Zacks Small-Cap Research

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BioLife Solutions Inc (BLFS-OTCBB)

BLFS: Q3 Results Beat Big. Revenue Guidance Increased

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/29/12
Current Price (11/15/12)	$0.32
Target Price	**$0.50**

OUTLOOK

Demand for biopreservation media is estimated to grow at an annual rate of almost 20% over the next several years, largely driven by rapid growth of the emerging field of regenerative medicine (including cell therapy and tissue engineering). BioLife's strategy is to build greater visibility and awareness of the benefits of their biopreservation products compared to the "home-brews" that currently dominate the market. Meanwhile, the company's contract manufacturing business, which is expected to generate ~$2MM in revenue in 2012 as a result of the signing if a key customer during 2011, is expected to provide a source of near-term revenue and cash flow to help fund the further development and commercialization of the biopreservation media business, which is expected to provide the bulk of revenue and drive earnings for the long-term. Moving our price target from $0.30 to $0.50.

SUMMARY DATA

52-Week High	**$0.40**
52-Week Low	**$0.03**
One-Year Return (%)	**633.33**
Beta	**-0.51**
Average Daily Volume (sh)	**26,953**
Shares Outstanding (mil)	**70**
Market Capitalization ($mil)	**$23**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-42.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	611 A	623 A	716 A	810 A	2759 A
2012	836 A	1097 A	1682 A	1356 E	4971 E
2013					5869 E
2014					7008 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.03 A
2012	-$0.00 A	-$0.01 A	-$0.01 A	-$0.01 E	-$0.02 E
2013					-$0.02 E
2014					-$0.02 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW……

Q3 Results

BioLife reported financial results for the third quarter ending September 30, 2012 on November 13th. Results were well ahead of our estimates, beating our numbers on both the top and bottom lines with sales benefitting from a huge jump in contract manufacturing revenue which, combined with flat operating expense, resulted in net income coming in almost $300k better than our estimate. BLFS continues to hit financial milestones, turning in another record revenue quarter (marking the 9th in a row) which also generated positive cash from operations (albeit just barely and was negative ex-changes in working capital). Perhaps even more important is that management continues to expect strong growth in Q4 and raised their full-year revenue guidance to $5 million (up from $4.1 million previously). And while BLFS does not provide specific financial or operational guidance beyond the current year, based on communications in recent press/earnings releases and public filings relative to business activities and market opportunities/trends, we have a greater sense that their awareness-building efforts relative to the competitive benefits of their biopreservation media have and will continue pay dividends in the form of increasing the customer base and growing revenues. As such we have made some material upward adjustments to our revenue estimates for 2012 as well as for our out-years. The adjustments to our financial model, which drives our valuation of BLFS, has pushed our per share price target up from $0.30 to $0.50.

Revenue Up 135%, Op Expenses Remain Low
Q3 revenue was $1.7 million, up 135% yoy, up 53% sequentially and well ahead of our $854k estimate. The majority of the $828k top-line beat came from significantly higher than modeled ($1.1MM A vs. $379k E) contract manufacturing revenue. The recent commencement of deliveries to the new contract manufacturing customer helped push contract manufacturing revenue up from $102k in Q3 2011 and $341k in Q2 2012. For Q3 2012 contract manufacturing accounted for 63% of total revenue and contributed 99% and 122% of the total revenue growth on a yoy and sequential basis, respectively.

Product sales to direct ($446k) and indirect ($174k) customers were up slightly (2%) on a yoy basis and down 17% on a sequentially. As noted in previous updates, we would not read much into the quarterly gyrations and repeat that likely more representative of a long-term outlook for product sales is that BioLife recently added headcount to its direct and indirect sales teams (as well as production personnel) in order "to manage growing demand and projections."

Gross margin was 35.4% compared to our 42.5% estimate which is directly attributable to the big beat in contract manufacturing revenue, which carries a lower GM compared to product sales. We model GM for the full year 2012 of 41.7% (GM averaged 45.5% through first nine months).

Operating expenses of $744k were about 8% lower than our $808k estimate. Net income and EPS were ($352k) and (0.01) compared to our ($640k) and ($0.01) estimates.

Cash
BioLife exited Q3 with $8k in cash and equivalents, down from $155k at the end of Q2. Cash used in operating activities in Q3 was an inflow of $121. Ex-changes in working capital cash used in operating activities was an outflow of $226k. BLFS expects to achieve positive cash flow from operations in Q4 as well.

Our Outlook
Our fundamental long-term outlook remains intact following Q3 results. And as indicated, given the stronger than anticipated recent financial results and near-term guidance along with our view that certain business activities and opportunities are materializing more rapidly than perhaps we had previously anticipated, we have made some upward adjustments to our modeled revenue for both the remainder of the current year as well as for out-years. We now model 2012 revenue and EPS of $5.0 million and ($0.02), up from $3.8 million and ($0.03) prior to Q3 results.

Our 2015 revenue estimate has moved from to $8.9 million, up from $6.9 million previously. The upward revisions to our model have moved our price target from $0.30/share to $0.50/share. Our valuation methodology is based on comp valuations (see our valuation at the end of this report).

KEY POINTS

- Demand for biopreservation media is estimated to grow at an annual rate of almost 20% over the next several years

- BioLife expects to benefit from the emerging field of regenerative medicine which has recently experienced rapid growth, largely as a result of recent advancements and findings using stem cells to regenerate and repair tissues and organs

- BioLife's strategy is to build greater visibility and awareness of the benefits of their biopreservation products compared to the "home-brews" that currently dominate the market. Key advantages such as CGMP (Good Manufacturing Process) serum-free and protein-free manufacturing, extended shelf-life and higher preserved-cell yields translate into lower input costs, greater stability of finished products, and reduced quality risks for customers in regenerative medicine, biobanking and drug discovery

