BIOLIFE SOLUTIONS INC
Form 10-K
March 15, 2019

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the year ended December 31, 2018

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 001-36362

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

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

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 No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (S232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such said files). Yes 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.

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of the registrant’s most recently completed second fiscal quarter, the aggregate market value of common equity (based on closing price of $11.41 per share) held by non-affiliates was approximately $115 million.

As of March 8, 2019, 18,651,678 shares of the registrant’s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, is incorporated herein by reference from the registrant’s definitive proxy statement relating to the Annual Meeting of Shareholders to be held in 2019, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

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PART I

ITEM 1. BUSINESS

References in this Form 10-K to "BioLife", the "Company," "we," "us" or "our" refer to BioLife Solutions, Inc. The informa
in this Annual Report on Form 10-K contains certain forward-looking statements, including statements related to our products, customers, regulatory approvals, markets for our products, future financial and operational performance, capital requirements, intellectual property, suppliers, joint venture partners, controlling shareholders and trends in our business that involve risks and uncertainties. Our actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as those discussed elsewhere in this Annual Report on Form 10-K.

Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Report

Overview

We develop, manufacture and market biopreservation tools for cells and tissues. Our products are used in basic and applied research, and commercial manufacturing of biologic based therapies by maintaining the health and function of biologic source material and finished products during manufacturing, distribution, and patient delivery of cells and tissues. Our products are designed to allow biologic manufacturing to be more efficient and effective.

Our product offerings include:

- Proprietary hypothermic storage and cryopreservation freeze media products for cells, tissues, and organs
- Generic blood stem cell freezing and cell thawing media products
- Custom product formulation and custom packaging services

Our proprietary, clinical grade HypoThermosol® FRS and CryoStor® biopreservation media products are marketed to the regenerative medicine, biobanking, and drug discovery markets. Our customers include cell and gene therapy

companies, research institutions, hospital-based stem cell transplant centers, cell therapy contract manufacturing organizations (CMOs) and contract development manufacturing organizations (CDMOs), pharmaceutical companies, cord blood and adult stem cell banks, hair transplant centers, suppliers of cells to the drug discovery, and toxicology testing and diagnostic markets. All of our biopreservation media products are serum-free and protein-free, fully defined, and are manufactured under current Good Manufacturing Practices (cGMP). We strive to source the highest available grade components.

Our proprietary biopreservation media products are formulated to reduce preservation-induced, delayed-onset cell damage and death. Our platform enabling technology provides our customers significant shelf life extension of biologic source material and final cell products, and also greatly improves post-preservation cell and tissue viability and function. We estimate our products have been incorporated in over 300 regenerative medicine applications, including numerous chimeric antigen receptor (CAR) T cell and other cell types.

Additionally, we have a 44% ownership position in SAVSU Technologies, Inc. (“SAVSU”). SAVSU, a privately held company headquartered in Albuquerque, New Mexico, designs, manufactures and markets, integrated, innovative hardware and software solutions designed to protect living biologic materials during transport and storage. SAVSU’s customers include cell and gene therapy companies, specialty couriers, and research institutions.

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Products and Services Overview

Biopreservation Media

Stability (shelf life) and functional recovery are crucial aspects of academic research and clinical practice in the biopreservation of biologic-based source material, intermediate derivatives, and isolated/derived/expanded cellular products and therapies. Limited stability is especially critical in the regenerative medicine field, where harvested cells and tissues, if not maintained appropriately at normothermic body temperature (37ºC) or stored in a hypothermic state in an effective preservation medium, will lose viability over time. Chilling (hypothermia) is used to reduce metabolism and delay degradation of harvested cells, tissues, and organs. However, subjecting biologic material to hypothermic environments induces damaging molecular stress and structural changes. Although cooling successfully reduces metabolism (i.e., lowers demand for energy), various levels of cellular damage and death occur when using suboptimal methods. Traditional biopreservation media range from simple “balanced salt” (electrolyte) formulations to complex mixtures of electrolytes, energy substrates such as sugars, osmotic buffering agents and antibiotics. The limited stability which results from the use of these traditional biopreservation media formulations is a significant shortcoming that our optimized proprietary products address with great success.

Our scientific research activities over the last 20+ years enabled a detailed understanding of the molecular basis for the hypothermic and cryogenic (low-temperature induced) damage/destruction of cells through apoptosis and necrosis. This research led directly to the development of our HypoThermosol® FRS and CryoStor® technologies. Our proprietary preservation media products are specifically formulated to:

- Minimize cell and tissue swelling
- Reduce free radical levels upon formation
- Maintain appropriate low temperature ionic balances
- Provide regenerative, high energy substrates to stimulate recovery upon warming
- Avoid the creation of an acidic state (acidosis)
- Inhibit the onset of apoptosis and necrosis

A key feature of our preservation media products is their “fully-defined” profile. All of our cGMP products are serum-free, protein-free and are formulated and filled using aseptic processing. We strive to use USP/Multicompendial grade or the highest quality available synthetic components. All of these features benefit prospective customers by facilitating the qualification process required to incorporate our products into their regulatory filings and hence patient delivery processes.

The results of independent testing demonstrate that our biopreservation media products significantly extend shelf-life and improve cell and tissue post-thaw viability and function, which may, in turn, improve clinical and commercial

outcomes for existing and new cell and tissue therapy applications. Our products have demonstrated improved biopreservation outcomes for a broad array of cell and tissue types including stem cells isolated from umbilical and peripheral blood, bone marrow, adipose tissue, liver, tendon, and umbilical cord, in addition to T-cells, pluripotent stem cells including hepatocytes, endothelial cells, and neuronal cells, hepatocytes isolated from non-transplantable livers, chondrocytes isolated from cartilage, and dermal fibroblasts and muscle cells isolated from tissue biopsies.

Competing biopreservation media products are often formulated with simple isotonic media cocktails, animal serum, potentially a single sugar or human protein. A key differentiator of our proprietary HypoThermosol FRS formulation is the engineered optimization of the key ionic component concentrations for low temperature environments, as opposed to normothermic body temperature around 37°C, as found in culture media or saline-based isotonic formulas. Competing cryopreservation freeze media is often comprised of a single permeating cryoprotectant such as dimethyl sulfoxide (“DMSO”). Our CryoStor formulations incorporate multiple permeating and non-permeating cryoprotectant agents which allow for multiple mechanisms of protection and reduces the dependence on a single cryoprotectant.

Across a broad spectrum of cell and tissue types, our products have proven more effective in reducing post-preservation and post-thaw necrosis and apoptosis as compared to commercial and home-brew isotonic and extracellular formulations. This results in greatly extended shelf life and improved post-preservation viability.

Regenerative Medicine

The emerging field of regenerative medicine is unique in its aim to augment, repair, replace or regenerate organs and tissue that have been damaged by disease, injury or even the natural aging process. This rapidly evolving, interdisciplinary field is transforming healthcare by translating fundamental science into a variety of regenerative technologies including biologics, chemical compounds, materials and devices. It differs from other fields of medicine in the array of disciplines it brings together and in its ability to create or harness the body’s innate healing capacity.

We continue to educate the regenerative medicine market about the impact of effective biopreservation on the ability to create commercially viable manufactured products with participation in scientific conferences and industry trade events by exhibiting, presenting scientific and business lectures, and sponsoring industry association events. We are a corporate or affiliate member of the Alliance for Regenerative Medicine, the BEST Collaborative, and the International Society for Cellular Therapy.

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We have secured a valuable position as a supplier of critical reagents to hundreds of cell and gene therapy companies, including two companies with FDA approved commercial products. We estimate that our biopreservation media products are incorporated in over 300 applications for new cell and tissue-based regenerative medicine products and therapies. A significant number of applications involve CAR-T cell and other types of T cells, mesenchymal stem cells targeting blood cancers, solid tumors and other leading causes of death and disability. We estimate that annual revenue from each application in which our products are used could range from $0.5 million to $2.0 million, if such application is approved and our customer commences large scale commercial manufacturing of the biologic based therapy.

Principal Products

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 subzero temperatures (most often utilized within the range of -80 to -196°C). All CryoStor products are pre-formulated with USP/EP grade DMSO, a permeating cryoprotective agent which helps mitigate damage from the formation of intracellular and extracellular ice. CryoStor is offered in several packages and pre-formulated with DMSO in final concentrations of 2%, 5%, and 10%. CryoStor is manufactured under cGMP and is tested to USP <71> Sterility and USP <85> Endotoxin standards.

HypoThermosol FRS biopreservation media is a novel, engineered, optimized hypothermic storage and shipping media product. 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. Serum-free, protein-free HypoThermosol FRS is designed to provide maximum storage and shipping stability for biologics at 2° to 8°C. HypoThermosol FRS is manufactured under cGMP and is tested to USP <71> Sterility and USP <85> Endotoxin standards.

BloodStor® freeze media is a series of generic cGMP freeze media products used to cryopreserve stem and other cells isolated from umbilical cord blood, peripheral blood, and bone marrow where the processing methods require addition of high concentration DMSO. BloodStor 55-5 is pre-formulated with 55% (w/v) DMSO USP/EP, 5% (w/v) Dextran-40 USP/EP, and Water for Injection (WFI) quality water. BloodStor 100 contains 100% (w/v) DMSO USP/EP. BloodStor 27 NaCl is pre-formulated with 27% (w/v) DMSO in saline USP-grade components and Water for Injection (WFI) quality water. BloodStor is manufactured under cGMP and tested to USP <71> Sterility and USP <85> Endotoxin standards.

Cell Thawing Media provides Dextran and saline for washing cryopreserved cells and tissues to dilute or remove cryoprotectants. Cell thawing media is pre-formulated with 10% Dextran 40 in 0.9% NaCl and 10% Dextran 40 in 5% Dextrose.

Competition

Biopreservation Media

We believe that in-house formulated biopreservation media, whereby the user purchases raw ingredients and manually mixes the ingredients, satisfies the large majority of the annual worldwide demand. Commercial competitors, in most cases, are supplying isotonic, non-optimized preservation media and include VWR, Sigma-Aldrich, Lonza, Life Technologies, STEMCELL Technologies, and several smaller companies. Several of our competitors also distribute our premium products.

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We believe that our products offer significant advantages over in-house formulations including, time saving, improved quality of components, more rigorous quality control release testing, more cost effective and improved preservation efficacy. We believe that a company's competitive position in the markets we compete in is determined by product function, product quality, speed of delivery, scientific customer support, price, and distribution capabilities. Our customers are diverse and may place varying degrees of importance on the competitive attributes listed above. While it is difficult to rank these attributes for all our customers in the aggregate, we believe we are well positioned to compete in each category.

Business Operations

Sales and Marketing

We market and sell our products through direct sales and third party distribution. Our products are marketed and distributed by STEMCELL Technologies, MilliporeSigma, VWR, Thermo Fisher and several other regional distributors under non-exclusive agreements. In 2018, sales to third party distributors' accounted for 33% of our revenue compared to 29% in 2017. We employ scientific team members in sales and support roles because we believe that is what makes us a trusted and critical supplier to our customers. Our technical application support team consists of individuals with extensive experience in cell processing, biopreservation, and cryobiology.

In the years 2018 and 2017, we derived approximately 29% of our product revenue from two customers and approximately 12% of our revenue from one customer, respectively.

