but does not delegate these responsibilities. The Audit Committee met three times in fiscal 2008 in which they reviewed and discussed the financial statements as presented in form 10-Q for periods ended March 31, June 30, and September 30, 2008.

Compensation Committee

The Company s Compensation Committee was formed on February 11, 2008 and consists of Messrs., Hinson, Cohen and Girschweiler. The Compensation Committee did not meet in fiscal 2008. The Compensation Committee will award stock options to officers and employees. The Compensation Committee has overall responsibility for approving and evaluating the executive officer compensation plans, policies and programs of the Company.

Nominating and Corporate Governance Committee

The Company s Nominating and Corporate Governance Committee was formed on February 11, 2008 and consists of Messrs. Hinson, de Greef and Breslow. The Nominating and Corporate Governance Committee did not meet in fiscal 2008. The Nominating and Corporate Governance Committee is responsible for (1) reviewing suggestions of candidates for director made by directors and others; (2) identifying individuals qualified to become Board members, and recommending to the Board the director nominees for the next annual meeting of stockholders; (3) recommending to the Board director nominees for each committee of the Board; (4) recommending to the Board the corporate governance principles applicable to the Company; and (5) overseeing the annual evaluation of the Board and management. Pursuant to the Nominating and Corporate Governance Committee Charter, there is no difference in the manner in which a nominee is evaluated based on whether the nominee is recommended by a stockholder or otherwise.

Section 16(a) Beneficial Ownership Reporting Compliance

The Company s executive officers, directors, and beneficial owners of more than 10% of any class of its equity securities registered pursuant to Section 12 of the Securities Exchange Act of 1934 (collectively, the Reporting Persons) are required to file reports of ownership and changes in beneficial ownership of the Company s equity securities with the Securities Exchange Commission. Copies of those reports also must be furnished to the Company. Based solely on review of the copies of such forms furnished by the Company, the Company believes that during the year ended December 31, 2008, the Reporting Persons complied with all applicable Section 16(a) filing requirements.

Code of Ethics

The Company has always encouraged its employees, including officers and directors to conduct business in an honest and ethical manner. Additionally, it has always been the Company s policy to comply with all applicable laws and provide accurate and timely disclosure. Accordingly, the Board has adopted a formal written code of ethics for all employees, and an additional corporate code of ethics for its Chief Executive Officer and Senior Financial Officers. The code of ethics is designed to deter wrongdoing and promote honest and ethical conduct and compliance with applicable laws and regulations. These codes also incorporate the Company s expectations of its executives which enables it to provide accurate and timely disclosure of its filings with the Securities and Exchange Commission and other public communication. The code of ethics is posted on its website, www.biolifesolutions.com. Any future changes or amendments to its code of ethics, and any waiver of its codes of ethics will be posted on the website when applicable.

ITEM 11.

EXECUTIVE COMPENSATION

The following table sets forth certain information concerning the compensation paid by the Company to its Chief Executive Officer, and any additional executive officers that received salary and bonus payments in excess of $100,000 during the fiscal year ended December 31, 2008 (collectively the Named Executive Officers).

SUMMARY COMPENSATION TABLE

Name and Principal Positions	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f) (1)	(g)	(h)	(i)	(j)
Michael Rice	2008	300,000	30,000						330,000
President, Chief Executive Officer and Director (8/06 present)	2007	200,000	100,000		39,461 (2)				339,461

(1)

See Item 8, note 1, for a description on the valuation methodology of stock option awards.

(2)

Amount is a result of options granted to officer.

Employment Agreements

The Company has an employment agreement with Michael Rice, its President and Chief Executive Officer, which automatically renews for successive one year periods in the event either party does not send the other a termination notice no less than 90 days prior to the expiration of the initial term or any subsequent term. The agreement provided for a salary of $200,000 per year and an incentive bonus based on certain quarterly milestones, to be determined by the Board of Directors. The officer also received ten-year incentive stock options to purchase 1,500,000 shares of common stock at $.07 per share (the fair market value on the date of grant), which vest to the extent of 500,000 shares on each of the first three anniversary dates of the date of grant. The Company amended this employment agreement on February 7, 2007 to provide that if, in connection with a change in control, Mr. Rice s employment is terminated without Cause or he resigns for Good Reason, he will be entitled to the continued payment of salary and bonuses and the reimbursement of medical insurance premiums for 24 months following the change in control event. On February 11, 2008, Mr. Rice s salary was increased to $300,000 per annum, retroactive to January 1, 2008 and his quarterly bonus plan was supplanted for 2008 with an annual review by the Board of Directors to take place in early 2009.

The following table provides information related to outstanding equity awards for each of the Named Executive Officers as of December 31, 2008:

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	OPTION AWARDS					STOCK AWARDS			
Name (a)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested ($) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) (j)
Michael Rice	1,000,000	500,000		0.07	8/7/2016 (1)				
Michael Rice	333,333	666,667		0.08	2/7/2017 (2)				

(1)

This award vests 500,000 shares on each of 8/7/2007, 8/7/2008, and 8/7/2009

(2)

This award vests 333,333 shares on each of 2/7/2008, 2/7/2009, and 333,334 shares on 2/7/2010

Compensation of Directors

Outside directors were compensated $1,500 per meeting for attending board meetings and $750 per meeting for telephonic board meetings. A total of $25,500 in director compensation was recorded during the year ended December 31, 2008.