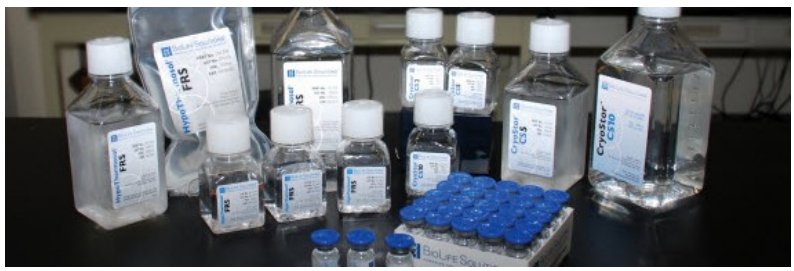
- Previous revenue guidance of $4.1 million (+49%) for 2012 was just increased to $5.0 million (+80%), driven by contribution from a new contract manufacturing customer. BLFS achieved positive cash flow from operations in Q3 2012 (albeit just barely and was negative ex-changes in working capital) and expects that to repeat in Q4

- BioLife's strategy to grow their customer base includes continuing to attend and present at industry conferences, active engagement and site visits with prospective customers by BLFS' Chief Technology Officer (a recognized expert in the field of biopreservation), and a recent free-sample campaign whereby BLFS is giving away samples of HypoThermosol and CryoStor so prospective customers can test for themselves the superiority of the products compared to competitors'

BACKGROUND

BioLife Solutions, Inc., headquartered in Bothell, Washington, has a main focus on the development and manufacture of biopreservation media products for cells, tissues and organs. Biopreservation media are solutions used to maintain the viability of biological material such as cells (including stem cells), whole blood, and tissues following removal from the body, during storage and transportation, and while undergoing handling, manipulation and processing by researchers engaged in regenerative medicine product development. Demand for biopreservation media is estimated to grow at an annual rate of almost 20% over the next several years. BioLife expects to benefit from the emerging field of regenerative medicine (including cell therapy and tissue engineering) which has recently experienced rapid growth, largely as a result of recent advancements and findings using stem cells to regenerate and repair tissues and organs, as well as to treat a number of diseases.

BioLife Solutions, Inc. biopreservation media products



The company's current suite of biopreservation media products includes HypoThermosol, CryoStor, and generic BloodStor which are marketed to regenerative medicine companies, hospital-based stem cell transplant centers, pharmaceutical companies, cord blood and adult stem cell banks, hair transplant surgeons, and suppliers of cells to the drug discovery, toxicology testing and diagnostic markets. The company also has a contract manufacturing business which provides aseptic media formulation, fill and finish services.

The contract manufacturing business, which contributed $1.4MM of revenue in the first nine months of 2012 (including $1.1MM in Q3) and which we expect to generate about two million dollars of revenue for the full-year 2012 as a result of the signing of a key customer during 2011, is expected to provide a source of near-term revenue and cash flow to help fund the further development and commercialization of the biopreservation business, which BioLife expects to provide the bulk of revenue and drive earnings for the long-term.

BioLife's strategy is to build greater visibility and awareness of the benefits of their biopreservation products compared to the "home-brews" that currently dominate the market. Key advantages such as extended shelf-life and higher preserved-cell yields translate into reduced input costs (i.e. - lower COGS) and greater stability of finished products for customers in regenerative medicine, biobanking and drug discovery. BioLife will use this as part of their marketing message as they look to grow their direct and distributor customer base which already encompasses ~400 organizations including some leading life sciences companies such as Life Technologies, Sigma-Aldrich, Cellular Dynamics and Athersys.

Revenue could potentially really ramp for the long-term if development-stage therapies using BLFS's biopreservation media gain FDA approval and are commercialized. This would offer a significantly greater upside revenue opportunity for BioLife as well as a much more stable source of revenue than as a supplier in the R&D process. BLFS recently noted that their products are now being used in more than 50 clinical trial-stage cellular therapies and that they believe they hold the number one supplier position among companies offering pre-formulated cell and tissue storage and freeze media used in clinical trial stage cellular therapies to treat the leading causes of death and disability such as cancer, heart disease, stroke, and joint/movement disorders.

BIOLOGICAL MATERIAL BIOPRESERVATION

Biological material such as cells, whole blood, tissue and organs begin degrading and losing viability immediately following removal from the donor body. For instance, stem cells extracted from the umbilical cord must be preserved immediately and effectively to retain their viability for use in regenerative medicine. Chilling (hypothermia) is often used to reduce metabolism (i.e. - chemical processes) and to help stabilize and reduce degradation of the biological material but it can also have the unintended effect of causing cellular damage and death, especially during long periods of non-frozen shipment, and the freezing and thawing process. Immediately following removal, biological material are bathed or stored in biopreservation solutions (i.e. - media) in order to maintain their viability and to protect cells from cellular and molecular damage during storage and transportation. Biopreservation media are also used by researchers engaged in regenerative medicine product development to maintain stability of cellular material during handling, manipulation and processing.

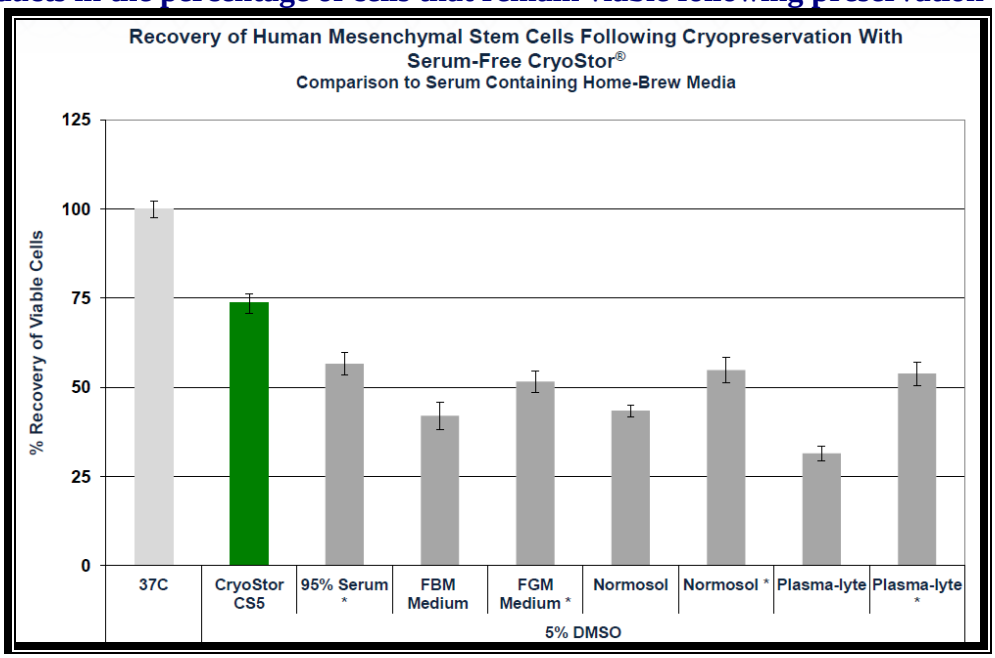
Depending on the biological material in question as well as the intended time until it will used, optimum chilling temperature could range from just above freezing (35˚F to 46˚F) to cryogenic (< -240˚F).