Manufacturing

We maintain and operate two independent cGMP clean room production suites for manufacturing sterile biopreservation media products. Our quality management system (QMS) was certified to the ISO 13485:2016 standard in 2018. Our QMS is aligned with applicable sections of 21 CFR Part 820 - Quality System Regulation for Good Manufacturing Practice of medical devices, 21 CFR Parts 210 and 211 - current Good Manufacturing Practices for Finished Pharmaceuticals, FDA Guidance - Sterile Drug Products, Volume 4, EU Guidelines Annex 1 - Manufacture of Sterile Medicinal Products, ISO 13408 - Aseptic Processing of Healthcare Products, and ISO 14644 - Clean Rooms and Associated Controlled Environments. To date, we have not experienced significant difficulties in obtaining raw materials for the manufacture of our biopreservation media products. Pursuant to our supply agreements, we are required to notify customers of any changes to our raw materials.

Support

We provide product support through a combination of channels including phone, web, and email. These support services are delivered by our customer care and scientific teams. These teams are responsible for providing timely, high-quality technical expertise on all our products.

Product Approval Regulation

Our products are not subject to any specific United States Food and Drug Administration ("FDA") or other international marketing regulations for drugs, devices, or biologics. We are not required to sponsor formal prospective, controlled clinical-trials in order to establish safety and efficacy. However, to support our current and prospective clinical customers, we manufacture and release our products in compliance with cGMP and other relevant quality standards.

To assist customers with their regulatory applications, we maintain Type II Master Files at the FDA for CryoStor, HypoThermosol FRS, BloodStor 27, and our Cell Thawing Media products, which provide the FDA with information regarding our manufacturing facility and process, our quality system, stability and safety, and any additional testing that has been performed. Customers engaged in clinical and commercial applications may notify the FDA of their intention to use our products in their product development and manufacturing process by requesting a cross-reference to our master files.

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Intellectual Property

Currently, our unexpired patents include 5 issued patents in the United States, 2 issued patents in Europe, 1 issued patent in Japan, 2 issued patents in Australia, and 2 issued patents in Canada. Our pending patents include 1 patent in Europe and 1 patent in Hong Kong. We have also obtained certain trademarks and tradenames for our products to distinguish our genuine products from our competitors' products and we maintain certain details about our processes, products, and strategies as trade secrets. 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, scientific expertise 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 and/or to obtain and use information that we regard as proprietary (see "Item 1A. Risk Factors" of this Report for additional details). 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.

Employees

As of March 8, 2019, we had 54 full time employees. Our employees are not covered by any collective bargaining agreement. We consider relations with our employees to be good.

Corporate History

We were incorporated in Delaware in 1987 under the name Trans Time Medical Products, Inc. In 2002, the Company, then known as Cryomedical Sciences, Inc. and engaged in manufacturing and marketing cryosurgical products, completed a merger with our wholly-owned subsidiary, BioLife Solutions, Inc., which was engaged as a developer and marketer of biopreservation media products for cells and tissues. Following the merger, we changed our name to BioLife Solutions, Inc.

Principal Offices; Available Information

Our principal executive offices are located at 3303 Monte Villa Parkway, Suite 310, Bothell, Washington 98021 and the telephone number is (425) 402-1400. We maintain a website at http://www.biolifesolutions.com. The information contained on or accessible through our website is not part of this Annual Report on Form 10-K and is not incorporated in any manner into this Annual Report. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the

Securities Exchange Act of 1934 (the "Exchange Act"), are available free of charge on our website as soon as reasonably practicable after we electronically file such reports with, or furnish those reports to, the Securities and Exchange Commission (the "SEC"). Any information we filed with the SEC may be accessed and copied at the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549. Information may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this annual report, before deciding to invest in our common stock. If any of the following risks materialize, our business, financial condition, results of operation and prospects will likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

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Risks Related to Our Business

The majority of our net sales come from a relatively small number of customers and products in a limited number of market sectors; if we lose any of these customers or if there are problems in those market sectors, our net sales and operating results could decline significantly.

In the years 2018 and 2017, we derived approximately 29% of our product revenue from two customers and approximately 12% of our revenue from one customer, respectively. No other customer accounted for more than 10% of revenue in 2018 or 2017. In the years 2018 and 2017, we derived approximately 88% and 77%, of our revenue from CryoStor products, respectively. Our principal customers may vary from period to period, and our principal customers may not continue to purchase products from us at current levels, or at all. Significant reductions in net sales to any of these customers or our failure to make appropriate choices to the customers we serve, could seriously harm our business. In addition, we focus our sales to customers in only a few market sectors. Each of these sectors is subject to macroeconomic conditions as well as trends and conditions that are sector specific. Shifts in the performance of a sector served by us, as well as the economic, business and/or regulatory conditions that affect the sector, or our failure to choose appropriate sectors can particularly impact us. Any weakness in the market sectors in which our customers are concentrated could negatively affect our business and results of operations.

While we have achieved net income for the fiscal year ended December 31, 2018, we have a history of losses and may not be able to sustain or increase our profitability in the future.

For the fiscal year ended December 31, 2018 we achieved net income attributable to common shareholders of $2.9 million. This was the first full year of profitability in our history and we have an accumulated deficit of $71.0 million as of December 31, 2018. Our ability to sustain or increase profitable operations is dependent on numerous factors, many of which are out of our control, including the continued use by our customers of our various products, the continued availability of the raw materials necessary to manufacture our products, our market share and our margins. If we fail to maintain or increase our revenue or manage our expenses, we may not sustain or increase profitability in the future.

We may engage in future acquisitions or strategic transactions which may require us to seek additional financing or financial commitments, increase our expenses and/or present significant distractions to our management.

We are actively evaluating opportunities to grow our portfolio of cell and gene therapy tools and services, including through the exercise of our option to purchase the remaining 56% of SAVSU that we do not currently own. In the event we engage in an acquisition or strategic transaction, including by making an investment in another company, we may need to acquire additional financing. Obtaining financing through the issuance or sale of additional equity and/or

debt securities, if possible, may not be at favorable terms and may result in additional dilution to our current stockholders. Additionally, any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, an acquisition or strategic transaction may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products or technologies;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

The success of our HypoThermosol FRS and CryoStor biopreservation media products is dependent, in part, on successful customer regulatory approvals and commercial success of new regenerative medicine products and therapies.

Our HypoThermosol FRS and CryoStor biopreservation media products are marketed to biotechnology companies and research institutions engaged in research and development of cell, gene and tissue engineering therapies. The end-products or therapies developed by these biotechnology companies and research institutions are subject to substantial regulatory oversight by the FDA and other regulatory bodies, and many of these therapies are years away from commercialization. Failure of the end-products that use our biopreservation media products to receive regulatory approvals and be successfully commercialized will have an adverse effect in the demand for our products.

We face significant competition.

The life sciences industry is highly competitive. We anticipate that we will continue to face increased competition as existing companies may choose to develop new or improved products and as new companies could enter the market with new technologies, any of which could compete with our product or even render our products obsolete. Many of our competitors are significantly larger than us and have greater financial, technical, research, marketing, sales, distribution and other resources than us. 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. Also, even if we can compete successfully, there can be no assurance that we can continue do so in a profitable manner.

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We are dependent on outside suppliers for all our manufacturing supplies.

We rely on outside suppliers for all 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 our demands on a timely basis. Unavailability of necessary components could require us to re-engineer our products to accommodate available substitutions, which could increase costs to us and/or have a material adverse effect on manufacturing schedules, products performance and market acceptance. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products. We might not be able to find a sufficient alternative supplier in a reasonable amount of time, or on commercially reasonable terms, if at all. If we fail to obtain a supplier for the components of our products, our operations could be disrupted.

Our investment in SAVSU may be adversely impacted by the failure of SAVSU.

We currently own a minority equity interest in SAVSU and until such time, if at all, as we exercise our option to purchase the remaining 56% of SAVSU not owned by us, we will have limited control over management decisions. Accordingly, our ability to profit from our equity interest in SAVSU will be largely dependent on the current management of SAVSU. SAVSU faces all the inherent risks associated with the development, marketing and operation of a new product line. If SAVSU fails to fulfill its obligations due to strategic business interests, financial condition or otherwise, SAVSU may be required to raise additional capital, which will dilute our ownership, or SAVSU may not be able to continue its operations, in which case we may suffer losses.

Our success will depend on our ability to attract and retain key personnel.

In order to execute our business plan, we must attract, retain and motivate highly qualified managerial, scientific, manufacturing, and sales personnel. If we fail to attract and retain skilled scientific and sales personnel, our 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.

Difficulties in manufacturing could have an adverse effect upon our expenses and our product revenues.

We currently manufacture all of our biopreservation media products. The manufacturing of our products is difficult and complex. To support our current and prospective clinical customers, we comply with and intend to continue to comply with cGMP in the manufacture of our products. Our ability to adequately manufacture and supply our biopreservation media products in a timely matter is dependent on the uninterrupted and efficient operation of our facilities and those of third-parties producing raw materials and supplies upon which we rely in our manufacturing. The manufacture of our products may be impacted by:

- availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;
- the ongoing capacity of our facilities;
- our ability to comply with new regulatory requirements, including our ability to comply with cGMP;
- inclement weather and natural disasters;
- changes in forecasts of future demand for product components;
- potential facility contamination by microorganisms or viruses;
- updating of manufacturing specifications; and
- product quality success rates and yields.

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If efficient manufacture and supply of our products is interrupted, we may experience delayed shipments or supply constraints. If we are at any time unable to provide an uninterrupted supply of our products to customers, our customers may be unable to supply their end-products incorporating our products to their patients and other customers, which could materially and adversely affect our product sales and results of operations.

While we are not currently subject to FDA or other regulatory approvals, if we become subject to regulatory requirements, the manufacture and sale of our products may be delayed or prevented, or we may become subject to increased expenses.

None of our products are subject to FDA or other regulatory approvals. In particular, we are not required to sponsor formal prospective, controlled clinical-trials to establish safety and efficacy. Additionally, we comply with cGMP requirements. This is done solely to support our current and prospective clinical customers. However, there can be no assurance that we will not be required to obtain approval from the FDA, or foreign regulatory authorities, as applicable, prior to marketing any of our products in the future. Any such requirements could delay or prevent the sale of our products or may subject us to additional expenses.

Risks Related to Our Intellectual Property

Expiration of our patents may subject us to increased competition and reduce our opportunity to generate product revenue.

The patents for our products have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. In some of the larger economic territories, such as the United States and Europe, patent term extension/restoration may be available. We cannot, however, be certain that an extension will be granted or, if granted, what the applicable time or the scope of patent protection afforded during any extended period will be. If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U.S. and non-U.S. patents.

US Patent 6,045,990, which provides patent coverage relating to HypoThermosol FRS, will expire in April 2019, and its foreign patent counterparts will expire in July 2019. This may reduce the barrier to entry for competition for this product, which may materially affect the pricing of HypoThermosol FRS and our ability to retain market share. We hold various trade secrets and other confidential know-how related to the manufacturing and testing of our products which limit our exposure upon the expiration of US patent 6,045,990.

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Our proprietary rights may not adequately protect our technologies and products.