The following table sets forth compensation paid to outside directors during the fiscal year ended December 31, 2008:

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(j)
Howard Breslow (1)	3,000						3,000
Thomas Girschweiler (2)	5,250						5,250
Roderick de Greef (3)	7,500					120,000	127,500
Raymond Cohen (4)	6,750						6,750
Andrew Hinson (5)	3,000						3,000

(1)

As of December 31, 2008, Mr. Breslow owned the following options and warrants, all of which were exercisable: options to purchase 500,000 shares of Common Stock and warrants to purchase 500,000 shares of Common Stock.

(2)

As of December 31, 2008, Mr. Girschweiler owned the following options, all of which were exercisable: options to purchase 250,000 shares of Common Stock.

(3)

As of December 31, 2008, Mr. de Greef owned the following options and warrants, all of which were exercisable: options to purchase 500,000 shares of Common Stock and warrants to purchase 1,250,000 shares of Common Stock.

(4)

As of December 31, 2008, Mr. Cohen owned the following options, of which 583,333 were exercisable: options to purchase 750,000 shares of Common Stock.

(5)

As of December 31, 2008, Mr. Hinson owned the following options, all of which were exercisable: options to purchase 250,000 shares of Common Stock.

On August 7, 2007, the Board of Directors of the Company agreed to outsource to Roderick de Greef, a director of the Company, the task of overseeing the Company s financing activities, internal accounting functions and SEC reporting, and assisting in the search for, and reviewing, strategic alternatives, on a part-time basis (up to 80 hours per month on an as needed basis), effective as of July 1, 2007 (since he was effectively serving the Company in such capacity since such date), on terms to be agreed upon by Mike Rice, the President of the Company, and Mr. de Greef, and approved by the Board. Subsequent to August 7, 2007, Mr. Rice and Mr. de Greef agreed to the following terms: (1) a fee of $10,000 per month, (2) reimbursement of business expenses, (3) 90 day advance notice of termination by the Company, and (4) the payment of one (1) year s fees ($120,000) if terminated in connection with a Change of Control transaction. As used herein the term Change of Control means (A) there shall be consummated (1) any consolidation or merger of the Company in which the Company is not the continuing or surviving corporation or pursuant to which shares of the Company s Common Stock would be converted into cash, securities or other property, other than a merger of the Company in which the holders of the Company s Common Stock immediately prior to the merger have the same proportionate ownership of at least 50% of common stock of the surviving corporation immediately after the merger, or (2) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all, or substantially all, of the assets of the Company; (B) the stockholders of the Company approve any plan or proposal for the liquidation or dissolution of the Company; or (C) any person (as such term is used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended (the Exchange Act)), shall become the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act) of 50% or more of the Company s outstanding Common Stock. On November 14, 2007, the arrangement was approved by the Board of Directors of the Company.

ITEM 12.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The following table sets forth, as of March 31, 2009, certain information regarding the beneficial ownership of Common Stock by (i) each stockholder known by the Company to be the beneficial owner of more than 5% of the outstanding shares thereof; (ii) each director of the Company; (iii) each Named Executive Officer of the Company; and (iv) all of the Company s current directors and executive officers as a group.

Name and Address of Beneficial Owner	Common Stock (1)	Percentage of Class (1)
Michael Rice (Officer and Director)	1,666,667 (2)	2.3%
c/o BioLife Solutions, Inc.		
3303 Monte Villa Pkwy, Suite 310		
Bothell, WA 98021		
John G. Baust	3,694,722	5.3%
175 Raish Hill Road		
Candor, NY 13743		
Howard S. Breslow, Esq. (Director)	1,053,600 (3)	1.5%
c/o Breslow & Walker, LLP		
767 Third Avenue		

New York, NY 10017		
Roderick de Greef (Director)	5,303,363 (4)	7.4%
c/o BioLife Solutions, Inc.		
3303 Monte Villa Pkwy, Suite 310		
Bothell, WA 98021		
Walter Villiger	19,240,081	27.6%
c/o BioLife Solutions, Inc.		
3303 Monte Villa Pkwy, Suite 310		
Bothell, WA 98021		
Thomas Girschweiler (Director)	14,656,552 (5)	21.0%
c/o BioLife Solutions, Inc.		
3303 Monte Villa Pkwy, Suite 310		
Bothell, WA 98021		
Beskivest Chart LTD	7,255,026	10.4%
Goodmans Bay Center		
West Bay Street & Sea View Drive		
Nassau, Bahamas		

Name and Address of Beneficial Owner	Common Stock (1)	Percentage of Class (1)
Raymond Cohen (Director)	805,000 (6)	1.1%
c/o BioLife Solutions, Inc.		
3303 Monte Villa Pkwy, Suite 310		
Bothell, WA 98021		
Andrew Hinson	250,000 (7)	0.3%
c/o BioLife Solutions, Inc.		
3303 Monte Villa Pkwy, Suite 310		
Bothell, WA 98021		
All officers and directors as a group	23,735,182	31.5%
(six persons)		

(1)

Shares of Common Stock subject to options and warrants that are exercisable or will be exercisable within 60 days are deemed outstanding for computing the number of shares beneficially owned. The percentage of the outstanding shares held by a person holding such options or warrants includes those currently exercisable or exercisable within 60 days, but such options and warrants are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the Company believes that the persons named in the table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

(2)

Includes 1,666,667 shares of Common Stock issuable upon the exercise of outstanding stock options under the Company s 1998 Stock Option Plan.

(3)

Includes 500,000 shares of Common Stock issuable upon the exercise of outstanding stock options under the Company s 1998 Stock Option Plan and 500,000 shares of Common Stock issuable upon the exercise of outstanding warrants, all of which options and warrants are currently exercisable, and 53,600 common shares.

