

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended September 30, 2018

OR

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: 001-37619

STELLAR BIOTECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

British Columbia, Canada
(State or other jurisdiction of
incorporation or organization)

N/A
(I.R.S. Employer
Identification No.)

332 E. Scott Street
Port Hueneme, California
(Address of principal executive offices)

93041
(Zip Code)

Registrant's telephone number, including area code: (805) 488-2800

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Shares, without par value	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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.

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
Non-accelerated filer

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 March 29, 2018, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's outstanding common shares held by non-affiliates was approximately \$8,149,918, which was calculated based on 1,502,870 common shares

outstanding as of that date, of which 1,419,871 common shares were held by non-affiliates at the closing price of the registrant's common shares on The Nasdaq Capital Market on such date.

As of November 28, 2018, the registrant had 5,330,715 common shares issued and outstanding. This amount reflects the one for seven reverse split of the registrant's outstanding common shares effected May 4, 2018.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

STELLAR BIOTECHNOLOGIES, INC.
ANNUAL REPORT ON FORM 10-K
Fiscal Year Ended September 30, 2018

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act) and, as such, may involve known and unknown risks, uncertainties and assumptions. Forward-looking statements are based upon our current expectations, speak only as of the date hereof, are subject to change and include statements concerning (i) our financial performance, (ii) our ability to offer and use our proprietary aquaculture technology and practices, (iii) our competitive position in the market, including the quality of our product and our competitors' reliance on wild populations of limpets, (iv) our growth potential, including with respect to our technologies, manufacturing operations and partnerships (v) our collaboration agreements and strategic arrangements, (vi) the speed in which pharmaceutical sectors are growing, (vii) the commercial success of Stellar KLH, (viii) the success of clinical trials and clinical milestones (ix) the regulatory environment, (x) the future issuance of dividends and (xi) our investments in capital expenditures. Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. You can generally identify forward-looking statements as those statements containing the words "anticipate," "believe," "plan," "estimate," "expect," "intend," "may," "will," "would," "could," "should," "might," "potential," "continue" or other similar expressions. You should not rely on our forward-looking statements as they are not a guarantee of future performance. There can be no assurance that forward-looking statements will prove to be accurate because the matters they describe are subject to assumptions, known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond our control. Our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors, some of which are listed under the "Risk Factors" section of this Annual Report. Risks and uncertainties include, among others,

- the availability of funds and resources to pursue our research and development projects,
- the successful and timely completion of preclinical or clinical studies by third parties in which our products are utilized,
- our ability to meet the goals of our joint ventures and strategic partnerships, the degree of market acceptance for our products or for other companies' products in which our products are components,
- our ability to take advantage of business opportunities in the pharmaceutical industry,
- changes in our strategy or development plans,
- our ability to protect our intellectual property,
- uncertainties related to governmental regulations and regulatory processes,
- the volatility of our common share price,
- the effect of competition,
- the effect of technological changes,
- reliance on key personnel,
- our ability to successfully estimate the impact of certain accounting and tax matters, and
- general changes in economic or business conditions.

Except as required by law, we undertake no obligation to update forward-looking statements.

As used in this Annual Report on Form 10-K, "Stellar," "the Company," "we," "us," and "our" refer to Stellar Biotechnologies, Inc. and our consolidated subsidiaries, except where the context otherwise requires.

Our logo, Stellar KLH and other trademarks or service marks of Stellar Biotechnologies, Inc. appearing in this Annual Report on Form 10-K are the property of Stellar Biotechnologies, Inc. This Annual Report on Form 10-K contains additional trade names, trademarks and service marks of other companies. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply relationships with, or endorsement or sponsorship of us by, these other companies.

All historical references to common shares, warrants and share options outstanding prior to May 4, 2018 and the related exercise prices in this Form 10-K have been adjusted to reflect the effect of the one for seven reverse split, effected at the close of market on May 4, 2018.

PART I

Item 1. BUSINESS.

Overview

We are a biotechnology company engaged in the aquaculture, research and development, manufacture and commercialization of KLH. KLH is an immune-stimulating protein with an extensive history of safe and effective use in immunological applications.