Our commercial success will depend on our ability to obtain patents and/or regulatory exclusivity and maintain adequate protection for our technologies and products in the United States and other countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We intend to apply for additional patents covering both our technologies and products, as we deem appropriate. We may, however, fail to apply for patents on important technologies or products in a timely fashion, if at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, the patent positions of life science industry companies are highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty. In addition, we cannot guarantee that:

- we were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our patents will be valid or enforceable;
- any patents issued to us will provide us with any competitive advantages, or will not be challenged by third parties; and
- we will develop additional proprietary technologies that are patentable, or the patents of others will not have an adverse effect on our business.

The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends on many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. Our ability to maintain and solidify our proprietary position for our products will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated, unenforceable or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. We also rely on trade secrets to protect some of our technology, especially where it is believed that patent protection is inappropriate or unobtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all our products in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products. These products may compete with our products and may not be covered by any patent claims or other intellectual property rights.

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

If we fail to protect our intellectual property rights, our competitors may take advantage of our ideas and compete directly against us.

Our success will depend to a significant degree on our ability to secure and protect intellectual property rights and enforce patent and trademark protections relating to our technology. While we believe that the protection of patents and trademarks is important to our business, we also rely on a combination of copyright, trade secret, nondisclosure and confidentiality agreements, know-how and continuing technological innovation to maintain our competitive position. From time to time, litigation may be advisable to protect our intellectual property position. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any litigation in this regard could be costly, and it is possible that we will not have sufficient resources to fully pursue litigation or to protect our intellectual property rights. This could result in the rejection or invalidation of our existing and future patents. Any adverse outcome in litigation relating to the validity of our patents, or any failure to pursue litigation or otherwise to protect our patent position, could materially harm our business and financial condition. In addition, confidentiality agreements with our employees, consultants, customers, and key vendors may not prevent the unauthorized disclosure or use of our technology. It is possible that these agreements will be breached or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Enforcement of these agreements may be costly and time consuming. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are invalid or unenforceable and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity or enforceability of these patents is upheld, the court will refuse to stop the other party on the grounds that such other party's activities do not infringe our rights.

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If we wish to use the technology claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity or enforceability of the patents or incur the risk of litigation in the event that the owner asserts that we infringed its patents. The failure to obtain a license to technology or the failure to challenge an issued patent that we may require to discover, develop or commercialize our products may have a material adverse effect on us.

If a third party asserts that we infringed its patents or other proprietary rights, we could face a number of risks that could seriously harm our results of operations, financial condition and competitive position, including:

- patent infringement and other intellectual property claims, which would be costly and time consuming to defend, whether or not the claims have merit, and which could delay a product and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that our product or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our technologies unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; and
- if a license is available from a third party, we may have to pay substantial royalties or lump-sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license.

The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent, and/or that the patent claims are invalid, and/or that the patent is unenforceable, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

U.S. patent laws as well as the laws of some foreign jurisdictions provide for provisional rights in published patent applications beginning on the date of publication, including the right to obtain reasonable royalties, if a patent subsequently issues and certain other conditions are met.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology.

Patent applications filed by third parties that cover technology similar to ours may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party files a U.S. patent application on an invention similar to ours, we may elect to participate in or be drawn into an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. We cannot predict whether third parties will assert these claims against us, or whether those claims will harm our business. If we are forced to defend against these claims, whether they are with or without any merit and whether they are resolved in favor of or against us, we may face costly litigation and diversion of management's attention and resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, if at all, which could seriously harm our business or financial condition.

Risks Related to our Common Stock and Other Securities

The market for our common stock is limited and our stock price is volatile.

Our common stock, traded on the NASDAQ Capital Market, is volatile and has experienced price and volume fluctuations.

The market prices of many publicly traded companies, including emerging companies in the life sciences industry, have been, and can be expected to be, highly volatile. The future market price of our common stock could be significantly impacted by numerous factors, including, but not limited to:

- Future sales of our common stock or other fundraising events;
- Sales of our common stock by existing shareholders;
- Changes in our capital structure, including stock splits or reverse stock splits;
- 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; and
- Other factors outside of our control.

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A significant percentage of our outstanding common stock is held by two stockholders, and these stockholders therefore have significant influence on us and our corporate actions.

As of December 31, 2018, two of our existing stockholders, Taurus4757 GmbH ("Taurus") and WAVI Holdings AG ("WAVI"), owned, collectively, 5.0 million shares of our common stock representing 27% of the issued and outstanding shares of common stock on December 31, 2018, warrants to purchase 3.9 million shares of our common stock and options to purchase 68,000 shares of our common stock. Taurus and WAVI were previously secured lenders to our Company, and the chairman of Taurus, Mr. Girschweiler, is a member of our board of directors. Accordingly, these stockholders have had, and will continue to have, significant influence in determining the outcome of any corporate transaction or other matter submitted to the stockholders for approval, including mergers, consolidations and the sale of all or substantially all our assets, election of directors and other significant corporate actions. In addition, without the consent of these stockholders, we could be prevented from entering into transactions that could be beneficial to us.

Anti-takeover provisions in our charter documents and under Delaware law could make a third-party acquisition of us difficult.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions include the ability of our board to designate the terms of and issue new series of preferred stock without stockholder approval and to amend our bylaws without stockholder approval. Further, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless certain specific requirements are met as set forth in Section 203. Collectively, these provisions could make a third-party acquisition of us difficult or could discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

Any future sales of our securities in the public markets may cause the trading price of our common stock to decline and could impair our ability to raise capital through future equity offerings.

Sales of a substantial number of shares of our common stock or other securities in the public markets, or the perception that these sales may occur, could cause the market price of our common stock or other securities to decline and could materially impair our ability to raise capital through the sale of additional securities. In addition to the 3.9 million warrants to purchase shares of our common stock owned by Taurus and WAVI, we have an additional 209,000 warrants exercisable to purchase shares of common stock outstanding which will be freely tradable upon exercise. We have agreed to use our best efforts to keep a registration statement registering the issuance and resale of many such shares effective during the term of the warrants. In addition, we have a significant number of shares of our common stock reserved for issuance pursuant to other outstanding options and rights. If such shares are issued upon exercise of options, warrants or other rights, or if we issue additional securities in a public offering or a private

placement, such sales or any resales of such securities could further adversely affect the market price of our common stock. The sale of a large number of shares of our common stock or other securities also might make it more difficult for us to sell equity or equity-related securities in the future at a time and at the prices that we deem appropriate.

We do not anticipate declaring any cash dividends on our common stock.

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and earnings for use in the operation and expansion of our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 32,000 square feet of property being used in current operations in our Bothell, Washington principal location which contains office, manufacturing, storage and laboratory facilities.

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We consider the facilities to be in a condition suitable for their current uses. Because of anticipated growth in the business and due to the increasing requirements of customers or regulatory agencies, we may need to acquire additional space or upgrade and enhance existing space prior to the expiry of the lease in 2021. We believe that adequate facilities will be available upon the conclusion of our leases.

All our products and services are manufactured or provided from our Bothell, Washington facility.

Additional information regarding our properties is contained in Note 8 to the Financial Statements included in this Annual Report on Form 10-K.

ITEM 3. LEGAL PROCEEDINGS

We are currently not subject to any material legal proceedings. However, we may from time to time become a party to various legal proceedings arising in the ordinary course of business. We currently maintain commercial general and umbrella liability policies and a product liability insurance policy.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Price Range of Common Stock

Our common stock is traded on the NASDAQ Capital Market exchange under the ticker symbol "BLFS."

As of March 6, 2019, there were approximately 348 holders of record of our common stock. We have never paid cash dividends on our common stock and do not anticipate that any cash dividends will be paid in the foreseeable future.

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Equity Compensation Plan Information

The following table sets forth information as of December 31, 2018 relating to all our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options (in thousands)	Weighted Average exercise price of outstanding options	Number of granted restricted stock awards outstanding (in thousands)	Number of securities remaining available for future issuance (in thousands)
Equity compensation plans not approved by security holders (1)	425	$ 1.32	—	—
Second amended and restated 2013 performance incentive plan	2,583	$ 1.99	280	860

(1) Represents shares of common stock issuable pursuant to non-plan stock option agreements entered into prior to the adoption of our 2013 Performance Incentive Plan. Prior to the adoption of our 2013 Performance Incentive Plan, we granted certain individuals stock options pursuant to stock option agreements that were not issued under a stockholder-approved plan. Each agreement entitles the holder to purchase from us a fixed number of shares of common stock at a fixed purchase price per share for a fixed period of time, which may not exceed ten (10) years. The specific terms and conditions of each option, including when the right to exercise the option vests, the number of shares subject to the option, the exercise price per share, the method of exercise, exercisability following termination, disability and death, and adjustments upon stock splits, combinations, mergers, consolidation and like events are specified in each agreement. In the event of a liquidation of the Company, or a merger, reorganization, or consolidation of the Company with any other corporation in which we are not the surviving corporation or we become a wholly-owned subsidiary of another corporation, any unexercised options shall be deemed canceled unless the surviving corporation elects to assume the options or to issue substitute options in place thereof. In the event of the forgoing, the holder will have the right to exercise the option during a ten-day period immediately prior to such liquidation, merger, or consolidation.

Issuer Repurchases of Equity Securities

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements". These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, revenues, costs and expenses, interest rates, outcome of contingencies, business strategies, regulatory filings and requirements, performance and market acceptance of our products, the estimated potential size of markets, capital requirements, the terms of any capital financing agreements and other statements that are not historical facts. You can find many of these statements by looking for words like "believes," "expects," "anticipates," "estimates," "may," "should," "will," "could," "intend," or similar expressions in this Annual Report on Form 10-K. We intend that such forward-looking statements be subject to the safe harbors created thereby.

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These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include those discussed under “Risk Factors,” as well as those discussed elsewhere in the Annual Report on Form 10-K.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K or, in the case of documents referred to or incorporated by reference, the date of those documents.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

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Overview

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

We 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 manufacturing, distribution and clinical administration.

Results of Operations

Overview for 2018

In 2018, we reported financial results that were consistent with the continued execution of our long-term plans. We believe we are the market leader for pre-formulated, clinical grade biopreservation media products. Our patented biopreservation media products are formulated to reduce preservation-induced, delayed-onset cell damage and death. Our platform enabling technology provides our customers significant shelf life extension of biologic source material and final cell products, and greatly improved post-preservation cell, and tissue, viability and function. Our products continue to be widely adopted by this segment. We believe that our products have been incorporated in over 300 applications for new cell and tissue-based regenerative medicine products and therapies.

We continue to implement strategies that will increase awareness of the need for improved biopreservation.

Summary of highlights for 2018

Executed on Biopreservation Media Sales, Distribution and Awareness;

Achieved full year net income. For the twelve months ended December 31, 2018, we had net income attributable to common shareholders of $2.9 million. This is compared to a net loss attributable to common shareholders of $2.7 million for the same period in 2017.

During 2018, we gained 179 new customers, including 84 in the regenerative medicine segment.

February 13, 2018, we announced an OEM agreement to supply our CryoStor cell freeze media and HypoThermosol cell storage and shipping media under private label to MilliporeSigma, the life science business of Merck KGaA, Darmstadt, Germany.

March 13, 2018, we announced that the performance of our proprietary, cGMP CryoStor cell freeze media was reported in the Mayo Clinic/MD Anderson journal Laboratory Investigation.