(4)

Includes 500,000 shares of Common Stock issuable upon the exercise of outstanding stock options under the Company s 1998 Stock Option Plan, 1,250,000 shares of Common Stock issuable upon the exercise of outstanding warrants, all of which options and warrants are currently exercisable, and 3,553,363 common shares.

(5)

Includes 250,000 shares of Common Stock issuable upon the exercise of outstanding stock options under the Company s 1998 Stock Option Plan, all of which options are currently exercisable, and 14,406,552 common shares.

(6)

Includes 750,000 shares of Common Stock issuable upon the exercise of outstanding stock options under the Company s 1998 Stock Option Plan, all of which options are exercisable within 60 days of March 31, 2009, and 55,000 common shares.

(7)

Includes 250,000 shares of Common Stock issuable upon the exercise of outstanding stock options under the Company s 1998 Stock Option Plan, all of which options are currently exercisable.

Securities Authorized for Issuance under Equity Compensation Plan

Plan category	Number of securities to be issued upon exercise of outstanding options and warrants (in thousands)	Weighted Average exercise price of outstanding options and warrants	Number of securities remaining available for future issuance (in thousands)
Equity compensation plans approved by security holders	7,050	$ .08	
Equity compensation plans not approved by security holders	3,169	$ .12	
Total	10,219	$ .09	

ITEM 13.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Howard S. Breslow, a director of the Company, is a member of Breslow & Walker, LLP, general counsel to the Company. Mr. Breslow currently owns 53,600 shares of Common Stock of the Company and holds rights to purchase an aggregate of 1,000,000 additional shares pursuant to stock options and warrants issued to him and/or affiliates. The Company incurred approximately $76,941 in legal fees during the year ended December 31, 2008 for services provided by Breslow & Walker, LLP. At December 31, 2008, accounts payable includes $8,866 due to Breslow & Walker, LLP.

In February 2007, in order to secure capital necessary to continue its operations, the Company borrowed $750,000 in equal amounts, from Thomas Girschweiler, a director and stockholder of the Company, and Walter Villiger, an affiliate of the Company, each a non-U.S. Person (as defined in Regulation S of the Securities Act of 1933, as amended) (collectively, the Investors). Each loan was evidenced by a Promissory Note (February Notes). Each February Note, together with interest accrued thereon at the rate of 7% per annum (collectively, the Conversion Amount), was due and payable in one lump sum on the earlier of (a) the second anniversary of the date of the February Note, (b) an Event of Default (as defined in the February Notes) or (c) sale, merger or change in control of the Company, as defined. In addition, if the February Note was outstanding at the time of any bona fide equity financing of the Company of at least $1,000,000 (excluding conversion of the February Notes) (a Financing), then the February Note holder was able to convert the February Note into that number of shares or units of the equity securities of the Company sold in the Financing (New Equity Securities) as is equal to the Conversion Amount divided by 85% of the per share or per unit purchase price of the New Equity Securities.

In June 2007, the Company borrowed an additional $1,000,000, in equal amounts, from the Investors. Each loan was represented by a Promissory Note (June Note). Each June Note, together with interest accrued thereon at the rate of 7% per annum (collectively, the Conversion Amount), was due and payable in one lump sum on the earlier of (a) June 30, 2008 or (b) an Event of Default (as defined in the June Notes). In addition, if the June Note was outstanding at the time of any bona fide equity financing of the Company of at least $1,000,000 (excluding conversion of the June Notes) (a Financing), then the June Note holder was able to convert the June Note into that number of shares or units of the equity securities of the Company sold in the Financing (New Equity Securities) as is equal to the Conversion Amount divided by 100% of the per share or per unit purchase price of the New Equity Securities.

In September 2007, the Company borrowed an additional $1,000,000, in equal amounts, from the Investors. Each loan was represented by a Promissory Note (September Note). Each September Note, together with interest accrued thereon at the rate of 7% per annum (collectively, the Conversion Amount), was due and payable in one lump sum on the earlier of (a) September 30, 2008 or (b) an Event of Default (as defined in the September Notes). In addition, if the September Note was outstanding at the time of any bona fide equity financing of the Company of at least $1,000,000 (excluding conversion of the February Notes, June Notes and September Notes) (a Financing), then the September Note holder was able to convert the September Note into that number of shares or units of the equity securities of the Company sold in the Financing (New Equity Securities) as is equal to the Conversion Amount divided by 100% of the per share or per unit purchase price of the New Equity Securities.

On January 11, 2008, the Company entered into a Secured Convertible Multi-Draw Term Loan Facility Agreement with each of the Investors, pursuant to which each Investor extended to the Company a secured convertible multi-draw term loan facility (the Facility) of $2,500,000, which Facility (a) incorporates (i) a refinancing of the existing indebtedness of the Company to the Investor, represented by the February Notes, June Notes and September Notes, and accrued interest thereon, in the aggregate amount of $1,431,563.30, (ii) a current advance of $300,000, and (iii) a commitment to advance to the Company, from time to time, additional amounts up to a maximum of $768,436.70, (b) bears interest at the rate of 7% per annum on the principal balance outstanding from time to time, (c) is evidenced by a secured convertible multi-draw term loan note (the Multi-Draw Term Loan Note),

due and payable, together with accrued interest thereon, the earlier of (i) January 11, 2010, or (ii) an Event of Default (as defined in the Multi-Draw Term Loan Note), (d) if outstanding at the time of any bona fide equity financing of the Company of at least Two Million Dollars ($2,000,000) (a Financing), at the option of the Investor, may be converted into that number of fully paid and non-assessable shares or units of the equity security(ies) of the Company sold in the Financing (New Equity Securities) as is equal to the quotient obtained by dividing the principal amount of the Facility outstanding at the time of the conversion plus accrued interest thereon by 85% of the per share or per unit purchase price of the New Equity Securities, and (e) is secured by all of the Company s

assets. The Multi-Draw Term Loan Note is secured by a lien on all the assets of the Company. In both May and July 2008, the Company received an additional $1,000,000 in total from the Investors pursuant to the Multi-Draw Term Loan Facility.