Immunotherapies (also known as therapeutic vaccines) are an emerging class of treatments that involve using the body's own immune system to target and treat disease. Today, multiple companies and institutions are developing drugs that combine disease-targeting agents with KLH. These disease-targeting agents do not evoke a robust immune response by themselves and thus require conjugation to a carrier molecule like KLH.

The versatility of the KLH molecule and its use in multiple drug development pipelines provide numerous commercial opportunities for us. KLH is currently utilized in immunotherapies in clinical or pre-clinical development for Alzheimer's disease, metastatic breast cancer, type 1 diabetes, dermatomyositis, systemic lupus erythematosus, ovarian cancer and various other cancers and diseases. The successful commercialization of one or more of these drug development pipelines, especially in a major indication, could have a significant impact on the industry's ability to produce sufficient quantities of KLH. The protein is derived only from the Giant Keyhole Limpet, a scarce ocean mollusk that is native to a limited stretch of Pacific Ocean coastline. Due in part to the inherent limitations of utilizing wild sources of KLH, we believe that aquaculture production methods, like the methods we practice, will be required to provide scalable, fully traceable supplies of KLH.

Based upon our specialized knowledge of aquaculture science and KLH, we have built unique land-based aquaculture, laboratory and production facilities in Port Hueneme, California, and developed production and manufacturing processes to produce clinical-grade KLH using Current Good Manufacturing Practices (GMP). Using our proprietary aquaculture technology, we can support the marine mollusk from embryo to protein-producing adult, and we now support multiple generations of limpets grown entirely within our land-based aquaculture facility. We believe that other KLH suppliers do not have this capability and thus are reliant on scarce, wild populations of limpets.

We market and sell our KLH products under the brand Stellar KLH. Our customers and partners include multinational biotechnology and pharmaceutical companies, academic institutions, clinical research organizations and research centers. We have multiple agreements to license and supply Stellar KLH and other technology in exchange for fees, revenues or royalties. Our customers manage and fund all product development and regulatory submissions for their respective drug products that utilize our KLH protein.

Competitive Strengths

We believe that we possess a number of competitive strengths that position us to become the world leader in the sustainable manufacture of GMP grade KLH, including:

- *Fully permitted, land-based aquaculture facility produces a barrier to market entry.* Our proprietary methods, infrastructure and aquaculture facility give us the capability to support the source animal in aquaculture. Due to the time needed to raise the source animal to maturity, and the time needed to build and validate facilities and manufacturing processes, including water discharge permits, we believe that we have a five to seven year lead over any new market entrants attempting to produce KLH in a similar manner. Due to its exceptional size and complexity, KLH has not been reproduced synthetically.
- *Fully traceable, GMP grade product offerings benefit commercialization programs.* Using our proprietary production and manufacturing methods, we are able to produce a high quality, GMP grade KLH product that is fully traceable and controlled from native source to finished product, which we believe are important considerations for our pharmaceutical partners as they pursue later-stage trials and commercial introductions subject to more rigorous regulatory standards than early-stage research. Due to the known origin of material and continuity of data, we believe we are able to create a more consistent, high quality, immunogenic product than other KLH proteins in the market. In contrast, commercial supplies of KLH from other sources have historically differed widely in their source, traceability, purity, form and preparation, as well as their immunogenicity (their ability to stimulate an immune response). We believe that we are the only company that offers GMP grade KLH supported by fully traceable manufacturing methods.
- *Business model leverages growth potential and builds long-term relationships.* We believe we have an attractive business model due to the unique nature of our product offerings, embedded growth opportunities within our customer base and operating leverage. We believe that our supply and collaboration agreements with drug developers, which include binding orders, allow us to better manage our working capital as well as build long-term relationships. As we increase production volumes and sales, we expect our operating expenses to decrease as a percentage of revenue, providing for greater operating leverage.