June 25, 2018, we joined the Russell Microcap® Index at the conclusion of the Russell US Indexes annual reconstitution

Institutional Ownership Increased and Funding for Future Acquisitions;

April 9, 2018, Casdin Capital LLC, ("Casdin") a New York-based, life science-focused investment firm, entered into an agreement to purchase 1,000,000 BioLife Solutions common shares in a private transaction from the Company's second largest shareholder; On August 8, 2018, Casdin agreed to invest an additional $20 million by purchasing 1,428,571 shares in BioLife to support the Company's growth strategy of acquiring synergistic cell and gene therapy manufacturing tools and services or technologies.

July 9, 2018, two funds managed by Sandler Capital Management, ("Sandler Capital") a New York-based, sophisticated investor, active in the life science tools and services space, entered into an agreement to purchase 500,000 BioLife Solutions common shares in a private transaction with the Company's two largest shareholders.

Redeemed Series A Redeemable Preferred Stock;

May 17, 2018, we redeemed 25% of the 4,250 shares of Series A Redeemable Preferred stock outstanding for $1,063,000.

November 27, 2018, we redeemed the remaining 3,187 shares of Series A Redeemable Preferred stock outstanding for $3,187,000. There are no Series A shares outstanding.

SAVSU Announcements, Increased Our Ownership in SAVSU;

January 18, 2018, SAVSU, announced the USPTO has issued a notice of allowance of a patent application titled "Biologic Stability, Delivery Logistics and Administration of Time and/or Temperature Sensitive Biologic Based Materials". Since the formation of the BioLife Solutions and SAVSU Technologies LLC joint venture in the fourth quarter of 2014, the companies have submitted 13 other patent applications related to novel innovations incorporated into current, or to be incorporated into future, precision thermal shipping containers under the evo brand.

January 23, 2018, SAVSU announced that it will supply SAVSU smart precision shipping containers throughout the World Courier network.

May 16, 2018, we made a $1 million equity investment in SAVSU. SAVSU's majority shareholder has also invested an additional $1 million in SAVSU.

September 5, 2018, we increased our ownership of SAVSU from approximately 31% to 44% with a $5 million investment. In connection with such investment, we also entered into a call option agreement with the majority owner of SAVSU, Savsu Origin, LLC, pursuant to which we have the option for 18 months to purchase from Savsu Origin all of its shares of SAVSU. SAVSU will use the investment to scale up its operations and inventory to support increased demand for its evo® Dry Vapor Shippers and other precision temperature-controlled shipping containers for cell and gene therapies.

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Financial Performance Summary for 2018

Revenue grew 79% over 2017 from $11.0 million to $19.7 million. This increase was driven by a 108% increase in revenue from the regenerative medicine market. We also drove more sales through our distributors, with an increase of 99% in revenue from distributors in 2018 compared to 2017.

Gross margin in 2018 was 69%, compared to 61% in 2017. The margin was higher due to a higher average selling price per liter sold and an increase in higher margin product mix, partially offset by an increase of direct overhead and raw materials.

Our 2018 operating expenses were $9.9 million compared to $7.8 million in 2017. The increase in expense is primarily the result of higher performance-based compensation, new hires and quality system consulting fees.

Our 2018 net income attributable to common shareholders was $2.9 million. This is compared to a net loss attributable to common shareholders of $2.7 million in 2017. The gain in net income is primarily the result of an increase in revenue and margin partially offset by an increase in performance-based compensation and quality system consulting fees.

Our cash and cash equivalents balance was $30.7 million at December 31, 2018 compared to $6.7 million in cash and cash equivalents at December 31, 2017. Our cash increased in 2018 primarily due to a $20.0 million private investment by Casdin Capital, $12.9 million in warrant and option exercises and $2.3 million in cash flow from operations, partially offset by the redemption of series A redeemable preferred stock for $4.3 million. We generated $2.3 million in cash from operations in 2018 compared to $0.6 million in 2017. The increase in cash from operations was a result of increased cash receipts from higher sales partially offset by increases in employee expenses and quality system consulting fees.

Comparison of Annual Results of Operations

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

Revenue and Gross Margin

Our revenue and gross margin for the years ended December 31, 2018 and 2017 were as follows:

(In thousands, except percentages)	Year Ended December 31, 2018	2017	% Change
Revenue	$19,742	$11,022	79 %
Cost of sales	6,217	4,276	45 %
Gross profit	$13,525	$6,746	100 %
Gross margin %	68.5 %	61.2 %	

Revenue. Our core products are sold through both direct and indirect channels to the customers in the biobanking, drug discovery, and regenerative medicine markets. Sales to our customers in 2018 increased compared to 2017 due to the combination of increased volume of liters sold (9,789 compared to 6,105), and a higher average selling price per liter ($2,017 compared to $1,805). The increase in average selling price is a result of our product mix, with 88% of our revenue derived from CryoStor products in 2018 compared to 77% in 2017. The revenue increase was primarily in sales to our regenerative medicine customers and distributors, which increased 108% and 99%, respectively, in 2018 compared to 2017. Revenue from the regenerative medicine market and our distributors should continue to increase in the next one to five years as some customers receive regulatory and marketing approvals for their clinical cell and tissue-based products.

Cost of Sales. Cost of sales consists of raw materials, labor and overhead expenses. Cost of sales in 2018 increased compared to 2017 due to increased sales volume and raw material costs per liter.

Gross Margin. Gross margin as a percentage of revenue increased to 68.5% in 2018 compared to 61.2% in 2017. Gross margin as a percentage of revenue increased in 2018, due to a higher average selling price per liter sold and lower overhead per liter sold, partially offset by an increase of direct overhead and raw material costs.

Revenue Concentration. For the years ended December 31, 2018 and 2017, we derived approximately 29% of our revenue from two customers and 12% of our revenue from one customer, respectively. Revenue from customers located in Canada represented 13% and in all other foreign countries represented 10% of total revenue during the year ended December 31, 2018. Revenue from customers located in Canada represented 11% and in all other foreign countries represented 16% of total revenue during the year ended December 31, 2017. All sales to foreign customers are denominated in United States dollars. In the years 2018 and 2017, we derived approximately 88% and 77%, respectively, of our revenue from our CryoStor products.

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Operating Expenses

Our operating expenses for the years ended December 31, 2018 and 2017 were as follows:

	Year Ended December 31,			
(In thousands, except percentages)	**2018**	**2017**	***% Change***	
Operating Expenses:				
Research and development	$1,298	$1,193	9	%
Sales and marketing	2,615	2,086	25	%
General and administrative	5,950	4,523	32	%
Total Operating Expenses	9,863	7,802	26	%
% of revenue	50 %	71 %		

Research and Development. Research and development expenses consist primarily of salaries and other personnel-related expenses, consulting and other outside services, laboratory supplies, and other costs. We expense all research and development costs as incurred. Research and development expenses for 2018 increased compared to 2017 due primarily to higher performance-based compensation.

Sales and Marketing. Sales and marketing expenses consist primarily of salaries, trade association sponsorships, and other personnel-related expenses, consulting, trade shows and advertising. The increase in sales and marketing expenses in 2018 compared to 2017 was primarily due to higher performance-based compensation, tradeshows, travel and market research.

General and Administrative Expenses. General and administrative expenses consist primarily of personnel-related expenses, non-cash stock-based compensation for administrative personnel and members of the board of directors, professional fees, such as accounting and legal, and corporate insurance. The increase in general and administrative expenses in 2018 compared to 2017 was primarily due to increased investor relations, quality system consulting fees, new hires, higher performance-based compensation and corporate non-income taxes.

Other Income (Expenses)

Interest Income. We earn interest on our money market account.

Interest Expense. For the year ended December 31, 2018, interest expense is related to equipment financing. For the year ended December 31, 2017, interest expense is due to equipment financing and to the note payable related to the credit facility financing arrangement entered into in May 2016 which was converted to preferred stock in 2017.

Amortization of Debt Discount. The amortization of short-term debt discount for the year ended December 31, 2017 is due to the amortization of the allocated value of the detachable warrants associated with the credit facility financing on the arrangement entered into in May 2017 which was fully amortized May 31, 2017.

Financing Costs and Write off of deferred financing costs. The financing costs in 2017 were due to various SEC filings related to potential stock issuances.

Loss on equity method investment. The non-cash loss associated with our proportionate share of the net loss in our investment in SAVSU.

Liquidity and Capital Resources

On December 31, 2018, we had $30.7 million in cash and cash equivalents, compared to $6.7 million at December 31, 2017. Based on our current expectations with respect to our revenue and expenses, we expect that our current level of cash and cash equivalents will be sufficient to meet our liquidity needs for the foreseeable future in excess of one year. If our revenues do not grow as expected and if we are not able to manage expenses sufficiently, we may be required to obtain additional equity or debt financing if our cash resources are depleted.

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We continue to monitor and evaluate opportunities to strengthen our balance sheet and competitive position over the long term. These actions may include acquisitions or other strategic transactions (including, potentially, the exercise of our option to purchase the remaining 56% of SAVSU that we do not currently own) that we believe would generate significant advantages and substantially strengthen our business. The consideration we pay in such transactions may include, among other things, shares of our common stock, other equity or debt securities of our Company or cash. We may elect to seek debt or equity financing in anticipation of, or in connection with, such transactions or to fund or invest in any operations acquired thereby. We may also seek equity or debt financing opportunistically for these purposes if we believe that market conditions are conducive to obtaining such financing.

Net Cash Provided by Operating Activities

During the year ended December 31, 2018, we generated $2.3 million in cash from operations compared to $605,000 for the year ended December 31, 2017. The increase in operating cash generated in 2018 was the result of an increase in revenue and gross margin due to an increase in liters sold and a higher average selling price per liter partially offset by an increase in operating expenses.

Net Cash Used In Investing Activities

Net cash used in investing activities was $6.5 million in 2018 compared to $144,000 in 2017. Cash used by investing activities increased in 2018 due to our $6.0 million investment in SAVSU and an increase in equipment purchases.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $28.1 million and $4.8 million in 2018 and 2017, respectively. In 2018, cash provided by financing activities was the result of a $20.0 million private investment by Casdin Capital, $12.9 million from the proceeds of stock option and warrant exercises, partially offset by the redemption of series A redeemable preferred stock and payments of preferred dividends, costs associated with the Casdin stock issuance and equipment financing and leasing payments.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate estimates, including, but not limited to those related to accounts receivable allowances, determination of fair value of share-based compensation, contingencies, income taxes, and expense accruals. We base our estimates on historical experience and on other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Share-based Compensation

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

Income Taxes

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

Equity Method Accounting

We account for our investment in SAVSU using the equity method of accounting. This method states that if the investment provides us the ability to exercise significant influence, but not control, over the investee, we account for the investment under the equity method. Significant influence is generally deemed to exist if the Company's ownership interest in the voting stock of the investee ranges between 20% and 50%, although other factors, such as representation on the investee's board of directors, are considered in determining whether the equity method of accounting is appropriate. Under the equity method of accounting, the investment is recorded at its initial carrying value in the balance sheet and is periodically adjusted for capital contributions, dividends received and our share of the investee's earnings or losses together with other-than-temporary impairments which are recorded as a component

of other income (expense), net in the statements of operations.

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Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet arrangements.

Contractual Obligations

For information regarding our current contingencies and commitments, see note 8 to the consolidated financial statements included in Item 8.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders

BioLife Solutions, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of BioLife Solutions, Inc. ("the Company") as of December 31, 2018 and 2017, the related statements of operations, shareholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 15, 2019, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates

made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/S/ PETERSON SULLIVAN LLP

We have served as the Company's auditor since 2007.