On October 20, 2008, each Facility was increased by $2,000,000 to $4,500,000 (an aggregate of $9,000,000), and, on October 24, 2008, the Company received an additional $600,000 in total from the Investors pursuant to the amended Multi-Draw Term Loan Facility. In January 2009, the Company received an additional $1,400,000 in total from the Investors pursuant to the amended Multi-Draw Term Loan Facility.

On August 7, 2007, the Board of Directors of the Company agreed to outsource to Roderick de Greef, a director of the Company, the task of overseeing the Company s financing activities, internal accounting functions and SEC reporting, and assisting in the search for, and reviewing, strategic alternatives, on a part-time basis (up to 80 hours per month on an as needed basis), effective as of July 1, 2007 (since he was effectively serving the Company in such capacity since such date), on terms to be agreed upon by Mike Rice, the President of the Company, and Mr. de Greef, and approved by the Board. Subsequent to August 7, 2007, Mr. Rice and Mr. de Greef agreed to the following terms: (1) a fee of $10,000 per month, (2) reimbursement of business expenses, (3) 90 day advance notice of termination by the Company, and (4) the payment of one (1) year s fees ($120,000) if terminated in connection with a Change of Control transaction. As used herein the term Change of Control means (A) there shall be consummated (1) any consolidation or merger of the Company in which the Company is not the continuing or surviving corporation or pursuant to which shares of the Company s Common Stock would be converted into cash, securities or other property, other than a merger of the Company in which the holders of the Company s Common Stock immediately prior to the merger have the same proportionate ownership of at least 50% of common stock of the surviving corporation immediately after the merger, or (2) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all, or substantially all, of the assets of the Company; (B) the stockholders of the Company approve any plan or proposal for the liquidation or dissolution of the Company; or (C) any person (as such term is used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended (the Exchange Act)), shall become the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act) of 50% or more of the Company s outstanding Common Stock. On November 14, 2007, the arrangement was approved by the Board of Directors of the Company. The Company paid consulting fees of $120,000 for year ended December 31, 2008.

ITEM 14

PRINCIPAL ACCOUNTANT FEES AND SERVICES

Aronson & Company acted as the independent auditors for the Company through the reporting period March 31, 2007. Beginning with the reporting period June 30, 2007 the Company retained the services of Peterson Sullivan LLP. The following table sets forth the aggregate fees billed and expected to be billed by Aronson & Company for review services rendered in connection with the financial statements and reports for the quarter ended March 31, 2007, and by Peterson Sullivan for audit and review services rendered in connection with the financial statements and reports for the year ended December 31, 2008, and all quarters during that year, and year ended December 31, 2007, and, quarters ended June 30, 2007 and September 31, 2007, on behalf of the Company:

ACCOUNTANT FEES AND SERVICES

	Years Ended December 31,	
Description	**2008**	**2007**
Audit Fees	$ 73,000	$ 102,779
Tax Fees	0	2,950

All Other Fees	0	0
Totals	$ 73,000	$ 105,729

The Board of Directors pre-approves all audit and non-audit services to be performed by the Company's independent auditors.

PART IV

ITEM 15.

EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

1.

Financial Statements

The financial statements required by this item are included herein:

(a)

3.

Exhibits

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

Exhibit Number	Document
3.1	Certificate of Incorporation, as amended. (1)
3.2	By-Laws, and amendment, dated March 19, 1990, thereto. (1)
4.1	Specimen of Common Stock Certificate. (1)
10.1	Stock Option Plan, dated July 7, 1988, and amendment, dated July 19, 1989. (1)
10.2	1998 Stock Option Plan (2)
10.3	Employment Agreement dated July 26, 2006 between the Company and Michael Rice (3) ^
10.4	Amendment to Employment Agreement dated February 7, 2007 between the Company and Michael Rice (4) ^
10.5	Manufacturing Service Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (5)
10.6	Quality Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (5)

10.7	Storage Services Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (5)
10.8	Order Fulfillment Services Agreement dated October 26, 2007 between the Company and Bioserv, Inc., a division of NextPharma Technologies, Inc. (5)
10.9	Lease Agreement dated August 1, 2007 for facility space 3303 Monte Villa Parkway, Bothell, WA 98021 (6)
10.10	Consulting Agreement dated August 7, 2007 between the Company and Roderick de Greef (7)
10.11	Secured Convertible Multi-Draw Term Loan Facility Agreement dated January 11, 2008, between the Company and Thomas Girschweiler (8)
10.12	Secured Convertible Multi-Draw Term Loan Facility Agreement dated January 11, 2008, between the Company and Walter Villiger (8)
10.13	First Amendment to the Secured Convertible Multi-Draw Term Loan Facility Agreement dated October 20, 2008, between the Company, Thomas Girschweiler, and Walter Villiger* *
10.14	Promissory Note dated October 20, 2008 issued by the Company to Thomas Girschweiler * *
10.15	Promissory Note dated October 20, 2008 issued by the Company to Walter Villiger * *
10.16	First Amendment to the Lease, dated the November 4, 2008, between the Company and Monte Villa Farms, LLC * *
31*	Amended Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32*	Amended Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1)

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

(2)

Incorporated by reference to the Company s Definitive Proxy Statement for the special meeting of stockholders held on December 16, 1998.