The majority (estimated at ~80% of the market) of **traditional biopreservation media** used today consist of "home-brews" or in-house solutions, the ingredients for which may be supplied by third parties but mixed by the end-user. BioLife Solutions believes, based on independent testing, that their products offer certain advantages over these home-brews in terms of performance, reliability, shelf-life and in the overall preservation of the viability and stability of cells. Per BioLife, the superior performance of their products is mostly a result of the use of different ingredients relative to competing products as well as optimization of concentrations of ingredients. Namely, unlike many competing solutions, BioLife's products do not contain animal serum or proteins which are facing increasing scrutiny from regulatory agencies due to the risk of xenographic disease transmission. BioLife also uses both DMSO (dimethyl sulfoxide), a common permeating cryoprotectant used for cryopreservation (i.e. - deep freeze), as well as non-permeating cryoprotectants in its cryopreservation products while most competing products use only DMSO. Furthermore, aside from the cryoprotectants, BioLife’s intracellular-like media ingredients are balanced specifically to protect cells during cold preservation conditions (similar to the design of organ transplant preservation solutions), in contrast to traditional home-brew cocktails and competing commercial media that are designed as isotonic solutions designed for normal body temperatures.

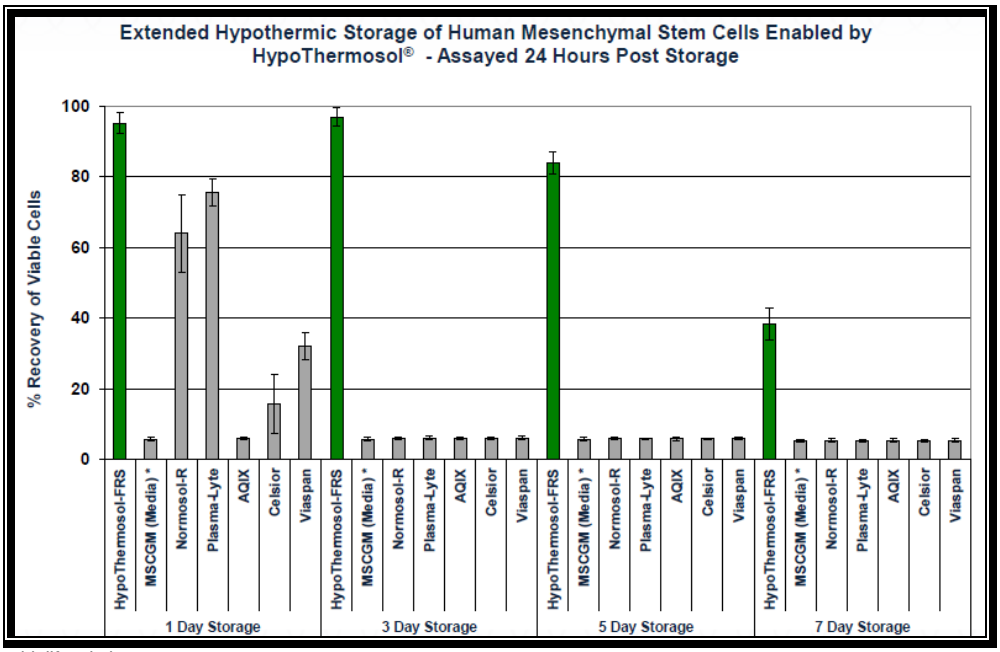
In addition and unlike home-brew solutions, BioLife's products are pre-formulated and sterile-filtered using high-grade USP (U.S. Pharmacopeia) components and manufactured under CGMP (good manufacturing practice) manufacturing standards, helping to assure product consistency and quality. By contrast, the components of home-brews are often sourced from multiple vendors, are typically not USP-grade, and must be mixed on-site, all or any of which can contribute to issues with consistency and quality. And by using CGMP-manufactured products, this facilitates BioLife's current and prospective customers with quality and regulatory approvals that may be required when using the company's products in their product development and manufacturing processes. This is a particularly key advantage as regulatory agencies (i.e. - FDA) will want to be assured that the quality and consistency of the biopreservation media used in clinical trials is similar to that used in the final approved product used for commercial production. BioLife's products offer this assurance, while almost all home-brews can not.

BioLife's over two decades of molecular research which focused on how chilling can damage cells provided the backbone for their product development as well as the differentiation and value-added of their products versus competing biopreservation media. Specifically, BioLife's research enabled them to better understand how chilling influenced cell apoptosis (programmed cell death) and necrosis (traumatic cell death) which guided their R&D strategy towards development of biopreservation media that reduced preservation-induced cell stress. This ultimately resulted in the development of a new class of biopreservation media which have shown an ability to significantly extend shelf life and stability of biological material. The initial product developed from this research was HypoThermosol which helped form the basis for product extensions including the development of CryoStor and BloodStor. The products are covered with six issued U.S. patents, one issued European patent, and one issued Japanese patent. In addition, there are several pending U.S. and international patent applications.

BioLife's studies have shown their biopreservation media outperform competing products in the percentage of cells that remain viable following preservation



* contains serum



SOURCE: biolifesolutions.com

* contains serum

Value-Added With Increased Biologic Stability….
Longer shelf-life and increased stability of preserved cells means lower input costs (from higher yields, less spoilage of source cells) and higher potency and stability of finished products for developers and manufacturers of cell therapy products. Extended shelf-life and stability equates to longer holding time which also means that the sourced cells and finished product can travel greater distances and, therefore, have a greater viable geographic footprint. The ability to have a bigger geographic footprint is becoming ever more important as drug discovery (including clinical trials), drug manufacturing and distribution, and cell input sourcing are all experiencing significant growth in overseas areas such as Europe and Asia. In fact, *Pharmaceutical Commerce*, a publication focused on the processes involved in getting new drugs to market, recently published a study on cold chain shipping related to life sciences called "Biopharma Cold Chain Sourcebook 2010." In it they note that cold-chain shipping to/from Asia and emerging markets is forecast to grow by about 50% and 33%, respectively.