- *Intellectual property portfolio includes protection for specialized systems and technologies.* We have intellectual property related to KLH development and manufacturing and to the environmental protection of the Giant Keyhole Limpet, including patents, trade secrets and know-how related to specialized aquaculture systems and technologies; spawning, selection and maintenance of the species; non-lethal KLH protein extraction methods; and the processing, purification and production of KLH formulations.
- *Safety profile and extensive citations in scientific literature contribute to the appeal of KLH as a carrier platform for immunotherapies.* KLH has been used for decades in immune system testing, it has an extensive safety record, and continues to be selected for new immunotherapies preparing to enter clinical testing. According to a search on PubMed, a service of the U.S. National Library of Medicine, there are more than 3,600 publications referencing Keyhole Limpet Hemocyanin in biomedical literature.
- *Sustainability practices protect marine source and promote scalability.* Our KLH protein is produced using environmentally sound, sustainable practices intended to protect and renew the live marine source. We believe this is a critical component of ensuring long-term, scalable supplies, since rapid growth in demand has had severe consequences to other related species. In California, for example, failure to manage wild populations of abalone resulted in dramatic declines and eventually led to closure of commercial abalone harvests.
- *Leadership team provides extensive aquaculture production and related industry expertise.* Our leadership team includes industry experts who have extensive experience in the field of aquaculture and Giant Keyhole Limpet production, and possess a deep understanding of a variety of biotechnology businesses. Our Chairman, President and CEO has more than 40 years of experience leading commercial aquaculture businesses and projects focused on mollusk domestication and production.

Our Strategy

Our strategy seeks to expand the company's growth potential while identifying opportunities to extract additional value from our KLH production capabilities and assets. Key elements of our business strategy include:

- *Sustain our market opportunity for KLH-conjugated vaccines.* We aim to preserve the readiness of our KLH production assets and capabilities as customers with KLH-based drug candidates conduct clinical studies. This strategy seeks to preserve the opportunity for Stellar to share in the successful development and commercialization of product candidates utilizing our aquaculture-produced KLH products, while prudently managing our working capital. In 2018, we completed certain infrastructure improvements that will allow us to rapidly expand our production systems in a modular manner. As a result, we are able to culture only the number of animals needed for current demand.
- *Explore strategic arrangements with complementary technologies or businesses synergistic with our business.* We are pursuing an array of opportunities within the field of biotechnology and immunotherapy with the aim to strengthen our technology portfolio as well as to create additional near-term value inflection opportunities. In particular we are interested in companies with validated clinical-stage assets, complementary technologies to KLH, and experienced clinical management staff.
- *Pursue additional supply and collaboration agreements.* We plan to continue pursuing opportunities for commercial growth that build on our strengths and core competencies in KLH, including additional supply and collaboration agreements.
- *Develop additional markets for our technology and products.* We are committed to exploring new high potential therapeutic applications for KLH, such as clinical indications where the adjuvant and immune-stimulating properties of KLH may increase the efficacy or potency or broaden the potential patient population for certain immunotherapies. We believe that the best way to advance this strategy is through partnering or other strategic arrangements.

Keyhole Limpet Hemocyanin

KLH is a safe, potent, immune-stimulating protein. Specifically, it is a very large, high molecular weight, oxygen-carrying glycoprotein. In addition to the native molecule, KLH can be chemically dissociated into a subunit formulation. Both the native, high molecular weight molecule and subunit forms of KLH are excellent immune stimulants. The KLH molecular structure offers numerous sites for conjugation, and can generate multiple product configurations. Because of its large size, immune-stimulating properties, numerous sites for conjugation, and safety profile, KLH is used by researchers and product developers as a vaccine carrier protein. However, due to its exceptional size and complexity, KLH has not been reproduced synthetically.

KLH can be used as a carrier molecule, or it can be used as a finished, injectable product.

As a carrier molecule, KLH is combined, or conjugated, to vaccine antigens that are used to promote the generation of antibody and cell-mediated immune responses against targeted diseases. By themselves, the small haptens (partial antigens) and vaccine antigens used to target these diseases are not usually immunogenic enough to awaken the immune system and therefore, require a carrier molecule or adjuvant, like KLH, in order to be effective. The combination of an antigen against specific pathogenic targets, such as tumors, and over-expressed proteins, conjugated to the immunogenic KLH molecule, is the basis for a promising new class of drugs in development known as active immunotherapies or therapeutic vaccines. Unlike preventative vaccines, active immunotherapies are designed to stimulate the body's own immune system to generate an immune response to target and attack an existing disease or condition. We believe immunotherapies are, and will continue to be, one of the fastest-growing sectors of pharmaceutical research and development. KLH is an important component for drugs used in clinical or pre-clinical development for Alzheimer's disease, metastatic breast cancer, type 1 diabetes, dermatomyositis, systemic lupus erythematosus, ovarian cancer and various other cancers and diseases.