(3)

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

(4)

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

(5)

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

(6)

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

(7)

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

(8)

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

*

Filed herewith

**

Previously filed

^

Compensatory plan or arrangement

SIGNATURES

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

Date:	August 27, 2009	BIOLIFE SOLUTIONS, INC. /s/MICHAEL RICE Michael Rice Chief Executive Officer and Chief Financial Officer

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

Date:	August 27, 2009	/s/MICHAEL RICE Michael Rice Director
Date:	August 27, 2009	/s/RODERICK DE GREEF Roderick de Greef Director
Date:	August 27, 2009	/s/HOWARD S. BRESLOW Howard S. Breslow Director
Date:	August 27, 2009	/s/THOMAS GIRSCHWEILER Thomas Girschweiler Director
Date:	August 27, 2009	/s/RAYMOND COHEN Raymond Cohen Director
Date:	August 27, 2009	/s/ANDREW HINSON Andrew Hinson Director

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders

BioLife Solutions, Inc.

Bothell, Washington

We have audited the accompanying balance sheets of BioLife Solutions, Inc. ("the Company") as of December 31, 2008 and 2007, and the related statements of operations, shareholders' equity (deficiency), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BioLife Solutions, Inc. as of December 31, 2008 and 2007, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has been unable to generate sufficient income from operations in order to meet its operating needs. Additionally, the Company used approximately $2.1 million in cash for operating activities during the year ended December 31, 2008, and has an accumulated deficit of approximately $47 million at December 31, 2008. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding those matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/S/ PETERSON SULLIVAN LLP

Seattle, Washington

March 24, 2009

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BioLife Solutions, Inc.

Balance Sheets

	December 31, 2008	December 31, 2007
Assets		
Current assets		
Cash and cash equivalents	$ 98,724	$ 56,497
Accounts receivable, trade, net of allowance for doubtful accounts of $29,000 and $5,000 at December 31, 2008 and 2007, respectively	279,192	300,505
Inventories	625,291	99,062
Prepaid expenses and other current assets	37,318	113,514
Total current assets	1,040,525	569,578
Property and equipment		
Leasehold improvements		42,448
Furniture and computer equipment	109,753	93,425
Manufacturing and other equipment	210,558	180,197
Subtotal	320,311	316,070
Less: Accumulated depreciation and amortization	(190,214)	(203,380)
Net property and equipment	130,097	112,690
Deferred financing costs, net		43,750
Total assets	$ 1,170,622	$ 726,018
Liabilities and Shareholders Equity (Deficiency)		
Current liabilities		
Accounts payable	$ 659,133	$ 97,138
Accrued expenses	52,722	87,246
Accrued interest, related parties		107,325
Accrued compensation	189,459	145,766
Deferred revenue	25,833	8,333
Total current liabilities	927,147	445,808
Long term liabilities		
Promissory notes payable, related parties	5,063,127	2,750,000
Accrued interest, related parties	278,961	
Deferred revenue, long term	72,500	
Total liabilities	6,341,735	3,195,808

Commitments and Contingencies (Note 8)		
Shareholders' equity (deficiency)		
Common stock, $0.001 par value; 100,000,000 shares authorized, 69,639,854 and 69,606,520 shares issued and outstanding at December 31, 2008 and 2007, respectively	69,640	69.607
Additional paid-in capital	42,202,117	42,128,356
Accumulated deficit	(47,442,870)	(44,667,753)
Total shareholders' equity (deficiency)	(5,171,113)	(2,469,790)
Total liabilities and shareholders' equity (deficiency)	$ 1,170,622	$ 726,018

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

BioLife Solutions, Inc.

Statements of Operations

	Years Ended December 31,	
	2008	**2007**
Revenue		
Product sales	$ 1,277,497	$ 945,595
Licensing revenue	45,000	26,667
Total revenue	1,322,497	972,262
Cost of product sales	770,646	463,106
Gross profit	551,851	509,156
Operating expenses		
Research and development	457,640	413,376
Sales and marketing	372,324	708,661
General and administrative	1,925,654	1,902,126
Manufacturing start-up costs	259,687	198,490
Total operating expenses	3,015,305	3,222,653
Operating loss	(2,463,454)	(2,713,497)
Other income (expenses)		
Interest income	6,354	12,196
Other income	10,495	1,497
Interest expense	(284,762)	(113,400)
Loss on disposal of property and equipment		(7,320)
Amortization of deferred financing costs	(43,750)	(31,250)
Total other income (expenses)	(311,663)	(138,277)
Net Loss	$ (2,775,117)	$ (2,851,774)
Basic and diluted net loss per common share	$ (0.04)	$ (0.04)
Basic and diluted weighted average common shares used to calculate net loss per common share	69,631,566	69,460,402

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

BioLife Solutions, Inc.

Statements of Shareholders Equity (Deficiency)

	Common Stock		Additional Paid-in	Accumulated	Stock Subscriptions	Total Shareholders' Equity
	Shares	Amount	Capital	Deficit	Receivable	(Deficiency)
Balance, January 1, 2007	68,773,188	$ 68,773	$ 41,936,284	$ (41,815,979)	$ (8,988)	$ 180,090
Stock issued for financing costs related to notes payable	833,332	834	74,166			75,000
Stock-based compensation			117,906			117,906
Collection of stock subscriptions receivable					8,988	8,988
Net loss				(2,851,774)		(2,851,774)
Balance, December 31, 2007	69,606,520	$ 69,607	$ 42,128,356	$ (44,667,753)		$ (2,469,790)
Exercise of options to purchase common stock	33,334	33	2,300			2,333
Stock-based compensation			71,461			71,461
Net loss				(2,775,117)		(2,775,117)
Balance, December 31, 2008	69,639,854	$ 69,640	$ 42,202,117	$ (47,442,870)	$	$ (5,171,113)

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

BioLife Solutions, Inc.