BIOLIFE SOLUTIONS' PRODUCTS *(descriptions per BLFS's website and public filings)*

- **HypoThermosol** biopreservation media is a novel, engineered, optimized hypothermic storage and shipping media product. Serum-free, protein-free HypoThermosol is designed to provide maximum storage and shipping stability for biologics at 2-8°C. This proprietary, optimized formulation mitigates temperature-induced molecular cell stress responses that occur during chilling and re-warming of biologics, intermediate products, and final cell products intended for research and clinical applications. Similar to our companion freeze media CryoStor, HypoThermosol FRS includes components that scavenge free radicals, provide pH buffering, oncotic/osmotic support, energy substrates, and ionic concentrations that balance the intracellular state at low temperatures. Across a broad spectrum of cell and tissue types, HypoThermosol product has proven much more effective in reducing post-preservation necrosis and apoptosis as compared to commercial and home-brew isotonic and extracellular-like formulations. This results in greatly extended shelf life and improved post-preservation viability. HypoThermosol is tested to USP <71> Sterility and USP <85> Endotoxin testing standards, and is manufactured under CGMP.

  HypoThermosol is packaged in four convenient alternatives:

  10mL Vial

  - HypoThermosol FRS 10mL Vial: Sterile vial filled with 10mL of HypoThermosol, closed with a flip top septum for needle access. Designed for initial product sampling or single-use applications.
  - HypoThermosol FRS 100mL Bottle: Nalgene PETG square media bottle with a screw cap, designed for applications requiring a larger volume of HypoThermosol, where repeated access to the container is not expected.

  500mL IV Bag

  - HypoThermosol FRS 500mL Bottle: Nalgene PETG square media bottle. Designed for even larger volume applications such as tissue transport and storage.
  - HypoThermosol FRS 500mL IV Bag: EVA media bag with syringe and spike ports. Designed for improved aseptic technique when aliquotting HypoThermosol for multiple doses or repeated processing.

- **CryoStor** cryopreservation freeze media products have been designed to mitigate temperature induced molecular cell stress responses during freezing and thawing. CryoStor proprietary freeze media products are intended for cryopreservation of biologics at -80 to -196°C and are based on the novel HypoThermosol formula. All CryoStor products are pre-formulated with USP-grade DMSO, a permeating cryoprotective agent which helps mitigate damage from the formation of intracellular ice. Across a broad spectrum of cell types, CryoStor products have proven much more effective in reducing post-preservation necrosis and apoptosis as compared to commercial and home-brew isotonic and extracellular formulations. This enables greatly improved post-thaw cell yield, viability, and recovery. CryoStor products are tested to USP <71> Sterility and USP <85> Endotoxin testing standards, and are manufactured under CGMP. CryoStor is offered in several packages and pre-formulated with DMSO in final concentrations of 2%, 5%, and 10%.

  CS10 Freeze Media

  - CryoStor CS10 Freeze Media: Pre-formulated with 10% DMSO, CryoStor CS10 has demonstrated remarkable biopreservation efficacy in numerous cell types, including sensitive cells such as hepatocytes.
  - CryoStor CS5 Freeze Media: Pre-formulated with 5% DMSO, CryoStor CS5 routinely outperforms competing freeze media containing 10% DMSO and is applicable for

cryopreservation of most cell types.

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

➢ **BloodStor** freeze media is a generic equivalent to a standard cryopreservation media for stem cells isolated from umbilical cord blood, peripheral blood, and bone marrow. BloodStor 55-5 is pre-formulated with 55% (w/v) DMSO USP, 5% (w/v) Dextran-40 USP, and water for injection (WFI) quality water. BloodStor 100 contains 100% (w/v) DMSO USP. BloodStor products are tested to USP <71> Sterility and USP <85> Endotoxin testing standards, and are manufactured under CGMP.

BloodStor 55-5

SOURCE: biolifesolutions.com

- BloodStor 55-5 Biopreservation Media: BloodStor 55-5 contains 55% USP grade DMSO and 5% USP-grade Dextran-40 in water for injection quality water (WFI) and supports a common cord blood processing protocol. The product is packaged in industry standard, single-use sterile vials with a fill volume of 7.2mL.

- BloodStor 100 Biopreservation Media: BloodStor 100 contains 100% USP grade DMSO and is packaged in 50ml and 100mL vials.

MARKETS

BioLife currently has over 400 customers and distributors in three main market segments; regenerative medicine, biobanking, and drug discovery. By some estimates, the biopreservation media market is expected to grow from about $150 million in 2011 to $500 million by the year 2018.

Regenerative Medicine

Regenerative medicine, as defined by the National Institute of Health, is "the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage, or congenital defects." It's focused on both regenerating damaged tissues and organs in the body as well as growing tissues and organs in the laboratory and then implanting them in the body. The field has expanded greatly to also include cellular based therapies used to treat numerous diseases and disorders.

The field of regenerative medicine is growing very rapidly, largely as a result of recent advancements and findings using stem cells to regenerate and repair tissues and organs. Stem cells are being investigated for variety of uses including diabetes, cardiac repair, bone regeneration, and brain injury repair. BioLife cites a study by MedMarket Diligence that estimates the worldwide market for regenerative medicine is growing at 20% per year. Another study, from Visiongain, also supports a robust outlook for regenerative medicine and predicts this market will grow from $1.4 billion in 2012 to $10 billion in 2020 (~28% CAGR).[1] BioLife expects to benefit from the emerging field of regenerative medicine and is positioning their HypoThermosol and CryoStor products as a better alternative to other branded biopreservation media and home-brews, the latter which are estimated to hold as much as 80% of the regenerative medicine market.