As a finished injectable product, KLH has been used extensively by pharmaceutical companies and researchers as a safe, immune-stimulating antigen in drug-screening, drug immunotoxicology, and assessment of immune status. KLH is a standard immunogen in T-Cell Dependent Antibody Response (TDAR), a functional assay which is widely recognized as a standard test for monitoring the effects of drugs on the immune system. Due to its adjuvant properties, finished injectable KLH has also been used to augment the efficacy of certain immunotherapies under development.

KLH protein is derived only from the Giant Keyhole Limpet (*Megathura crenulata*), a mollusk native only to a limited stretch of the Pacific Ocean coastline along Southern California and Baja California, Mexico. Historically, suppliers other than us have obtained KLH protein directly from wild and sensitive populations of Giant Keyhole Limpet, or have utilized lethal production processes. Based on publicly available information and reports, commercial supplies of KLH differ widely in their source, traceability, purity, form, and preparation, as well as in immunogenicity (their ability to stimulate an immune response). We believe that highly specialized aquaculture manufacturing methods, like the methods we practice, protect the KLH molecule's source species and provide sustainable, scalable supplies of quality KLH protein. The concept of sustainability involves sound, responsible management of environmental resources and, especially where biological systems are concerned, includes protecting native species so that the species thrive and remain diverse and productive over time. Further, we believe that environmentally sound methods associated with professional and specialized aquaculture can minimize variability in KLH products and assure full traceability to their biological source.

Our Technology

We have spent more than 15 years developing and optimizing sustainable KLH production methods, specifically focused on protection of the Giant Keyhole Limpet and a patented, non-lethal method to extract KLH protein. We believe our proprietary methods will provide a scalable supply of GMP grade KLH and meet pharmaceutical industry standards for immune response, consistency, purity and traceability while protecting the natural source species. Utilizing our patented non-lethal method, KLH can be extracted from mature limpets multiple times per year. Once extracted, our KLH is processed and purified through our proprietary methods, which are protected as trade secrets. In addition to our internal manufacturing capabilities, we rely on contract manufacturing organizations and contract testing organizations for certain steps of GMP processing and quality control testing. The services performed by these contract vendors have included sterile fill/finish and product release testing.

Our proprietary aquaculture technology involves methods we developed and optimized to control the reproduction and growth of the Giant Keyhole Limpet including culture systems, nutritional requirements and the recirculation of seawater. We believe that other KLH suppliers do not have this capability and thus are reliant on scarce, wild populations of limpets. In 2018, we completed certain infrastructure improvements that will allow us to rapidly expand our production systems in a modular manner. As a result, we are able to culture only the number of animals needed for current demand. We plan to incrementally expand aquaculture infrastructure, which will thereby increase our KLH production capacity, in order to meet the anticipated future multi-kilogram KLH requirements of immunotherapy commercialization.

We also plan to continue optimizing our protein manufacturing processes. These activities are intended to increase the scalability and throughput capacity of existing manufacturing systems, which were originally developed to provide clinical development stage quantities of our Stellar KLH products. We plan to upgrade and scale our manufacturing operations to produce KLH suitable for commercial drugs by the time our customers are ready to file marketing applications referencing our DMFs. This will involve, in part, transferring our manufacturing method to a new Stellar-operated location or to a contract manufacturing organization or partner. The timing of such decision will be based on customer demand for Stellar KLH, among other considerations.

As a result of these operational capabilities and plans, we believe we will be able to supply GMP grade KLH in commercial quantities to meet the anticipated long-term demand within the pharmaceutical industry, while protecting the natural source species. We base these beliefs on our intellectual property, achievements in aquaculture science, KLH production capabilities, KLH sustainable manufacturing know-how, and survey data used to estimate populations of Giant Keyhole Limpets in the wild.

Our Aquaculture and KLH Production Facilities

We maintain production facilities directly along the Pacific Ocean with dedicated, land-based aquaculture operations in Port Hueneme, California. We have approximately 37,000 square feet of leased aquaculture, manufacturing and laboratory space. At this location, our seawater supply and discharge system is fully permitted, which we believe is a competitive strength due in part to the time required and uncertainties related to obtaining new water discharge permits in the State of California. Our aquaculture operations include, among other specialized infrastructure, systems for spawning, larval development, and maturation of limpets, recirculating seawater supply systems and environmental controls. Our facility currently includes multiple production tanks and numerous individual limpet production modules in two independent aquaculture production systems. Each closed recirculating system is equipped with temperature controlled seawater distribution, filtration and treatment equipment.