Seattle, Washington

March 15, 2019

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BioLife Solutions, Inc.

Balance Sheets

(In thousands, except per share and share data)	**December 31, 2018**	**December 31, 2017**
Assets		
Current assets		
Cash and cash equivalents	$ 30,657	$ 6,663
Accounts receivable, trade, net of allowance for doubtful accounts of $0 and $6 at December 31, 2018 and 2017, respectively	3,045	1,021
Inventories	3,509	1,847
Prepaid expenses and other current assets	353	400
Total current assets	37,564	9,931
Property and equipment		
Leasehold improvements	1,284	1,284
Furniture and computer equipment	706	682
Manufacturing and other equipment	1,657	1,149
Subtotal	3,647	3,115
Less: Accumulated depreciation	(2,328)	(2,009)
Net property and equipment	1,319	1,106
Investment in SAVSU	6,548	1,070
Long-term deposits	36	36
Total assets	$ 45,467	$ 12,143
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 720	$ 691
Accrued expenses and other current liabilities	91	201
Accrued compensation	998	491
Deferred rent, current portion	130	130
Total current liabilities	1,939	1,513
Deferred rent, long-term	349	492
Other long-term liabilities	31	46
Total liabilities	2,319	2,051
Commitments and Contingencies (Note 8)		
Shareholders' equity		
Preferred stock, $0.001 par value; 1,000,000 shares authorized, Series A, 4,250 shares designated, and 0 and 4,250 shares issued and outstanding at December 31, 2018 and 2017, respectively	—	—
	19	14

Common stock, $0.001 par value; 150,000,000 shares authorized, 18,547,406 and 14,021,422 shares issued and outstanding at December 31, 2018 and 2017, respectively		
Additional paid-in capital	114,160	84,036
Accumulated deficit	(71,031)	(73,958)
Total shareholders' equity	43,148	10,092
Total liabilities and shareholders' equity	$45,467	$12,143

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

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BioLife Solutions, Inc.

Statements of Operations

	Years Ended December 31,	
	2018	**2017**
(In thousands, except per share and share data)		
Product sales	$19,742	$11,022
Cost of product sales	6,217	4,276
Gross profit	13,525	6,746
Operating expenses		
Research and development	1,298	1,193
Sales and marketing	2,615	2,086
General and administrative	5,950	4,523
Total operating expenses	9,863	7,802
Operating income (loss)	3,662	(1,056)
Other income (expenses)		
Interest income	281	1
Interest expense	(5)	(190)
Loss from equity-method investment in SAVSU	(672)	(1,005)
Financing costs and write off of deferred financing costs	—	(109)
Amortization of debt discount	—	(156)
Total other income (expenses)	(396)	(1,459)
Net income (loss) before provision for income taxes	3,266	(2,515)
Income taxes	—	—
Net income (loss)	3,266	(2,515)
Less: Preferred stock dividends and accumulated deficit impact of preferred stock redemption	(339)	(213)
Net income (loss) attributable to common stockholders	$2,927	$(2,728)
Basic net income (loss) per common share	$0.18	$(0.21)
Diluted net income (loss) per common share	$0.14	$(0.21)
Weighted average shares outstanding used to compute basic earnings per share	16,256,465	13,263,881
Weighted average shares outstanding used to compute diluted earnings per share	21,627,278	13,263,881

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

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BioLife Solutions, Inc.

Statements of Shareholders' Equity

(In thousands, except share data)	Preferred Stock Shares – Series A	Preferred Stock Amount – Series A	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
Balance, December 31, 2016			12,863,824	$ 13	$ 74,356	$ (71,202)	$ 3,167
Cumulative-effect adjustment resulting from adoption of ASU 2016-09					28	(28)	—
Vesting of JV related stock-based compensation					22		22
Series A preferred stock issued on conversion of related party note and accrued interest on June 30, 2017, net of stock issuance costs of $9	4,250	—			4,241		4,241
Stock based compensation					1,270		1,270
Stock option/warrant exercises			1,045,719	1	3,977		3,978
Stock issued – on vested RSUs			51,563	—	—		—
Stock issued for services			60,316	—	142		142
Preferred stock dividends						(213)	(213)
Net loss						(2,515)	(2,515)
Balance, December 31, 2017	4,250	$ —	14,021,422	$ 14	$ 84,036	$ (73,958)	$ 10,092
Series A preferred stock redemption	(4,250)				(4,241)	(9)	(4,250)
Stock issued for private equity transaction – Casdin Capital, net of legal fees of $85			1,428,571	2	19,913		19,915
Stock based compensation					1,519		1,519
Stock option/warrant exercises			2,974,827	3	12,897		12,900
Stock issued – on vested RSUs			116,647	—	(—)		—
Stock issued for services			5,939	—	36		36
Preferred stock dividends						(330)	(330)
Net income						3,266	3,266
Balance, December 31, 2018	—	—	18,547,406	$ 19	$ 114,160	$ (71,031)	$ 43,148

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

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BioLife Solutions, Inc.

Statements of Cash Flows

(In thousands)	Years Ended December 31, 2018	2017
Cash flows from operating activities		
Net income (loss)	$3,266	$(2,515)
Adjustments to reconcile net income (loss) to net cash provided by operating activities		
Depreciation	338	339
Stock-based compensation expense	1,519	1,270
Stock issued for services	—	107
Write off of deferred financing costs	—	68
Amortization of debt discount	—	156
Loss from equity-method investment in SAVSU	672	1,005
Amortization of deferred rent related to lease incentives	(127)	(127)
Change in operating assets and liabilities		
(Increase) Decrease in		
Accounts receivable, trade	(2,024)	172
Inventories	(1,662)	(89)
Prepaid expenses and other current assets	(104)	(181)
Increase (Decrease) in		
Accounts payable	(11)	21
Accrued compensation and other current liabilities	497	292
Accrued interest	—	152
Deferred rent	(16)	(65)
Net cash provided by operating activities	2,348	605
Cash flows from investing activities		
Investment in SAVSU	(6,000)	—
Purchase of property and equipment	(500)	(144)
Net cash used in investing activities	(6,500)	(144)
Cash flows from financing activities		
Proceeds from private equity transaction	20,000	—
Proceeds from note payable to related party	—	1,000
Proceeds from exercise of common stock options and warrants	12,900	3,978
Payments on equipment loan	(12)	(13)
Payments on capital lease obligation	(13)	(11)
Payments for redemption of preferred stock	(4,250)	—
Payments related to stock issuance	(43)	(9)
Payments of preferred stock dividends	(436)	(106)
Deferred costs paid related to potential stock issuance	—	(43)
Net cash provided by financing activities	28,146	4,796

Net increase in cash and cash equivalents	23,994	5,257
Cash and cash equivalents - beginning of year	6,663	1,406
Cash and cash equivalents - end of year	$30,657	$6,663
Non-cash investing and financing activities		
Series A preferred stock dividends accrued not yet paid	$—	$106
Stock issued for services in prior period included in liabilities at prior year-end	36	36
Receivables converted to equity investment in SAVSU	150	—
Preferred stock issued to convert related party note payable and accrued interest	—	4,250
Capital lease obligations incurred for purchase of equipment	—	52
Purchase of equipment with debt	18	39
Legal fees for private equity transaction not yet paid	44	—
Purchase of property and equipment not yet paid	54	22

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

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NOTES TO FINANCIAL STATEMENTS

1. Organization and Significant Accounting Policies

Business

BioLife Solutions, Inc. (“BioLife,” “us,” “we,” “our,” or the “Company”) is a developer, manufacturer and marketer of proprietary clinical grade cell and tissue hypothermic storage and cryopreservation freeze media. Our proprietary HypoThermosol® and CryoStor® platform of solutions are highly valued in the biobanking, drug discovery, and regenerative medicine markets. Our biopreservation media products are serum-free and protein-free, fully defined, and are formulated to reduce preservation-induced cell damage and death. Our enabling technology provides commercial companies and clinical researchers significant improvement in shelf life and post-preservation viability and function of cells, tissues, and organs. Additionally, for our direct, distributor, and contract customers, we perform custom formulation, fill, and finish services.

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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.

Earnings per share

Basic earnings per share is calculated by dividing the net income (loss) attributable to common stockholders 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 as determined by the treasury method during the period. In periods when we have a net loss, common stock equivalents are excluded from our calculation of earnings per share as their inclusion would have an antidilutive effect. For the year ended December 31, 2018, we excluded a nominal amount of unvested stock awards from our calculation of diluted weighted average shares because they were antidilutive. For the year ended December 31, 2017, we excluded 3.4 million common stock options, 6.7 million warrants, and 238,000 unvested stock awards from our calculation of diluted weighted average shares because they were antidilutive.

The following table shows the calculation of basic and diluted earnings per share:

	Year Ended December 31,	
(In thousands, except share and earnings per share data)	**2018**	**2017**
Numerator:		
Net income (loss) attributable to common stockholders	$2,927	$(2,728)
Denominator:		
Weighted average basic shares outstanding	16,256,465	13,263,881
Effect of dilutive securities	5,370,813	—
Weighted average diluted shares	21,627,278	13,263,881
Basic earnings per share	$0.18	$(0.21)
Diluted earnings per share	$0.14	$(0.21)

Cash and cash equivalents

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

We paid $5,000 and $38,000 for interest for the years ended December 31, 2018 and 2017, respectively.

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Equity Method Investments

We account for our ownership in SAVSU Technologies, Inc. ("SAVSU") using the equity method of accounting. This method states that if the investment provides us the ability to exercise significant influence, but not control, over the investee, we account for the investment under the equity method. Significant influence is generally deemed to exist if the Company's ownership interest in the voting stock of the investee ranges between 20% and 50%, although other factors, such as representation on the investee's board of directors, are considered in determining whether the equity method of accounting is appropriate. Under the equity method of accounting, the investment is recorded at its initial carrying value in the balance sheet and is periodically adjusted for capital contributions, dividends received and our share of the investee's earnings or losses together with other-than-temporary impairments which are recorded as a component of other income (expense), net in the statements of operations. On January 22, 2018, as a result of SAVSU signing a global distribution agreement with World Courier, we amended our agreement with SAVSU to fix our equity position at 35%, prior to any dilution created by financing activities post December 31, 2016. Our ownership in SAVSU was 35% at December 31, 2017. As a result of an additional $6 million in cash contributions made by us and additional contributions made by the majority stockholder, our effective ownership was 44.4% at December 31, 2018. Additionally, we have an 18-month purchase option which provides us, at our sole discretion, with the right to acquire the 56% ownership interest of SAVSU not already owned, in exchange for the greater of 1,000,000 shares of our common stock, or approximately $23 million of our common stock, calculated on the day of exercise.

As of December 31, 2018, SAVSU had current assets and total assets of $5.8 million and $11.0 million, respectively and liabilities of $0.5 million. As of December 31, 2017, SAVSU had current assets and total assets of $0.6 million and $5.5 million, respectively and liabilities of $0.2 million. For the years ended December 31 2018 and 2017, SAVSU's net loss totaled $1.9 million and $2.2 million, respectively. The carrying value of our investment in SAVSU is in excess of the underlying equity in net assets of SAVSU as of December 31, 2018, due to the net assets of SAVSU recorded at historical cost.