The regenerative medicine market segment is comprised of nearly 700 commercial companies and numerous other hospital-based transplant centers developing and delivering cellular therapies such as stem cells isolated from bone marrow, peripheral and umbilical cord blood as well as engineered tissue-based products. BioLife's initial focus relative to regenerative medicine is as a supplier of reagents to life sciences companies using stem cells and other biological material in research and development of novel therapies. BioLife notes that they have shipped their biopreservation media products to over 250 regenerative medicine customers and estimate that their products are now incorporated in over 50 regenerative medicine cell or tissue-based products in pre-clinical and clinical trial stages of development. BioLife believes that they hold the number one supplier position among companies offering pre-formulated cell and tissue storage and freeze media used in clinical trial stage cellular therapies to treat the leading causes of death and disability such as cancer, heart disease, stroke, and joint/movement disorders.

[1] *Translational Regenerative Medicine: Market Prospects 2012-2022.* Visiongain, August 31, 2012

As a supplier in the R&D chain, BioLife's revenue can be choppy, inconsistent and highly dependent on the progress and success of their customers' research projects. However, if and when these development-stage therapies gain FDA approval, the opportunity for BioLife could be as a direct supplier of their biopreservation media to their customers' commercial product development. This would offer a significantly greater upside revenue opportunity for BioLife as well as a much more stable source of revenue than as a supplier in the R&D process. BioLife believes that annual revenue from a typical regenerative medicine customer could reach $1 million per year within three to five years following their product approval.

Biobanking
Biobanking refers to a repository that stores human biological samples for research. Over the past 20 years, biobanking of human specimens has become a central activity underpinning all aspects of biomedical research as well as the development of personalized medicine. Biobanking encompasses a wide range of specimen types and sample collection designs, ranging from population-based biobanking of specimens from healthy subjects in large, epidemiological cohorts to specific biobanking of diseased tissues obtained in the course of clinical interventions. Human tissue biobanking is of particular importance for implementation of novel biomarkers into clinical trials, as well as for the application of a wide range of new technologies to the discovery and validation of new, molecular patterns of disease.[2]

BioLife's biobanking customers include public and private cord blood banks, adult stem cell banks, tissue banks, hair transplant centers, and biorepositories. The company notes that since the launch in the third quarter of 2009, BloodStor continues to realize increased sales in the biobanking market. Sales of CryoStor and HypoThermosol in this segment also continue to increase as they displace home-brews.

Contract Manufacturing

BioLife's contract manufacturing business provides aseptic media formulation, fill and finish services. During 2011 BioLife signed a multi-year contract manufacturing agreement with a new multinational customer. Specific terms of the contract (including the $ amount, term, or customer's name) were not released although BioLife did indicate at the time that their contract manufacturing revenue should increase significantly in 2012 as a direct result of this new agreement. The initial revenue from this contract commenced in Q2 and just as management predicted, contract manufacturing revenue jumped shortly afterwards - to $341k in Q2 and to $1.1MM in Q3.

In March 2012 BioLife increased its leased space, doubling its leased footprint to over 21k sf, significantly increasing its manufacturing capacity to accommodate the new contract manufacturing deal as well as anticipated increased demand for its biopreservation products. BioLife completed the build out of this additional manufacturing space during Q2 2012.

The contract manufacturing business, while providing a source of near-term revenue and cash flow and upping utilization of fixed assets and manufacturing space, is not necessarily expected to become a fundamental part of BioLife's long-term growth strategy. It does, however, offer a source of funding for the further development and commercialization of the biopreservation products business, which BioLife expects to provide the bulk of future revenue and drive earnings for the long-term.

Drug Discovery
BioLife supplies biopreservation media to pharmaceutical companies and cell suppliers which grow and preserve various cell types which act as the "guinea pigs" for testing new drug candidates. BioLife notes that their key customers in the drug screening segment include eight of the top ten largest cell suppliers and numerous pharmaceutical companies.

[2] *The role of the pathologist in tissue banking: European Consensus Expert Group Report.* Generoso Bevilacqua, Fred Bosman, Thibaut Dassesse, Heinz Höfler, Anne Janin, Rupert Langer, Denis Larsimont, Manuel M. Morente, Peter Riegman, Peter Schirmacher, Giorgio Stanta, Kurt Zatloukal, Elodie Caboux, Pierre Hainaut Virchows Arch. 2010 April; 456(4): 449–454. Published online 2010 February 16. doi: 10.1007/s00428-010-0887-7

FINANCIAL CONDITION / CAPITAL STRUCTURE

Cash
Cash position is tight and despite management's expectations of positive operating cash flow in 2012, we think BioLife may still possibly need to raise additional funds in the near term.

BioLife exited Q3 with $8k in cash and equivalents, down from $155k at the end of Q2. Cash used in operating activities in Q3 was an inflow of $121. Ex-changes in working capital cash used in operating activities was an outflow of $226k. BLFS expects to achieve positive cash flow from operations in Q4 as well.

Debt
Debt consists of $10.6 million and $2.6 million in promissory notes and related accrued interest, respectively. The loans (2 loans for $5.25MM each) were issued to two private investors, one of which is a director of BLFS, in October 2008 with an original maturity date in January 2010. The notes are secured by all of BioLife's assets and accrue annual interest at 7% (payable at maturity).

The maturity date of the promissory notes has been extended several times, the most recent of which was announced in June 2012 - extending the maturity to January 2016. In connection with the most recent maturity extension, the amount of the loans were increased to $5.75 million ($11.5 million in aggregate). In consideration of amending the maturity date to 2016, the two investors of the loans were each issued five-year warrants to purchase 1 million shares of BLFS common stock at $0.08/share. The three-year maturity extension reduces liquidity risk.

Share Count
As of 6/30/2012 the basic and diluted share count outstanding stood at about 70 million. We think the likely game plan relative to the promissory notes is to eventually take them out with equity (either through a conversion amendment, swap or with proceeds from an outright equity sale). At the current ($0.30) market price, $11.5 million in principal plus $2.6 million in interest would require the issuance of over 45 million new shares (even more with transaction and issuance costs).

We note this only as a hypothetical situation and to illustrate the potential that the share count could increase substantially if these notes are taken out with stock. That said, we expect management would act opportunistically relative to when and at what price they might look to sell new equity. The stock price is up almost 300% since we initiated coverage of BLFS in July 2012 which while we think makes taking them out with equity more palatable - the 2016 maturity date gives management sufficient breathing room and opportunity to strategize a game plan to address the outstanding debt and, if equity is decided to be the best-route, to further increase the share price by continuing to deliver on operational strategy and thereby minimizing any potential dilution.