We are also investigating the establishment of additional aquaculture capabilities in Baja California, Mexico, including research collaborations with local organizations and companies, site suitability studies, raw material sourcing and the development of regional marine resources. We have also leased undeveloped land in Baja California since 2015. We believe these early-stage activities in Mexico will support our goal to meet the anticipated long-term industry demand for KLH protein.

Research and Development

Our research and development is focused primarily on the aquaculture of the Giant Keyhole Limpet as well as improvements in KLH protein characterization and manufacturing. These activities involve both internal programs and external collaborations with other biopharmaceutical companies or research organizations.

Our internal research has included, among other activities, improvement of methods for the culture and growth of Giant Keyhole Limpet, developing proprietary formulated limpet diets, innovations in aquaculture systems and infrastructure, biophysical and biochemical characterization of the KLH molecule, analytical processes to enhance performance of our products, KLH manufacturing process improvements, new KLH formulations and KLH-related technologies, and new uses for KLH in immunotherapy and immunodiagnostic applications.

Our external collaborations have historically involved both development and evaluation projects, with multiple biopharmaceutical companies and research institutions, for the use of Stellar KLH in their programs. We believe that these collaborations provide for strategic, revenue and clinical opportunities for our future business by extending the commercial use of Stellar KLH and furthering our understanding of the KLH molecule.

For the years ended September 30, 2018 and 2017, our research and development expense were \$2.09 million and \$1.97 million, respectively. These amounts related mainly to research and development in aquaculture, improvements in analytical, manufacturing, and purification processes, stability studies and formulation development.

Our Stellar KLH Products

We offer Stellar KLH protein in various grades, formulations, custom configurations and fill finishes for both drug development and research applications. Our portfolio includes GMP products suitable for our customers' Phase 1 and Phase 2 clinical studies as well as research-grade products. Our KLH is primarily intended for: conjugation as a carrier molecule in therapeutic vaccines; assessing immune function; augmenting the efficacy of immunotherapies; and, in immunotoxicology studies, for monitoring the immunomodulatory effects of drug candidates. We also offer KLH-based *in vitro* diagnostic kits for research and preclinical use.

The list price for bulk Stellar KLH protein ranges from approximately \$25,000 to \$55,000 per gram, depending on the purity, grade, preparation, packaging configuration and volume ordered. We also market certain custom vial formulations at a significant premium over bulk pricing. We currently have limited revenue from sales of our Stellar KLH products. Product sales volumes have been highly dependent and subject to variability associated with the rate of development and progression of clinical studies of third-party immunotherapies and other technologies that utilize our products. The rate of progression towards later stage studies is expected to continue to affect the timing and volume of future product sales. The advancement and commercial success of third-party products utilizing Stellar KLH is dependent upon many factors, including available capital, trial recruitment and progress, trial success, and regulatory review and approval.

Revenues from the sale of products and contract services revenues in fiscal years 2018 and 2017 are as follows:

	Fiscal Years Ended	
	September 30, 2018	September 30, 2017
Product sales	\$ 211,849	\$ 178,287
Contract services revenue	-	50,000

The geographic breakdown of revenues in fiscal years 2018 and 2017 are as follows:

	2018	2017
Europe	51%	64%
North America	45%	33%
Asia	4%	3%

We have submitted Type II Master Files for Stellar KLH to the FDA. A Master File is a confidential, detailed dossier kept on file at the FDA that contains the proprietary information on the manufacture and safety of a drug component. These files can be used to support the regulatory approval process for customers' immunotherapy products that use our Stellar KLH, while allowing us to control access to our manufacturing data.

Customers

We primarily market and distribute our products directly to biotechnology and pharmaceutical companies, academic institutions, clinical research organizations and research centers. Products are shipped to our customers from our facilities in Port Hueneme, California using a common carrier chosen by the customer. The geographic markets of our customers are principally Europe, North America and Asia.