Inventories

Inventories represent biopreservation solutions, raw materials used to make biopreservation solutions and are stated at the lower of cost or net realizable value. 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. We provide 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

Property and equipment are stated at cost and are depreciated using the straight-line method over estimated useful lives of three to ten years.

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Deferred rent

For our operating leases, we recognize rent expense on a straight-line basis over the terms of the leases and, accordingly, we record the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Landlord-funded leasehold improvements, to the extent the improvements are not landlord property upon lease termination, are also recorded as deferred rent liabilities and are amortized as a reduction of rent expense over the non-cancelable term of the related operating lease.

Revenue recognition

On January 1, 2018, we adopted Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers and other related ASUs (Topic 606) using the modified retrospective approach applied to those contracts in effect as of January 1, 2018. Under this transition method, results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under Topic 605, Revenue Recognition. Adoption of the new standard did not have an impact on the amounts reported in our financial statements and there were no other significant changes impacting the timing or measurement of our revenue or our business processes and controls.

To determine revenue recognition for contractual arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify each contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to our performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the relevant performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. Our revenues are primarily generated from the sale of our biopreservation media products. We generally recognize product revenue, including shipping and handling charges billed to customers, when we transfer control of our products to our customers as our contracts have a single performance obligation (transfer of control generally occurs upon shipment of our product). Shipping and handling costs are classified as part of cost of product sales in the statement of operations. We are not required to disclose the value of unsatisfied performance obligations as our contracts have a duration of one year or less.

We invoice and receive payment from our customers after we recognize revenue, resulting in receivables from our customers that are presented as accounts receivable on our balance sheet. Accounts receivable consist of short-term amounts due from our customers (generally 30 to 90 days) and are stated at the amount we expect to collect. We establish an allowance for doubtful accounts based on our assessment of the collectability of specific customer accounts. Changes in accounts receivable are primarily due to the timing and magnitude of orders of our products, the timing of when control of our products is transferred to our customers and the timing of cash collections.

Income taxes

We account 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. We evaluate the likelihood of realization of deferred tax assets and provide an allowance where, in management's opinion, it is more likely than not that the asset will not be realized. We have not recorded any liabilities for uncertain tax positions or any related interest and penalties. Our tax returns are open to audit for years ending December 31, 2015 to 2018.

Advertising

Advertising costs are expensed as incurred and totaled $30,000 and $39,000 for the years ended December 31, 2018 and 2017, respectively.

Operating segments

As described above, our activities are directed in the life sciences field of biopreservation products and services. As of December 31, 2018, and 2017 this is the Company's only operating unit and segment.

Concentrations of credit risk and business risk

In the years 2018 and 2017, we derived approximately 29% of our revenue from two customers and 12% of our revenue from one customer, respectively. Revenue from customers located in Canada represented 13% and in all other foreign countries represented 10% of total revenue during the year ended December 31, 2018. Revenue from customers located in Canada represented 11% and in all other foreign countries represented 16% of total revenue during the year ended December 31, 2017. All revenue from foreign customers are denominated in United States dollars. At December 31, 2018, three customers accounted for 71% of gross accounts receivable. At December 31, 2017, two customers accounted for 41% of gross accounts receivable. In the years 2018 and 2017, we derived approximately 88% and 77%, respectively, of our revenue from CryoStor products.

Research and development

Research and development costs are expensed as incurred.

Stock Based Compensation

We use the Black-Scholes option pricing model as our method of valuation for stock option awards. Restricted stock unit grants are valued at the fair value of our common stock on the date of grant. Share-based compensation expense is based on the value of the portion of the stock-based award that will vest during the period, adjusted for forfeitures. Our determination of the fair value of stock option awards on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the expected life of the award, expected stock price volatility over the term of the award and historical and projected exercise behaviors. The estimation of share-based awards that will ultimately vest requires judgment, and to the extent actual or updated results differ from our current estimates, such amounts will be recorded in the period estimates are revised. Although the fair value of stock option awards is determined in accordance with authoritative guidance, the Black-Scholes option pricing model requires the input of highly subjective assumptions and other reasonable assumptions could provide differing results. Share-based compensation expense is recognized ratably over the applicable requisite service period based on the fair value of such share-based awards on the grant date.

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The fair value of options at the date of grant is determined under the Black-Scholes option pricing model. We did not have any stock option grants for the year ended December 31, 2018. During the year ended December 31, 2017, the following weighted-average assumptions were used:

Assumptions	**2017**
Risk-free rate	2.12%
Annual rate of dividends	—
Historical volatility	74 %
Expected life (in years)	5.7

The risk-free interest rate was based on the U.S. Treasury yield curve in effect at the time of grant. We do not anticipate declaring dividends in the foreseeable future. Volatility was based on historical data. We utilize the simplified method in determining expected life. The simplified method is used due to the fact that we have had significant structural changes in our business such that our historical exercise data may not provide a reasonable basis to estimate option lives. Our stock price volatility and expected life 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 model and, ultimately, the expense that will be recognized over the life of the option.

Management adopted Financial Accounting Standards Board ("FASB") Accounting Standard Update No. 2016-09 on January 1, 2017. Due to the adoption of ASU 2016-09 an accounting policy change was made to account for forfeitures as they occur and not estimated. As a result, we had a cumulative-effect adjustment to accumulated deficit and additional paid in capital of $28,000 resulting from adoption.

Recent accounting pronouncements

In August 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (ASU 2016-15). The updated guidance clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows. We adopted the new standard on January 1, 2018, with no material impact on our financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases: Topic 842 (ASU 2016-02) that replaces existing lease guidance. The new standard is intended to provide enhanced transparency and comparability by requiring lessees to record right-of-use assets and corresponding lease liabilities on the balance sheet. Under the new guidance, leases will continue to be classified as either finance or operating, with classification affecting the pattern of expense recognition in the Statements of Operations. Lessor accounting is largely unchanged under ASU 2016-02. The new guidance will be effective for fiscal years and interim periods within those years beginning after December 15, 2018. We will adopt Topic 842 effective January 1, 2019 using the additional transition

option for the modified retrospective method and will not restate comparative periods. Based on our portfolio of leases as of December 31, 2018, approximately $1.8 million of right-of-use assets, $1.9 million lease liabilities and a nominal reduction in retained earnings will be recognized on our balance sheet upon adoption, primarily relating to real estate leases.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities: Topic 825 (ASU 2016-01). The updated guidance enhances the reporting model for financial instruments, which includes amendments to address aspects of recognition, measurement, presentation and disclosure. We adopted the new standard on January 1, 2018, with no material impact on our financial statements.

With the exception of the new standards discussed above, there have been no new accounting pronouncements not yet effective that have significance, or potential significance, to our Financial Statements.

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2. Fair Value Measurement

In accordance with FASB ASC Topic 820, "Fair Value Measurements and Disclosures," ("ASC Topic 820"), the Company measures its cash and cash equivalents at fair value on a recurring basis. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, ASC Topic 820 establishes a three-tier value fair hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than quoted prices included in Level 1 for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3 – Unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

As of December 31, 2018 and 2017, the Company does not have liabilities that are measured at fair value.

The following tables set forth the Company's assets measured at fair value on a recurring basis as of December 31, 2018 and December 31, 2017, based on the three-tier fair value hierarchy:

(In thousands)

As of December 31, 2018	**Level 1**	**Level 2**	**Total**
Total Cash and cash equivalents	$30,657	$ —	$30,657

As of December 31, 2017	**Level 1**	**Level 2**	**Total**

Total Cash and cash equivalents	$6,663	$ —	$6,663

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The fair values of bank deposits and money market funds classified as Level 1 were derived from quoted market prices as active markets for these instruments exist. The Company has no Level 2 or Level 3 assets. The Company did not have any transfers between Level 1 and Level 2 of the fair value hierarchy during the years ended December 31, 2018 and 2017.

3. Inventories

Inventories consist of the following at December 31, 2018 and 2017:

(In thousands)	**2018**	**2017**
Raw materials	$1,453	$583
Work in progress	652	454
Finished goods	1,404	810
Total	$3,509	$1,847

4. Deferred Rent

Deferred rent consists of the following at December 31, 2018 and 2017:

(In thousands)	**2018**	**2017**
Landlord-funded leasehold improvements	$1,125	$1,125
Less accumulated amortization	(757)	(630)
Total (current portion $130 at December 31, 2018 and 2017)	368	495
Straight line rent adjustment	111	127
Total deferred rent	$479	$622

During each of the years ended December 31, 2018 and 2017, the Company recorded $127,000 in deferred rent amortization of landlord funded leasehold improvements.

In addition, during the years ended December 31, 2018 and 2017, the company recorded a decrease of deferred rent of $16,000 and $65,000, respectively, which represented the difference between cash rent payments and the recognition of rent expense on a straight-line basis over the terms of the lease.

5. Income Taxes

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

(In thousands)	**2018**	**2017**
Federal tax expense (benefit) on net income/loss at statutory rate	$686	$(855)
Change in valuation allowance	(412)	(3,419)
Basis difference related to investment in SAVSU	—	(110)
Return to provision	52	(1,038)
Federal rate change true-up	—	5,421
Stock compensation	(748)	—
Book loss in SAVSU	141	—
162(m) limitation on executive compensation deductibility	296	—
Other	(15)	1
Benefit (expense) for income taxes, net	$—	$—

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At December 31, 2018 and 2017, the components of the Company's deferred taxes are as follows:

(In thousands)	2018	2017
Deferred tax assets (liabilities)		
Net operating loss carryforwards	$7,381	$8,162
Accrued compensation	181	32
Depreciation	(24)	43
Section 263a inventory adjustment	42	29
Stock-based compensation	664	688
Deferred rent	101	—
Outside basis difference in SAVSU	—	(225)
Other	—	28
Total	8,345	8,757
Less: Valuation allowance	(8,345)	(8,757)
Net deferred tax asset	$—	$—

On December 22, 2017, "H.R.1", known as the "Tax Cuts and Jobs Act", was signed into law in the United States. Among other items, H.R.1 reduces the federal corporate tax rate to 21% from the existing maximum rate of 35%, effective January 1, 2018. As a result, the Company revalued its net deferred tax asset at the new lower tax rate during the year ended December 31, 2017. The Company has reduced the value of the deferred tax asset before valuation allowance by $5.4 million at December 31, 2017. Based on our estimated 2018 pre-tax income of $2.3 million, we reduced our usable net operating loss carryforwards by $2.3 million.

The Company has the following net operating loss tax carryforwards available at December 31, 2018:

(In thousands) Year of Expiration	Net Operating Losses
2019	$ 259
2020	2,849
2021	4,168
2023	1,217
2024	646
2025	589
2026	873
2027	2,607
2028	2,512
2029	2,196
2030	1,232
2031	1,028
2032	437

2033	37
2034	6,409
2035	3,093
2036	4,995
Total	$ 35,147

Based on historical losses and potential future changes in the ownership of the Company, the utilization of such loss and tax credit carryforwards could be substantially limited.

We have recorded a full valuation allowance against our deferred tax assets. As we trend towards positive net income, we will continue to assess our valuation allowance. Based on all available evidence, we determined that we have not yet attained a sustained level of profitability. Therefore, we have maintained the full valuation allowance at December 31, 2018. We may release all, or a portion, of the valuation allowance in the near-term, dependent on the verifiable positive evidence observed in future years.