OUTLOOK

BioLife sells their biopreservation products directly to customers as well as indirectly through distributors. Approximately 80% of the $2.8 million in total revenue in 2011 came from product sales directly to customers. Contract manufacturing revenue had been immaterial but recently jumped as a result of the aforementioned contract signed in late 2011.

Q3 revenue of $1.7 million, represents y-o-y and sequential growth of 135% and 53%, respectively, and marks the ninth straight quarter of record revenue. Through the first nine months revenue is up 85%. And while contract manufacturing has been the major revenue driver in 2012, product sales also continue to grow, increasing 30% through the first three quarters of the year.

Management increased their full-year revenue guidance from $4.1 million to $5.0 million. While management's guidance also includes lower gross margins in 2012 due to a greater percentage of revenue coming from the lower margin contract manufacturing business as well as a forecasted increase in operating expenses (as a result of increased selling/mktg spend), management believes the anticipated growth in revenue will push them to positive operating cash flow again in Q4.

BioLife is focused on not only growing revenue but also on diversifying the customer base in order to dilute customer concentration and the related revenue volatility risk. To that point, they continue to increase their total (indirect and direct) customer base (currently at ~400) and in 2011 had no customer that accounted for more than 10% of revenue. This compares to 2009 and 2010 when one customer accounted for 21% and 16% of sales, respectively.

We now model 2012 revenue of $5.0 million. We assume sales to the new contract manufacturing customer, which commenced in Q2, push contract manufacturing revenue to $2.0 million for the full year 2012. While it now appears BioLife will be able to achieve positive cash flow from operations in 2012, on an ex-changes in working basis (op cash flow benefits from the accrual of deferred rent which will then amortize), we think operating cash flow will be negative by almost $1MM. We also think BioLife will need to raise additional operating capital in the near-term which we believe would likely continue to come from promissory notes.

BioLife's strategy to grow their customer base includes building greater visibility and awareness of the benefits of their biopreservation products compared to competitors', especially the various "home-brews" that currently dominate the market. This includes continuing to attend and present at industry conferences, active engagement and site visits with prospective customers by BLFS' Chief Technology Officer (a recognized expert in the field of biopreservation), maintaining current and building new distribution relationships, and a recent free-sample campaign whereby BLFS is giving away samples of HypoThermosol and CryoStor so prospective customers can test for themselves the superiority of the products compared to competitors'.

Our out-year (≥ 2013) revenue estimates are based on very general assumptions, including that contract manufacturing revenue can be maintained at the ~$2.0 - $3.0 million annual level and biopreservation product sales are driven largely from continued increases in the customer base. If and when one or more therapies currently in clinical testing that are using BioLife's biopreservation media gain FDA approval, this could spark a significantly greater ramp in revenue. Management believes that each regenerative medicine product that reaches worldwide commercialization could be worth as much as $1 million - $2 million in revenue (three to five years after launch) to BioLife as the biopreservation media supplier. While we do not yet model any revenue contribution related to supplying an approved therapy, when there is greater visibility on the potential for that happening, we will update our model accordingly.

VALUATION / RECOMMENDATION

Our comparable group used to value BLFS consists of direct competitors as well as small stem cell therapeutics and regenerative medicine companies. Our valuation metrics include enterprise value-to-sales (EV/Sales) and price-to-sales (P/Sales) multiples using sales at trailing twelve months (ttm), estimated 2012, and estimated 2013 (estimates from analyst forecasts).

Based on these six metrics, BioLife is valued between $0.24/share (based on an average 9.8x EV/Sales ttm) and $0.87/share (based on an average 12.2x P/Sales 2012 E). Average valuation of all six metrics is about $0.50/share, which is up from about $0.30/share since our last update on BLFS. BLFS currently trades at $0.32, which is below what we calculate to be fair value. We are moving our price target from $0.30/share to $0.50/share as a result of the upward revisions to our model. We are maintaining our Outperform rating.

	TICKER						Implied
METRIC	STEM	LIFE	SIAL	ISCO	CYTX	Average	BLFS pps
EV/ Sales (ttm)	19.2	2.7	3.2	3.3	20.9	9.8	$0.24
EV/ Sales (2012 E)	20.0	2.7	3.2	3.2	17.6	9.3	$0.51
EV/ Sales (2013 E)	15.8	2.6	3.0	2.0	8.0	6.3	$0.38
P/ Sales (ttm)	12.8	2.1	3.4	7.7	19.0	9.0	$0.48
P/ Sales (2012 E)	32.0	2.1	3.2	2.6	21.3	12.2	$0.87
P/ Sales (2013 E)	15.8	2.6	3.0	2.0	8.0	6.3	$0.70
						Avg.	**$0.53**

RISK FACTORS

- Cash position is tight and despite management's expectations of positive operating cash flow in 2012, we think BioLife may need to raise additional funds in the near term

- The expected revenue growth in 2012 is largely from the contract manufacturing business which is not only lower margin, it is a much less stable and predictable source of revenue than biopreservation media products sales

- Our modeled revenue growth of biopreservation media beyond the current year is largely best-guesses at this point based on growth in the customer base. Revenue could underperform relative to our model if the customer base does not grow at our assumed forecast or is less correlated to revenue growth than what we are assuming. As contract manufacturing revenue can be unpredictable, it's very difficult to gauge whether our estimates (particularly in the out-years) will prove accurate

- Long-term viability of BLFS might require one or more therapies using BioLife's biopreservation media gaining FDA approval. While it's conceivable that this might happen over the next two years, it's also possible that it could take significantly longer or never happen at all

- Balance sheet is highly levered with ~$10.6 million in debt and $2.6 million in accrued interest outstanding. This risk is at least somewhat mitigated by the fact that it is owned by a director of BLFS who has obvious interests in amending terms of the debt when needed (as evidenced at various times in the past) and we presume that it will eventually be retired with or converted to equity

- If and when the debt is retired with/converted to equity, depending on the conversion/equity sale price, it could potentially increase the share count very significantly and be highly dilutive to existing shareholders

FINANCIAL MODEL

BioLife Solutions Inc.