The customers that represent 10% or more of our total consolidated revenue in the fiscal years 2018 and 2017 are as follows:

Customer	Percentage
Fiscal Year Ended September 30, 2018	
Neovacs SA	36%
Zoetis LLC	23%
Fiscal Year Ended September 30, 2017	
Araclon Biotech, SL	57%
Matrivax R&D Corporation	22%

Supply Agreements, Collaboration Agreements and Contracts

We have entered into, and intend to continue to enter into, agreements with third parties that will allow us to supply Stellar KLH in exchange for fees, revenues or royalties. Supply agreements generally involve a customer's commitment to purchase our Stellar KLH for use in the customer's own immunotherapy products or as a finished product in their development programs or therapies. In return, we license and provide exclusive or priority supply in a given field and territory, and provide technical and regulatory support. When applicable, we also agree to maintain a drug master file with the U.S. Food and Drug Administration (FDA) for the KLH product. Our current supply agreements are limited to clinical trials and typically have an initial multi-year term, which may be renewed by customers for additional one-year periods. Our supply agreements also typically provide us with first negotiation rights for the supply of KLH in connection with potential future commercialization of a customer's products.

To date, our Stellar KLH protein has been used in research and development, preclinical and clinical phases of development but has not yet been used in any commercialized and marketed drug products. Quantities required for clinical trials depend on, among other variables, the nature of the trial, the clinical indication, the number of patients enrolled, dosing regimens and vaccine manufacturing processes. We plan to upgrade and scale our manufacturing operations to produce KLH suitable for commercial drugs by the time our customers are ready to file marketing applications referencing our DMFs.

We have supply agreements with Araclon Biotech SL, a privately-held biotechnology company headquartered in Spain and majority-owned by global healthcare company Grifols; Amaran Biotechnology, Inc., a biopharmaceuticals manufacturer based in Taiwan that manufactures a KLH conjugate vaccine for OBI Pharma, Inc., a publicly-listed Taiwan biotech company; and Neovacs S.A., a publicly listed French biotechnology company. Our customers manage and fund all product development and regulatory submissions for their respective drug products that utilize Stellar KLH.

Neostell Joint Venture Agreement

In May 2016, we entered into a joint venture agreement with Neovacs S.A., a publicly-held biotechnology company in Paris, France for the formation of a joint venture company to manufacture and sell conjugated therapeutic vaccines. In July 2016, Neostell S.A.S., a French simplified stock corporation (Neostell), was formed to carry out the business of the joint venture. Neostell is expected to produce Neovacs' Kinoid immunotherapy product candidates which utilize Stellar KLH as a carrier molecule. Neostell may also manufacture and sell other KLH-based immunotherapy products for third-party customers worldwide. We hold a 30% equity interest in the joint venture in exchange for an initial capital contribution of €120,000. One-half of the initial contribution, approximately \$67,000, was paid in June 2016 with the balance due upon the occurrence of certain defined future events. We will also provide additional financing to Neostell, as may be required, on a pro rata basis in line with our equity interest. According to the joint venture agreement, as amended February 2018, if certain milestones are not achieved by December 31, 2018, Neostell will be dissolved, unless the parties mutually agree to pursue the joint venture arrangement, or either party decides to purchase the equity interests of the other party. On July 3, 2018, Neovacs published the results of its Phase 2b clinical study for IFN-Alpha-Kinoid immunotherapy in systemic lupus erythematosus, and the parties are currently in discussions regarding certain Neostell milestones and the advancement of Neovacs' KLH based immunotherapy in lupus. Each of the parties is entitled, upon the occurrence of certain defined events, to acquire the interest of the other party. Except as otherwise described herein, the joint venture has an initial ten-year term, renewable for successive five-year terms. If either party provides notice at least six months prior to the expiration date of an applicable term that it does not wish to continue its participation in the joint venture, the other party will have a right to acquire all of such terminating party's equity interests in Neostell. In connection with the formation of Neostell and the execution of its strategy, the parties intend over time to enter into an exclusive supply agreement within a limited field of use for Stellar to supply KLH to Neostell, a supply agreement designating Neostell as the exclusive manufacturer and supplier of the Neovacs' vaccines, and services agreements for the provision of various knowledge and expertise by each of the parties. Neovacs will also license certain of its intellectual property to Neostell.