Statements of Cash Flows

	Years Ended December 31,	
	2008	**2007**
Cash flows from operating activities		
Net loss	$ (2,775,117)	$ (2,851,774)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	29,281	30,313
Loss on disposal of property and equipment		7,320
Amortization of deferred financing costs	43,750	31,250
Stock-based compensation expense	71,461	117,906
Change in operating assets and liabilities		
(Increase) Decrease in		
Accounts receivable, trade	21,313	(201,525)
Inventories	(526,229)	(6,311)
Prepaid expenses and other current assets	76,196	(99,101)
Increase (Decrease) in		
Accounts payable	561,995	6,841
Accrued compensation and other expenses	9,169	140,444
Accrued interest, related parties	284,763	107,325
Deferred revenue	90,000	8,333
Net cash used in operating activities	(2,113,418)	(2,708,979)
Cash flows from investing activity		
Purchase of property and equipment	(46,688)	(105,546)
Net cash used in investing activity	(46,688)	(105,546)
Cash flows from financing activities		
Decrease in restricted cash		190,837
Proceeds from notes payable	2,200,000	2,750,000
Principal payments on note payable		(197,477)
Proceeds from exercise of options	2,333	
Collection of stock subscriptions receivable		8,988
Net cash provided by financing activities	2,202,333	2,752,348
Net increase (decrease) in cash and cash equivalents	42,227	(62,177)

Cash and cash equivalents - beginning of year		56,497		118,674
Cash and cash equivalents - end of year	$	98,724	$	56,497

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

NOTES TO FINANCIAL STATEMENTS

1.

Organization and Significant Accounting Policies

Business

BioLife Solutions, Inc. ("BioLife or the Company), develops and markets patented hypothermic storage and cryopreservation solutions for cells, tissues, and organs, and provides contracted research and development and consulting services related to optimization of biopreservation processes and protocols. Its proprietary HypoThermosol® and CryoStor™ biopreservation media products are marketed to companies, laboratories, and academic institutions engaged in research and commercial clinical applications. The Company s line of serum-free and protein-free biopreservation solutions 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 improvement in biologic source material shelf life and also post-thaw isolated cell, tissue, and organ viability and function.

Use of estimates

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

Reclassifications

Certain prior period amounts in the financial statements have been reclassified to conform to current period presentation. There has been no impact on previously reported net loss or shareholders equity.

Net income (loss) per share

Basic net income (loss) per common share is calculated by dividing the net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated using the weighted average number of common shares outstanding plus dilutive common stock equivalents outstanding during the period. Common stock equivalents are excluded for the years ending December 31, 2008 and 2007 as they are anti-dilutive. Common stock equivalents include stock options, warrants, and promissory notes payable.

Cash and cash equivalents

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

Inventories

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

Accounts receivable

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

Property and equipment

Furniture and equipment are stated at cost and are depreciated using the straight-line method over estimated useful lives of three to five years. Leasehold improvements are stated at cost and are amortized using the straight-line method over the lesser of the life of the asset or the remaining term of the lease.

Revenue recognition

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

Income taxes

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

Effective January 1, 2007, the Company adopted the provisions of the Financial Accounting Standards Board, or FASB, Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with Statement of Financial Accounting Standards (SFAS) No. 109. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than 50% likely of being realized upon ultimate settlement. The Company considers many factors when evaluating and estimating its tax positions and tax benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes. Based on the implementation guidance set forth in the pronouncement and the Company s review of its tax positions leading up to and subsequent to adoption, FIN 48 did not have a material impact on its financial position, results of operations, or cash flows. As such, the Company has not recorded any liabilities for uncertain tax positions or any related interest and penalties. The Company s tax returns are open to audit for years ending December 31, 2005 to 2008.

Advertising

Advertising costs are expensed as incurred and totaled $7,620 and $2,853 for the years ended December 31, 2008 and 2007, respectively.

Manufacturing start-up costs

During the third quarter of 2007, as a result of relocating the Company from Owego, NY to Bothell, WA, management of the Company decided to outsource manufacturing and entered into a contract with a Contract Manufacturing Organization (CMO). One-time start-up costs related to the outsourcing of manufacturing were expensed as incurred and amounted to $198,490 for the year ended December 31, 2007. In the third quarter of 2008, in order to lower its cost of product sales, based on anticipated future sales volume, management of the Company decided to transition to internal manufacturing and maintain its relationship with the CMO as a contingency for additional production capacity. One-time start-up costs related to the transition to internal manufacturing were expensed as incurred and amounted to $259,687 for the year ended December 31, 2008.

Fair value of financial instruments

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

Business segments

As described above, the Company s activities are directed in the life sciences field of biopreservation products and services. As of December 31, 2008 and 2007 this is the Company s only business segment.

Research and Development

Research and development costs are expensed as incurred.

Stock-based compensation

The Company adopted SFAS No. 123(R) (revised 2004) "Share-Based Payment" (SFAS 123(R)) effective January 1, 2006 and is recognizing the cost of stock-based compensation, consisting primarily of stock options and warrants, using the Modified Prospective Application transition method whereby the cost of new awards and awards modified, repurchased or cancelled after January 1, 2006 and the portion of awards for which the requisite service has not been rendered (unvested awards) that were outstanding as of January 1, 2006, is recognized as the requisite service is rendered on or after the effective date, January 1, 2006. Stock-based compensation awards are measured at their fair value at the date of grant. The resulting compensation expense is recognized in the Statements of Operations ratably over the vesting period of the award (requisite service period).