	2011 A	Q1A	Q2A	Q3A	Q4E	2012 E	2013 E	2014 E	2015 E
Product Sales & Ctrct Manuf	$2,738.7	$830.9	$1,092.4	$1,676.5	$1,351.2	$4,951.0	$5,849.3	$6,988.2	$8,865.2
YOY Growth	*32.8%*	*37.2%*	*76.8%*	*136.0%*	*67.9%*	*80.8%*	*18.1%*	*19.5%*	*26.9%*
Licensing Revenue	$20.0	$5.0	$5.0	$5.0	$5.0	$20.0	$20.0	$20.0	$20.0
YOY Growth	*0.0%*	*92.8%*	*129.2%*	*270.8%*	*66.1%*	*145.9%*	*0.0%*	*0.0%*	*0.0%*
Total Revenues	$2,758.7	$835.9	$1,097.4	$1,681.5	$1,356.2	$4,971.0	$5,869.3	$7,008.2	$8,885.2
YOY Growth	*32.5%*	*36.9%*	*76.2%*	*135.0%*	*67.5%*	*80.2%*	*18.1%*	*19.4%*	*26.8%*
Cost of Product Sales	$1,355.6	$346.1	$641.7	$1,086.0	$824.9	$2,898.8	$3,229.5	$3,754.1	$4,580.7
Gross Income	$1,403.2	$489.8	$455.7	$595.4	$531.3	$2,072.2	$2,639.8	$3,254.1	$4,304.5
Gross Margin	*50.9%*	*58.6%*	*41.5%*	*35.4%*	*39.2%*	*41.7%*	*45.0%*	*46.4%*	*48.4%*
R&D	$516.5	$116.5	$126.6	$110.7	$128.0	$481.8	$521.0	$605.3	$660.4
% R&D	*18.7%*	*13.9%*	*11.5%*	*6.6%*	*9.4%*	*9.7%*	*8.9%*	*8.6%*	*7.4%*
Selling & Mktg	$267.1	$73.4	$160.7	$145.7	$152.0	$531.8	$616.3	$700.8	$799.7
% Sell&Mktg	*9.7%*	*8.8%*	*14.6%*	*8.7%*	*11.2%*	*10.7%*	*10.5%*	*10.0%*	*9.0%*
G&A	$1,892.3	$479.1	$475.0	$487.7	$512.0	$1,953.9	$2,289.0	$2,593.0	$3,109.8
% G&A	*68.6%*	*57.3%*	*43.3%*	*29.0%*	*37.8%*	*39.3%*	*39.0%*	*37.0%*	*35.0%*
Operating Income	($1,272.7)	($179.3)	($306.6)	($148.7)	($260.7)	($895.3)	($786.5)	($645.0)	($265.4)
Operating Margin	*-46.1%*	*-21.4%*	*-27.9%*	*-8.8%*	*-19.2%*	*-18.0%*	*-13.4%*	*-9.2%*	*-3.0%*
Total Other Inc. (Exp.)	($747.0)	($117.6)	($192.3)	($203.5)	($205.0)	($718.4)	($894.0)	($965.0)	($1,021.0)
Pre-Tax Income	($2,019.6)	($296.9)	($498.9)	($352.2)	($465.7)	($1,613.7)	($1,680.5)	($1,610.0)	($1,286.4)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	-	-	-	-	-	-	-	-
Net Income	($2,019.6)	($296.9)	($498.9)	($352.2)	($465.7)	($1,613.7)	($1,680.5)	($1,610.0)	($1,286.4)
YOY Growth	*-1.8%*	*-52.9%*	*14.2%*	*-26.4%*	*-1.8%*	*-20.1%*	*4.1%*	*-4.2%*	*-20.1%*
Net Margin	*-73.2%*	*-35.5%*	*-45.5%*	*-20.9%*	*-34.3%*	*-32.5%*	*-28.6%*	*-23.0%*	*-14.5%*
EPS	($0.03)	($0.00)	($0.01)	($0.01)	($0.01)	($0.02)	($0.02)	($0.02)	($0.02)
YOY Growth	*1.8%*	*-52.9%*	*14.2%*	*-26.4%*	*-1.8%*	*-20.1%*	*3.7%*	*-4.2%*	*-20.1%*
Diluted Shares O/S	69,680	69,680	69,680	69,680	69,680	69,680	70,000	70,000	70,000

Brian Marckx, CFA

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MANAGEMENT

Michael Rice
Chairman & Chief Executive Officer

Mike Rice became president and chief executive officer and a member of our Board of Directors in August 2006, and Chairman in August 2007. He has more than 20 years of leadership and entrepreneurial experience in the medical and high tech industries. He was most recently the senior business development manager for medical and wireless products at AMI Semiconductor (NASDAQ:AMIS). Mr. Rice also served as the director of marketing and business development at Cardiac Science, Inc., a manufacturer of automated external defibrillators. Prior to that, he was the Vice President, Sales and Marketing for TEGRIS Corporation, a privately held network services provider. Mr. Rice also spent 12 years at Physio Control Corporation in several sales and marketing management roles prior to its acquisition by Medtronic Inc.

Aby J. Mathew, Ph.D.
Sr. Vice President and Chief Technology Officer

Dr. Mathew was part of the founding team of BioLife Solutions, and is a co-developer of BioLife′s biopreservation media solutions. He is a co-inventor on multiple issued and pending patents related to methods, devices, and formulations for the preservation of cells, tissues, and organs. He holds a Ph.D. in Biological Sciences within the Biochemistry, Cell and Molecular Biology Program from Binghamton University and a B.S. in Microbiology from Cornell University. Dr. Mathew has been researching low temperature biopreservation since 1994, and his studies contributed to the development of BioLife′s current commercial HypoThermosol and CryoStor product platforms and intellectual property foundation. Dr. Mathew was part of the scientific team that linked cell death via apoptosis (programmed cell death) to exposure to hypothermic and/or freezing temperatures. These discoveries were integral to the development of BioLife′s improved intracellular-like biopreservation solutions, and also contributed to improvements in cryosurgical ablation of cancer. Dr. Mathew is currently active in, or previously a member of, the International Society for Cell Therapy (ISCT), AABB (formerly the American Association of Blood Banks), BEST (the Biomedical Excellence for Safer Transfusion collaborative), Tissue Engineering & Regenerative Medicine International Society (TERMIS), Society for Cryobiology, International Society for Biological and Environmental Repositories (ISBER), American Society for Cell Biology, and the Society for In Vitro Biology.