Intellectual Property and License Agreements

We hold important proprietary intellectual property related to KLH development and manufacture and to the environmental protection of the Giant Keyhole Limpet, which we protect primarily as trade secrets. This intellectual property includes specialized aquaculture systems and technologies; spawning, selection and maintenance of the Giant Keyhole Limpet; non-lethal KLH protein extraction methods; and the processing, purification and production of KLH formulations. Our proprietary methods also include methods for the control of larval development, metamorphosis and maturation of the Giant Keyhole Limpets.

Our success depends in part on our ability to obtain and maintain proprietary protection for our product technology and know-how, to operate without infringing proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing, when appropriate, U.S. and foreign patent applications relating to our technology, inventions and improvements that are important to our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position. We require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationship with us. We also require our employees, and to the extent practicable, our consultants and advisors with whom we expect to work on our products to agree to disclose and assign to us all inventions made in the course of our working relationship with them, while using our intellectual property or which relate to our business.

We hold patent protection for our non-lethal extraction methods of hemocyanin in the United States and other countries, including one issued patent in the United States, U.S. Patent No. 6,852,338, which currently expires in 2023, and covers a two-step method for obtaining hemolymph from a live gastropod mollusk. This U.S. patent was originally granted to our Chief Executive Officer, Frank Oakes, who assigned the patent to the Company in August 2002. Foreign patent counterparts were granted in Canada, France and Germany.

The scope of any patent protection may not exclude competitors or provide competitive advantages to us, and any of our patents may not be held valid if subsequently challenged, and others may claim rights in or ownership of our patents and proprietary rights. Furthermore, others may develop products similar to our products and may duplicate any of our products or design around our patents.

Our common law trademarks include, but are not limited to, “Powering and Improving Immunotherapy™”, “Stellar KLH™” and “KLH Site™”. In addition to patents and trademarks, we rely on trade secrets and other intellectual property laws, nondisclosure agreements and other measures to protect our intellectual property rights.

Competition

The immunotherapy industry is rapidly evolving and new competitors with competing technologies and products are regularly entering clinical development and the market. We compete on the basis of: the advantages and disadvantages of Stellar KLH as compared to other KLH proteins manufactured by our competitors; our ability to educate the industry about the high quality, and sustainable and traceable features, of Stellar KLH; our future ability to supply scalable quantities of GMP grade KLH; product efficacy; customer service; and the price and demonstrated cost-effectiveness of Stellar KLH as compared to our competitors. We believe that our products and services currently compete favorably with respect to such factors. However, we may not be able to maintain our competitive position against current and potential competitors. We compete directly with Biosyn Corporation, and with SAFC, a division of Sigma-Aldrich that has historically offered KLH products. In addition to competition from current suppliers of KLH, we also face indirect competition from developers of other carrier proteins, adjuvants or therapeutic vaccine platforms. We are unable to predict what effect evolution of the KLH and immunotherapy industries and potential new entrants may have on price, selling strategies, intellectual property or our competitive position.

Government Regulation

Our operations, including our aquaculture and harvesting activities, as well as production operations, manufacturing site development, and drug research, development and sales, are subject to complex regulation at the local, state and federal levels in the United States by a number of regulatory agencies including the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Secretary of the Navy, the Regional Water Quality Control Board Los Angeles Region, the California Department of Fish and Wildlife, the California Coastal Commission, the California Air Pollution Control Board, the County of Ventura, the City of Port Hueneme and the Oxnard Harbor District.

We are subject to laws and regulations covering clean water and waste discharge, and are required to hold licenses for the aquaculture production and wild harvesting of the Giant Keyhole Limpet. Our aquaculture facility is subject to regulation by the California Department of Fish and Wildlife and the Regional Water Quality Control Board, Los Angeles Region. These agencies impose regulations that restrict any activity that could pose a potential risk to the California marine environment including, but not limited to, seawater waste discharge limitations specified in our National Pollution Discharge Elimination Systems (NPDES) permit. We regularly monitor our KLH production and manufacturing processes for material compliance with applicable regulations.

In addition to regulations in the United States, we may be subject to a variety of foreign regulations related to research, manufacturing, and the commercial sale and distribution of our products, to the extent we choose to manufacture, sell or distribute any products outside of the United States. The requirements governing our activities in jurisdictions outside the United States vary greatly from country to country.