The fair value of options and warrants at the date of grant is determined under the Black-Scholes option-pricing model. During the years ended December 31, 2008 and 2007, the following weighted-average assumptions were used:

Assumptions	2008	2007
Risk-free rate	2.55 %	4.67 %
Annual rate of dividends		
Historical volatility	69.38 %	74.56 %
Option life	7 years	6.4 years

SFAS No. 123(R) requires that the Company recognize compensation expense for only the portion of options that are expected to vest. Therefore, management applies an estimated forfeiture rate that is derived from historical employee termination data and adjusted for expected future employee turnover rates. The Company s stock price volatility, option lives and expected forfeiture rates involve management s best estimates at the time of such determination, all of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. The Company utilizes the simplified method as allowed by SEC Staff Accounting Bulletin No. 107 and 110 in determining option lives. The simplified method is used due to the fact that the Company has had significant structural changes in its business such that its historical exercise data may not provide a reasonable basis to estimate option lives.

Recent Accounting Pronouncements

In May 2008, the FASB issued FASB Staff Position, or FSP, Accounting Principles Board (APB) (FSP APB 14-1), Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement). FSP APB 14-1 applies to convertible debt instruments that, by their stated terms, may be settled in cash (or other assets) upon conversion, including partial cash settlement of the conversion option. FSP APB 14-1 requires bifurcation of the instrument into a debt component that is initially recorded at fair value and an equity component. The difference between the fair value of the debt component and the initial proceeds from issuance of the instrument is recorded as a component of equity. The liability component of the debt instrument is accreted to par using the effective yield method; accretion is reported as a component of interest expense. The equity component is not subsequently re-valued as long as it continues to qualify for equity treatment. FSP APB 14-1 must be applied

retrospectively to previously issued cash-settleable convertible instruments as well as prospectively to newly issued instruments. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Though the Company does not believe FSP APB 14-1 will have an effect on its current financial position, the Company is currently evaluating the requirements of FSP APB 14-1 with respect to its recent convertible debt financing and has not yet determined the impact on the Company s financial statements.

In February 2008, the FASB issued FSP 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2. FSP 157-2 delays the effective date of *Fair Value Measurements*, or SFAS No. 157 for nonfinancial assets and nonfinancial

liabilities, except for certain items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The Company has applied the provisions of SFAS 157 to financial assets and liabilities prospectively as of January 1, 2008. The Company will be required to apply the provisions of SFAS 157 to these nonfinancial assets and nonfinancial liabilities as of January 1, 2009 and is currently evaluating the impact of the application of SFAS 157 as it pertains to these items.

In November 2007, the Emerging Issues Task Force of the FASB, or EITF, ratified a consensus of EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF 07-1, which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 is effective for the Company beginning in the first quarter of 2009. The Company does not expect the adoption of EITF 07-1 to have a material impact on its results of operations, financial condition and disclosures.

2.

Financial Condition

The Company has been unable to generate sufficient income from operations in order to meet its operating needs and has an accumulated deficit of approximately $47 million at December 31, 2008. This raises doubt about the Company s ability to continue as a going concern.

At December 31, 2008, the Company had cash and cash equivalents of $98,724, compared to cash and cash equivalents of $56,497 at December 31, 2007. At December 31, 2008, the Company had working capital of $113,378, compared to working capital of $123,770 at December 31, 2007.

During the year ended December 31, 2008, net cash used in operating activities was $(2,113,418) as compared to net cash used by operating activities of $(2,708,979) for the year ended December 31, 2007.

Net cash used in investing activities totaled $(46,688) during the year ended December 31, 2008 which resulted from the purchase of property and equipment. Net cash used in investing activities totaled $(105,546) during the year ended December 31, 2007 resulting from the purchase of property and equipment.

Net cash provided by financing activities totaled $2,202,333 for the year ended December 31, 2008, which resulted primarily from the draws taken on the Multi-Draw Term Loan Note due to two shareholders. Net cash provided by financing activities totaled $2,752,348 for the year ended December 31, 2007 resulting from the issuance of promissory notes to the same two shareholders.

In February, June and September, 2007, in order to secure capital necessary to continue its operations, the Company borrowed an aggregate of $2,750,000 in equal amounts, from Thomas Girschweiler, a director and stockholder of the Company, and Walter Villiger, an affiliate of the Company, each a non-U.S. Person (as defined in Regulation S of the Securities Act of 1933, as amended) (collectively, the Investors). Each loan was evidenced by a Promissory Note (collectively, Notes). Each Note, together with interest accrued thereon at the rate of 7% per annum (collectively, the Conversion Amount), was due and payable in one lump sum on the earlier of (a), in the case of the February Notes, the second anniversary of the date thereof and, in the case of the June Notes and the September Notes, June 30, 2008 and September 30, 2008, respectively, (b) an Event of Default (as defined in the Notes) or (c) sale, merger or change in control of the Company, as defined. In addition, if any Note was outstanding at the time of any bona fide equity financing of the Company of at least $1,000,000 (a Financing), then the Note holder was able to convert the Note into that number of shares or units of the equity securities of the Company sold in the Financing (New Equity Securities) as is equal to the Conversion Amount divided by, in the case of the February Notes, 85% of the per share or per unit

purchase price of the New Equity Securities and, in the case of the June Notes and September Notes, 100% of the per share or per unit purchase price of the New Equity Securities.