Mark Sandifer
Vice President of Quality

Mark′s background is in drug development and clinical administration. He has more than ten years of experience in quality assurance. His keen interest in how the quality aspects of our products support cell therapies comes from his work with Georgetown University Medical Center′s bone marrow transplant program in association with the National Marrow Donor Program. He directed BioLife′s effort in achieving ISO 13485:2003 certification and led the team effort in ISO 14644 qualification of BioLife′s CGMP production facility. Mark holds an M.S. in Biotechnology from Johns Hopkins University and a B.S. in Biology from George Mason University.

Daphne Taylor
Vice President, Finance & Administration, Chief Financial Officer

Daphne Taylor has served as Vice President, Finance & Administration, and Chief Financial Officer since August 2011. She has 20 years experience as a finance professional. Prior to joining BioLife, Ms. Taylor served as Vice President, Corporate Controller and Chief Accounting Officer of Cardiac Science Corporation from November 2005 through January 2009. From April 2002 through November 2005, she held various positions, including Vice President and Corporate Controller for LookSmart, a publicly held Internet technology company. In 2001, Ms. Taylor was Controller at SpeedTrak Communications and prior to that she was Controller for ViroLogic, a publicly held biotechnology company. Ms. Taylor held various finance positions at Core-Mark International, a distribution company, from 1996 to 2000. From 1991 to 1994, she was in public accounting with Coopers & Lybrand and is a licensed CPA. Ms. Taylor holds a B.A. in Management/Accounting from Sonoma State University, California.

Joe Annicchiarico
Director of Manufacturing

Joe joined BioLife Solutions in December 2011 after serving for six years at MediQuest Therapeutics, Inc. in Bothell, Washington, where he was an integral part of the company′s first NDA filing. He spearheaded process scale-up and validation efforts, patent protection, and clinical trial supply chain management. His tenure at MediQuest included time as a Scientist, Formulation Manager, and most recently, as Director of Manufacturing and Clinical Supplies. Prior to his tenure at MediQuest, he worked in speciality chemical sales at Drummond American and spent four years as a formulation

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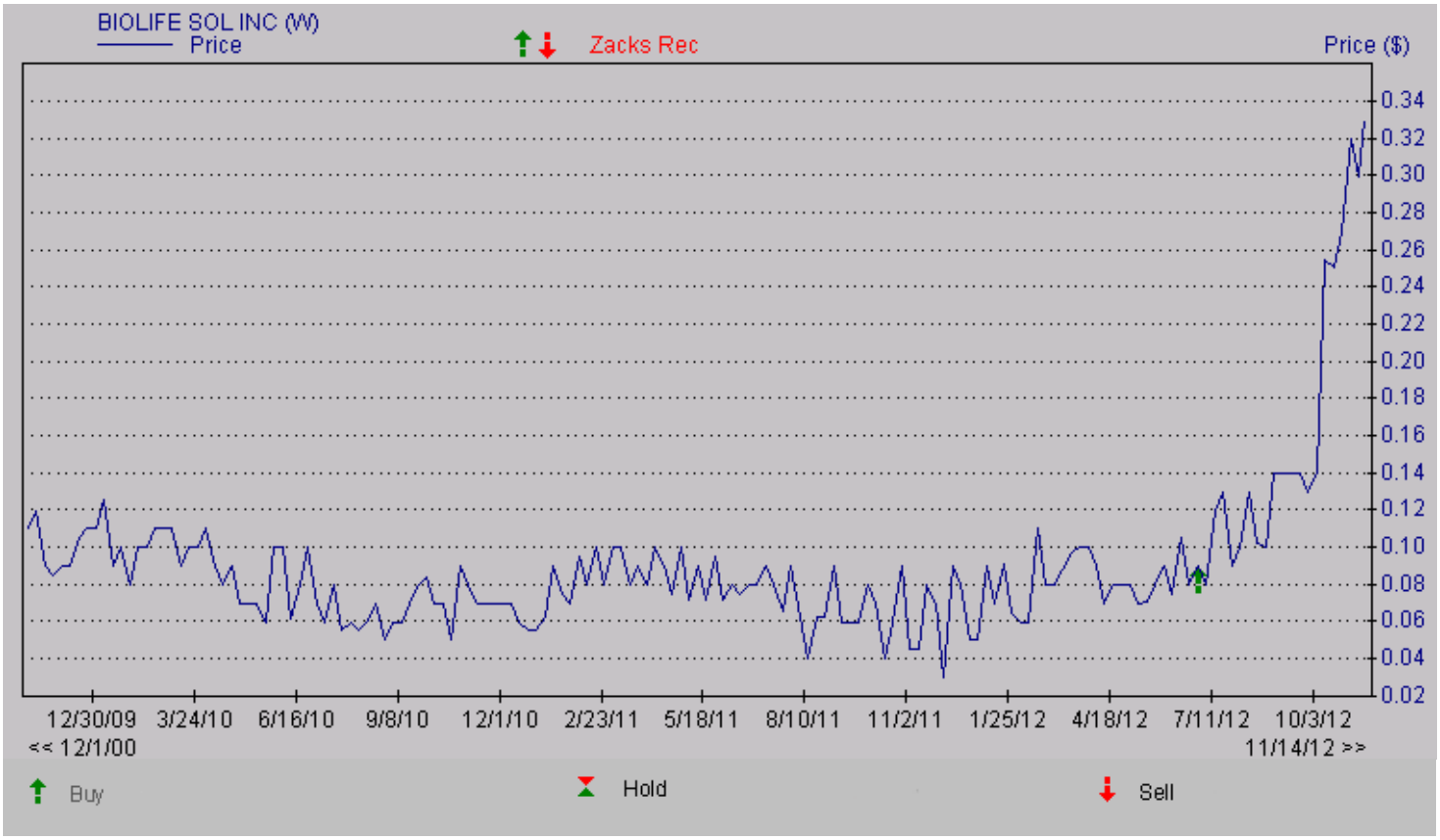
development Chemist at a pair of personal care products companies in New Jersey. Joe earned his Bachelor's Degree in Biology from The Johns Hopkins University in Baltimore, Maryland, in 1997.

HISTORICAL ZACKS RECOMMENDATIONS



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