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6. Warrants

The following table summarizes warrant activity for the years ended December 31, 2018 and 2017:

(In thousands, except exercise price)	**Year Ended December 31, 2018**		**Year Ended December 31, 2017**	
	Shares	**Wtd. Avg. Exercise Price**	**Shares**	**Wtd. Avg. Exercise Price**
Outstanding at beginning of year	6,689	$ 4.50	7,603	$ 4.46
Exercised	(2,609)	4.75	(914)	4.18
Outstanding and exercisable at end of year	4,080	$ 4.35	6,689	$ 4.50

The outstanding warrants have expiration dates between March 2021 and May 2021.

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7. Stock-Based Compensation

Stock Compensation Plans

Our stock-based compensation programs are long-term retention programs that are intended to attract, retain and provide incentives for talented employees, officers and directors, and to align stockholder and employee interests. We have the following stock-based compensation plans and programs:

During 2013, we adopted the 2013 Performance Incentive Plan (the "2013 Plan"), which allows us to grant options or restricted stock units to all employees, including executive officers, outside consultants and non-employee directors. An aggregate of 3.1 million shares of common stock were initially reserved for issuance under the 2013 Plan. In May 2017, the shareholders approved an increase in the number of shares available for issuance to 4.1 million shares. As of December 31, 2018, there were outstanding options to purchase 2.6 million shares of Company common stock and 280,000 unvested restricted stock awards outstanding under the 2013 Plan.

The Company also issued, outside any approved compensation plans, non-incentive stock options. As of December 31, 2018, there were 425,000 such options outstanding.

Issuance of Shares

When options and warrants are exercised, it is the Company's policy to issue new shares.

Stock Option Activity

Service Vesting-Based Stock Options

The following is a summary of service vesting-based stock option activity for 2018 and 2017, and the status of service vesting-based stock options outstanding at December 31, 2018 and 2017:

	Year Ended December 31, 2018		Year Ended December 31, 2017	
	Shares	Wtd. Avg. Exercise Price	Shares	Wtd. Avg. Exercise Price
Outstanding at beginning of year	2,390,012	$ 1.85	2,513,861	$ 1.78
Granted	—	—	155,000	2.93
Exercised	(330,983)	1.36	(131,427)	1.17
Forfeited	(15,627)	4.34	(52,932)	3.45
Expired - vested	—	—	(94,490)	1.78
Outstanding at end of year	2,043,402	$ 1.91	2,390,012	$ 1.85
Stock options exercisable at year end	1,661,999	$ 1.87	1,583,585	$ 1.72

We recognized stock compensation expense of $597,000 and $612,000 related to service vesting-based options during the years ended December 31, 2018 and 2017, respectively. Weighted average fair value of service vesting-based options granted was none and $1.91 per share for the years ended December 31, 2018 and 2017, respectively.

During the year ended December 31, 2018, service vesting-based options covering 330,983 shares of common stock with a total intrinsic value of $3.8 million were exercised. During the year ended December 31, 2017, service vesting-based options covering 131,427 shares of common stock with a total intrinsic value of $91,817 were exercised.

As of December 31, 2018, there was $20.7 million of aggregate intrinsic value of outstanding service vesting-based stock options, including $16.9 million of aggregate intrinsic value of exercisable service vesting-based stock options. Intrinsic value is the total pretax intrinsic value for all “in-the-money” options (i.e., the difference between the Company’s closing stock price on the last trading day of 2018 and the exercise price, multiplied by the number of shares) that would have been received by the option holders had all option holders exercised their options as of December 31, 2018. This amount will change based on the fair market value of the Company’s stock.

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The following table summarizes information about service vesting-based stock options outstanding at December 31, 2018:

Range of Exercise Prices	Number Outstanding at December 31, 2018	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$0.49 - 1.00	3,571	2.91	$ .49
$1.01 - 1.50	412,073	1.91	$ 1.24
$1.51 - 2.50	1,549,367	6.52	$ 1.94
$2.51 - 8.60	78,391	6.69	$ 4.99
	2,043,402	5.59	$ 1.91

The weighted average remaining contractual life of exercisable service vesting-based options at December 31, 2018, is 5.4 years. Total unrecognized compensation cost of service vesting-based stock options at December 31, 2018 of $531,000 is expected to be recognized over a weighted average period of 1.5 years.

Performance-based Stock Options

The Company's Board of Directors implemented a Management Performance Bonus Plan for 2017. Based on achieving varying levels of specified revenue for the year ending December 31, 2017, up to 1,000,000 options to purchase shares of the Company's common stock may be vested. The options have an exercise price of $1.64, and if revenue levels for 2017 were met, vest 50% on the release of the Company's audited financial statements for 2017, and 50% one year thereafter. If the minimum performance targets are not achieved, no options will vest. On February 27, 2018, the Company's Board of Directors determined that, subject to the completion of the 2017 audit, the specified revenue target had been achieved. Accordingly, 999,997 options to purchase shares of the Company's common stock will vest as follows: 50% of the options vested on March 8, 2018 and the remaining 50% vested on March 8, 2019.

The following is a summary of performance-based stock option activity under our stock option plans for 2018 and 2017, and the status of performance-based stock options outstanding at December 31, 2018 and 2017:

	Year Ended December 31, 2018		Year Ended December 31, 2017	
		Wtd. Avg.		Wtd. Avg.

	Shares	Exercise Price	Shares	Exercise Price
Outstanding at beginning of year	999,997	$ 1.64	999,997	$ 1.64
Granted	—	—	—	—
Exercised	(35,000)	1.64	—	—
Outstanding at end of year	964,997	$ 1.64	999,997	$ 1.64
Stock options exercisable at year end	465,001	$ 1.64	—	$ —

We recognized stock compensation expense of $509,000 related to performance-based options during each of the years ended December 31, 2018 and 2017. During the year ended December 31, 2018, performance-based options covering 35,000 shares of common stock with a total intrinsic value of $285,000 were exercised. As of December 31, 2018, there was $10.0 million of aggregate intrinsic value of outstanding performance-based stock options including $4.8 million of aggregate intrinsic value of exercisable performance-based stock options. The weighted average remaining contractual life of outstanding and exercisable performance-based options at December 31, 2018, is 3.0 years. All compensation cost related to the 2017 performance-based stock options was recognized at December 31, 2018.

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Restricted Stock

The following is a summary of unvested restricted stock activity for 2018 and 2017, and the status of unvested restricted stock outstanding at December 31, 2018 and 2017:

	Year Ended December 31, 2018		**Year Ended December 31, 2017**	
	Shares	**Wtd. Avg. Grant Date Fair Value**	**Shares**	**Wtd. Avg. Grant Date Fair Value**
Outstanding at beginning of year	237,926	$ 1.79	98,439	$ 1.90
Granted	181,268	7.02	207,350	1.76
Vested	(116,647)	1.81	(51,563)	1.90
Forfeited	(22,628)	3.95	(16,300)	1.76
Non-vested at end of year	279,919	$ 5.00	237,926	$ 1.79

The aggregate fair value of the awards granted during the years ended December 31, 2018 and 2017 was $1.3 million and $365,000, respectively, which represents the market value of BioLife common stock on the date that the restricted stock awards were granted. The aggregate fair value of the restricted stock awards that vested during the years ended December 31, 2018 and 2017 was $1.1 million and $154,000, respectively.

We recognized stock compensation expense of $413,000 and $149,000 related to restricted stock awards during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, there was $1.1 million in unrecognized compensation costs related to restricted stock awards. We expect to recognize those costs over 3.0 years.

We recorded total stock compensation expense for the years ended December 31, 2018 and 2017, as follows:

	Year Ended December 31,	
(In thousands)	**2018**	**2017**
Research and development costs	$260	$237
Sales and marketing costs	269	231

General and administrative costs	809	638
Cost of product sales	181	164
Total	$1,519	$1,270

8. Commitments and Contingencies

Leases

We lease approximately 32,000 square feet in our Bothell, Washington headquarters. The term of our lease continues until July 31, 2021 with two options to extend the term of the lease, each of which is for an additional period of five years, with the first extension term commencing, if at all, on August 1, 2021, and the second extension term commencing, if at all, immediately following the expiration of the first extension term. In accordance with the amended lease agreement, our monthly base rent is approximately $59,000 at December 31, 2018, with scheduled annual increases each August and again in October for the most recent amendment. We are also required to pay an amount equal to the Company's proportionate share of certain taxes and operating expenses.

The following is a schedule of future minimum lease payments required under the facility leases as of December 31, 2018:

(In thousands)	Year Ending December 31
2019	$748
2020	764
2021	452
Total	$1,964

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Rental expense for this facility lease for the years ended December 31, 2018 and 2017 totaled $809,000 and $755,000, respectively. These amounts include the Company's proportionate share of property taxes and other operating expenses as defined by the lease.

Employment agreements

We have employment agreements with our Chief Executive Officer, Chief Financial Officer, Chief Technology Officer, Vice President of Operations, Vice President of Marketing, and Vice President of Sales. None of these employment agreements is for a definitive period, but rather each will continue indefinitely until terminated in accordance with its terms. The agreements provide for a base annual salary, payable in monthly (or shorter) installments. In addition, the agreement with the Chief Executive Officer provides for incentive bonuses at the discretion of the Board of Directors. Under certain conditions and for certain of these officers, we may be required to pay additional amounts upon terminating the officer or upon the officer resigning for good reason.

Litigation

From time to time, the Company is subject to various legal proceedings that arise in the ordinary course of business, none of which are currently material to the Company's business.

9. Preferred Stock

On June 30, 2017, we modified our existing credit facility with WAVI, a principal stockholder of the Company. Pursuant to the modification, WAVI agreed to exchange its existing credit facility, including $4.25 million of principal and accrued interest outstanding as of June 1, 2017, for 4,250 shares of the Company's Series A Preferred Stock. No additional consideration was provided to WAVI for entering into this agreement. The exchange resulted in no gain or loss on the transaction. As of December 31, 2017, we had 4,250 preferred shares outstanding at $1,000 par value with an annual dividend of 10%. On May 17, 2018 we redeemed 25%, or 1,063 shares of Series A Redeemable Preferred stock outstanding for $1,063,000. On November 27, 2018 we redeemed the remaining 3,187 shares of Series A Redeemable Preferred stock outstanding for $3,187,000. There are no Series A shares outstanding and no accrued preferred dividends as of December 31, 2018.

10. Revenue

The following table disaggregates revenue by market segment and distributors:

	Year Ended December 31,	
(In thousands)	**2018**	**2017**
Regenerative Medicine	$11,029	$5,307
Distributors	6,418	3,232
Drug discovery	1,199	1,318
BioBanking	1,096	1,165
Total	$19,742	$11,022

11. Subsequent Event

Astero Acquisition

On March 13, 2019, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement"), by and among the Company, Astero Bio Corporation, a Delaware corporation ("Astero"), the stockholders of Astero set forth in Annex I of the Purchase Agreement (collectively, the "Sellers", and together with the Company, the "Seller Parties"), and Timothy C. Bush, in the capacity of the representative of the Sellers (the "Seller Representative") in accordance with the Purchase Agreement, pursuant to which the Company will purchase from the Sellers one hundred percent (100%) of the issued and outstanding capital shares or other equity interests of Astero (the "Acquisition").