On January 11, 2008, the Company entered into a Secured Convertible Multi-Draw Term Loan Facility Agreement with each of the Investors, pursuant to which each Investor extended to the Company a secured convertible multi-draw term loan facility (the Facility) of $2,500,000, which Facility (a) incorporates (i) a refinancing of the existing indebtedness of the Company to the Investor, represented by the Notes, and accrued interest thereon, in the aggregate amount of $1,431,563.30, (ii) a current advance of $300,000, and (iii) a commitment to advance to the Company, from time to time, additional amounts up to a maximum of $768,436.70, (b) bears interest at the rate of 7% per annum on the principal balance outstanding from time to time, (c) is evidenced by a secured convertible multi-draw term loan note (the Multi-Draw Term Loan Note), due and payable, together with accrued interest

thereon, the earlier of (i) January 11, 2010, or (ii) an Event of Default (as defined in the Multi-Draw Term Loan Note), (d) if outstanding at the time of any bona fide equity financing of the Company of at least Two Million Dollars ($2,000,000) (a Financing), at the option of the Investor, may be converted into that number of fully paid and non-assessable shares or units of the equity security(ies) of the Company sold in the Financing (New Equity Securities) as is equal to the quotient obtained by dividing the principal amount of the Facility outstanding at the time of the conversion plus accrued interest thereon by 85% of the per share or per unit purchase price of the New Equity Securities, and (e) is secured by all of the Company s assets.

In May and July 2008, the Company received an additional $1,000,000 in total from the Investors pursuant to the Multi-Draw Term Loan Facility. On October 20, 2008, each Facility was increased by $2,000,000 to $4,500,000 (an aggregate of $9,000,000), and, on October 24, 2008, the Company received an additional $600,000 in total from the Investors pursuant to the amended Multi-Draw Term Loan Facility and in January 2009, the Company received an additional $1,400,000 in total from the Investors pursuant to the amended Multi-Draw Term Loan Facility, which brought the Company s total principal balance owed under the Multi-Draw Term Loan Notes to $6,463,127, which leaves $2,536,873 left to draw from the Facility.

Management believes that continued access to the amended Multi-Draw Term Loan Note, in combination with cash generated from operations, will provide sufficient funds through at least the next twelve months. However, the Company would require additional capital in the immediate short term if its ability to draw on the amended Multi-Draw Term Loan Note is restricted or terminated. Other factors that would negatively impact the Company s ability to finance its operations include (i) significant reductions in revenue (ii) increased capital expenditures (iii) significant increases in cost of goods and operating expenses or; (iv) an adverse outcome resulting from current litigation. The Company expects that it may need additional capital to reach a sustainable level of positive cash flow. Although the Investors who have provided the amended Multi-Draw Term Loan Note have historically demonstrated a willingness to grant access to the Facility, there is no assurance they will continue to do so in the future. If the Investors were to become unwilling to provide access to additional funds through the amended Multi-Draw Term Loan Note, the Company would need to find immediate additional sources of capital. There can be no assurance that such capital would be available at all, or if available, that the terms of such financing would not be dilutive to other stockholders. If the Company is unable to secure additional capital as circumstances require, it may not be able to continue its operations.

These financial statements assume that the Company will continue as a going concern. If the Company is unable to continue as a going concern, it may be unable to realize its assets and discharge its liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or to amounts and classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

3.

Inventories

Inventories consist of the following at December 31, 2008 and 2007:

	2008	2007
Raw materials	$ 9,820	$ 9,820
Work in progress	113,382	
Finished goods	502,089	89,242
Total	$ 625,291	$ 99,062

4.

Promissory Notes Payable

At December 31, 2008 and 2007, notes payable consisted of the following:

		2008		2007
Notes payable to Thomas Girschweiler and Walter Villiger, secured by all assets of the Company, principal balances of all notes payable outstanding due in full in January 2010, including interest of 7% (see Note 2)	$	5,063,127	$	2,750,000
Total notes payable, long-term	$	5,063,127	$	2,750,000

5.

Income Taxes

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

	2008	2007
Federal tax (benefit) at statutory rate	$ (943,540)	$ (969,603)
State income tax (benefit), net of federal tax (benefit)	(137,368)	(141,163)
Expiration of net operating loss carryforwards	2,295,296	1,754,509
Expiration of tax credits	150,000	125,000
Change in valuation allowance	(1,365,397)	(773,234)
Other	1,009	4,491
Provision for income taxes, net	$	$

At December 31, 2008 and 2007, the components of the Company s deferred taxes are as follows:

	2008	2007
Deferred tax assets (liabilities)		
Net operating loss carryforwards	$ 10,890,618	$ 12,207,688
Tax credits	292,000	442,000
Accrued compensation	47,308	45,425
Depreciation	(8,148)	(3,379)
Stock-based compensation	118,522	90,688
Accrued related party interest	108,655	41,803
Other	11,820	1,948
Total	11,460,775	12,826,173
Less: Valuation allowance	(11,460,775)	(12,826,173)
Net deferred tax asset	$	$

The Company has the following net operating loss and research and development (R&D) tax credit carryforwards available at December 31, 2008:

Year of Expiration	Net Operating Losses	R&D Tax Credits
2009	$ 1,431,000	$ 114,000
2010	1,562,000	145,000

2011		5,277,000		33,000
2012		1,570,000		
2013		1,425,000		
2014		1,234,000		
2020		2,849,000		
2021		4,168,000		
2023		1,217,000		
2024		646,000		
2025		589,000		
2026		873,000		
2027		2,607,000		
2028		2,512,000		
Total	$	27,960,000	$	292,000

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

6.

Shareholders Equity

Warrants

The following table summarizes warrant activity for the years ended December 31, 2008 and 2007:

	Year Ended December 31, 2008		Year Ended December 31, 2007
		Wgtd. Avg.	