In connection with the Acquisition, the Company will pay to the Sellers (i) a base payment in the amount of $12,500,000, consisting of (x) an initial cash payment of $8,000,000 (the "Initial Cash Payment") payable at the closing of the transactions contemplated by the Purchase Agreement (the "Closing"), subject to adjustment for working capital, net debt and transaction expenses, and (y) a deferred cash payment of $4,500,000 payable upon the earlier of Astero meeting certain product development milestones or one year after the date of the Closing (the "Product Milestone Payment"), and (ii) earnout payments in calendar years 2019, 2020 and 2021 of up to an aggregate of $3,500,000, which shall be payable to Sellers upon Astero achieving certain specified revenue targets in each year and a separate earnout payment of $5,000,000 for calendar year 2021 which shall be payable to Sellers upon Astero achieving a cumulative revenue target over the three-year period from 2019 to 2021 (such amounts, collectively, the "Purchase Price").

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The obligations of the parties to consummate the Acquisition is subject to the following closing conditions: (i) the satisfaction of the representations and warranties in the Purchase Agreement, by each party, (ii) performance in all material respects each parties respective obligations in all materials respects of the Purchase Agreement by each party, (iii) delivery of the closing deliverables by each party and (iv) for only Astero and the Sellers, proof that no Material Adverse Effect (as defined in the Purchase Agreement) has occurred between the signing of the Purchase Agreement and the Closing.

Pursuant to the terms of the Purchase Agreement, at or prior to the Closing, the Company, the Seller Representative, and Continental Stock Transfer & Trust Company (the "Escrow Agent"), shall enter into an escrow agreement (the "Escrow Agreement"). At the Closing, the Company shall pay to the Escrow Agent by wire transfer in immediately available funds (i) $1,000,000 (the "Indemnity Escrow Amount"), consisting of (x) $250,000 otherwise payable to the Sellers from the Initial Cash Payment at the Closing and (y) $750,000 otherwise payable to the Sellers from the Product Milestone Payment, to be set aside by the Escrow Agent for a period of 18 months in a separate escrow account (the "Indemnity Escrow Account") and (ii) $3,750,000 (the "Product Milestone Escrow Amount", and together with the Indemnity Escrow Amount, the "Escrow Amount"), to be set aside by the Escrow Agent in a separate escrow account, which shall be held until the earlier of (i) the date that the Product Milestone has been met and (ii) the one-year anniversary of the Closing hereto (the "Product Milestone Escrow Account" and together with the Indemnity Escrow Account, the "Escrow Accounts"), and, in each case, held, invested and disbursed by the Escrow Agent in accordance with the terms and conditions of the Escrow Agreement.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K were effective in providing reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within BioLife Solutions have been detected.

(b) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) of the Securities Exchange Act of 1934 as amended (the Exchange Act)). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control—Integrated Framework (2013 framework). Based on our assessment

under the framework in Internal Control—Integrated Framework (2013 framework), our management concluded that our internal control over financial reporting was effective as of December 31, 2018 . The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by Peterson Sullivan, LLP, an independent registered public accounting firm, as stated in their report that is included herein.

(c) Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders

BioLife Solutions, Inc.

Opinion on Internal Control over Financial Reporting

We have audited BioLife Solutions, Inc. ("the Company") internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the criteria established in *Internal Control – Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the balance sheets of the Company as of December 31, 2018 and 2017, the related statements of operations, shareholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"), and our report dated March 15, 2019, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit

also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ PETERSON SULLIVAN LLP

Seattle, Washington

March 15, 2019

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ITEM 9B. OTHER INFORMATION

None.

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PART III

Certain information required by Part III is omitted from this Form 10-K in that we will file a definitive proxy statement pursuant to Regulation 14A with respect to our 2019 Annual Meeting (the "Proxy Statement") no later than 120 days after the end of the fiscal year covered by this Form 10-K, and certain information included therein is incorporated herein by reference. Only those sections of the Proxy Statement which specifically address the items set forth herein are incorporated by reference. In addition, we have adopted a code of ethics which can be reviewed and printed from our website www.biolifesolutions.com.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANTING FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements (Included Under Item 8): The Index to the Financial Statements is included on page 28 of this Annual Report on Form 10-K and is incorporated herein by reference.

(2) Financial Statement Schedules:

None.

(b) Exhibits

Exhibit Number	Document
3.1	Amended and Restated Certificate of Incorporation of BioLife Solutions, Inc. (included as Exhibit 4.1 to the Registration Statement on Form S-8 filed on June 24, 2013)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation

	of BioLife Solutions, Inc. (included as Exhibit 3.1 to the Current Report on Form 8-K filed on January 30, 2014)
3.3	Amended and Restated Bylaws of BioLife Solutions, Inc., effective April 25, 2013 (included as Exhibit A to the Registrant's Definitive Information Statement on Schedule 14C filed March 27, 2013)
3.4	Certificate of Designations, Preferences, and Rights of Series A Preferred Stock (included as Exhibit 3.1 to the current report on Form 8-K filed on July 6, 2017)
10.1**	Amended and Restated 2013 Performance Incentive Plan (included as Appendix A to the Registrant's Definitive

	Proxy Statement filed on March 24, 2015)
10.2**	BioLife Solutions, Inc. Form of Non-Plan Stock Option Agreement (included as Exhibit 4.4 to the Registration Statement on Form S-8 filed on June 24, 2013)

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10.3	Lease Agreement dated August 1, 2007 for facility space 3303 Monte Villa Parkway, Bothell, WA 98021 (included as Exhibit 10.27 and Exhibit 10.29 to the Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007 filed April 1, 2008)
10.4	First Amendment to the Lease, dated November 4, 2008, between the Company and Monte Villa Farms, LLC (included as Exhibit 10.16 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2008 filed March 31, 2009)
10.5	Second Amendment to the Lease, dated March 2, 2012, between the Company and Monte Villa Farms, LLC (included as Exhibit 10.30 to the Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 filed May 14, 2012)
10.6	Third Amendment to the Lease, dated June 15, 2012, between the Company and Monte Villa Farms, LLC (included as Exhibit 10.37 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed March 29, 2013)
10.7	Fourth Amendment to the Lease, dated November 26, 2012, between the Company and Monte Villa Farms, LLC (included as Exhibit 10.41 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed March 29, 2013)
10.8	Fifth Amendment to Lease, dated August 19, 2014, by and between the Company and Monte Villa Farms LLC (included as Exhibit 10.1 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 filed on November 6, 2014)
10.9	Form of Warrant issued to purchasers in the March 25, 2014 public offering (incorporated by reference to Exhibit 4.1 to the Company's report on Form 8-K filed March 20, 2014)
10.10**	Employment Agreement dated December 13, 2017 between the Company and Michael Rice (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed March 9, 2018)
10.11**	Employment Agreement dated December 13, 2017 between the Company and Aby Mathew (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed March 9, 2018)
10.12**	Employment Agreement dated December 13, 2017 between the Company and Todd Berard (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed March 9, 2018)
10.13	Board of Directors Services Agreement entered into May 4, 2015 by and between the Company and Raymond Cohen (included as Exhibit 10.1 to the Current Report on Form 8-K filed on May 5, 2015)
10.14	Board of Directors Services Agreement entered into May 4, 2015 by and between the Company and Thomas Girschweiler (included as Exhibit 10.2 to the Current Report on Form 8-K filed on May 5, 2015)
10.15	Board of Directors Services Agreement entered into May 4, 2015 by and between the Company and Other Non-Employee Directors (included as Exhibit 10.3 to the Current Report on Form 8-K filed on May 5, 2015)
10.16	Employment Agreement effective December 13, 2017 between the Company and Karen Foster (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed March 9, 2018)
10.17	Employment Agreement dated December 13, 2017 between the Company and Roderick de Greef (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed March 9, 2018)
10.18	Form of Restricted Stock Purchase Agreement pursuant to the Amended & Restated 2013 Performance Incentive Plan (included as Exhibit 10.4 to the Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 filed on May 16, 2016)
10.19	Form of Stock Option Agreement pursuant to the Amended & Restated 2013 Performance Incentive Plan (included as Exhibit 10.5 to the Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 filed on May 16, 2016)
10.20	

	Common Stock Purchase Warrant issued to WAVI Holding AG (included as Exhibit 10.7 to the Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 filed on May 16, 2016)
10.21	Employment Agreement dated December 13, 2017 between the Company and James Mathers (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed March 9, 2018)
10.22	Contribution Agreement dated December 31, 2016 by and between the Company, Savsu Technologies, LLC and biologistex CCM, LLC (included as Exhibit 10.31 to the Annual Report on Form 10-K for the year ended December 31, 2016 filed on March 15, 2017)
10.23	Amended and Restated biologistex CCM, LLC Limited Liability Company Agreement dated December 31, 2016 (included as Exhibit 10.32 to the Annual Report on Form 10-K for the year ended December 31, 2016 filed on March 15, 2017)
10.24	Services Agreement dated December 31, 2016 by and between the Company and biologistex CCM, LLC (included as Exhibit 10.33 to the Annual Report on Form 10-K for the year ended December 31, 2016 filed on March 15, 2017)
10.25	Amendment to Amended and Restated biologistex CCM, LLC Limited Liability Company Agreement dated January 22, 2018 by and between the Company, Savsu Technologies, LLC and biologistex CCM, LLC (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed March 9, 2018)
10.26	Amendment No. 1 to Contribution Agreement dated January 22, 2018 by and between the Company, Savsu Technologies, LLC and biologistex CCM, LLC (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed March 9, 2018)
10.27	Share Purchase Agreement, dated May 15, 2018, by and between SAVSU Technologies, Inc., the Company and Savsu Technologies, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 17, 2018)
10.28	Share Purchase Agreement, dated August 9, 2018, by and between the Company and Casdin Partners Master Fund, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 15, 2018)
23.1	Consent of Peterson Sullivan LLP (filed herewith)
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith)
101.INS	XBRL Instance Document (filed herewith)
101.SCH	XBRL Taxonomy Extension Schema (filed herewith)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase (filed herewith)
101.DEF	XBRL Taxonomy Extension Definition Linkbase (filed herewith)
101.LAB	XBRL Taxonomy Extension Label Linkbase (filed herewith)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase (filed herewith)

* Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to an order granted by the SEC.

** Management contract or compensatory plan or arrangement.

(c) Excluded financial statements:

None.

ITEM 16. FORM 10-K Summary

The Company has elected not to include a summary pursuant to this Item 16.

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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: March 15, 2019 BIOLIFE SOLUTIONS, INC.

/s/ Michael Rice
Michael Rice
Chief Executive Officer and President
(principal executive officer) and Director

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: March 15, 2019 /s/ Michael Rice
Michael Rice
Chief Executive Officer and President
(principal executive officer) and Director

Date: March 15, 2019 /s/ Roderick de greef
Roderick de Greef
Chief Financial Officer (principal financial
officer and principal accounting officer)

Date: March 15, 2019 /s/ Raymond Cohen
Raymond Cohen
Chairman of the Board of Directors

Date: March 15, 2019 /s/ Thomas Girschweiler
Thomas Girschweiler
Director

Date: March 15, 2019 /s/ Andrew Hinson
Andrew Hinson
Director

Date: March 15, 2019 /s/ Joseph Schick
Joseph Schick
Director

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