In Mexico, our current research and development activities and collaborations, and potential future operations, are subject to regulation, permitting and oversight by the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), including the National Service of Health, Food Safety and Quality (SENASICA), the National Commission of Fisheries and Aquaculture (CONAPESCA), and the National Institute of Fisheries and Aquaculture (INAPESCA), all of which are administrative bodies of SAGARPA. We are also subject to regulation, permitting and oversight by the Secretariat of the Environment and Natural Resources (SEMARNAT), the Secretariat of Health's Federal Commission for the Protection Against Sanitary Risks (COFEPRIS), and by and other state and local agencies.

Compliance with Good Manufacturing Practices

The FDA and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacture of pharmaceutical and biologic products prior to approving a product. If, after receiving approval from regulatory agencies, a company makes a material change in manufacturing equipment, location or process, additional regulatory review and approval may be required. All facilities and manufacturing techniques used for the manufacture of our products must comply with applicable regulations governing the production of pharmaceutical products known as Current Good Manufacturing Practices (cGMP). These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Some manufacturing controls and the extent of manufacturing controls needed to achieve appropriate product quality differ not only between investigational and commercial manufacture, but also among the various phases of clinical trials, with later stage clinical trials requiring more extensive controls and documentation. In particular, concurrent with later stage clinical trials, suppliers of biologic materials, including KLH, must develop additional information about the physical characteristics of their biologic products as well as finalize a process for manufacturing the material in commercial quantities in accordance with cGMP requirements. Where applicable, manufacturers are also expected to implement manufacturing controls that reflect product and manufacturing considerations, evolving process and product knowledge, and manufacturing experience. We are responsible for regularly assessing compliance with GMP requirements through record reviews and periodic audits and for ensuring that we take corrective action for any identified deficiencies.

The FDA and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities and processes following initial approval of a product. If, as a result of these inspections, it is determined that our equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may issue warning or similar letters or may seek civil, criminal, or administrative sanctions against us. To date, we have not been subject to inspection by the FDA or other drug regulatory agency because none of our customers or partners has filed an application in any country for marketing approval of a product encompassing our Stellar KLH protein.

New Drug Development

None of our KLH products have been subject to approval as a drug by any regulatory authority. However, a number of our customers and strategic partners are utilizing Stellar KLH in the development of pharmaceuticals and immunotherapies that would be subject to the regulatory approval process in various jurisdictions. The regulatory approval process for new drugs under development by our customers is typically long and expensive. Clinical trials that they conduct may not be successful and such products may not receive regulatory approval. Delays by our customers in obtaining, or the inability to obtain, regulatory approvals for their products which use Stellar KLH will have a direct effect on the demand for our products.

Employees

As of November 28, 2018, we had 25 employees. We consider our employee relations to be good. None of our employees are represented by a labor union or collective bargaining agreement.

Corporate Information

We operate through our wholly-owned subsidiary, Stellar Biotechnologies, Inc., a California corporation which was organized September 9, 1999. We acquired the subsidiary on April 12, 2010 through a reverse merger and began trading on the TSX Venture Exchange (TSX-V) under the symbol "KLH" on April 19, 2010. We were originally incorporated in Canada on June 12, 2007 under the name China Growth Capital, Inc. and subsequently changed our name to CAG Capital, Inc. on April 15, 2008. We began trading on the TSX Venture Exchange as a Canadian capital pool company on August 29, 2008, and were continued as a British Columbia corporation on November 25, 2009. Our reverse merger in April 2010 constituted our "qualifying transaction" under Canadian law, at which time we changed our name to Stellar Biotechnologies, Inc. In January 2013, we began trading on the U.S. OTCQB Marketplace under the symbol "SBOTF" and, on November 5, 2015, our common shares began trading on The Nasdaq Capital Market (Nasdaq) under the symbol "SBOT." On March 29, 2016, at our request, our common shares were voluntarily delisted from the TSX-V in Canada and ceased trading on the TSX-V as of the close of business on April 8, 2016.

Our executive offices are located at 332 East Scott Street, Port Hueneme, California 93041. Our phone number is (805) 488-2800. Our website address is www.stellarbiotechnologies.com. The contents of our website are not part of this Annual Report on Form 10-K for any purpose or otherwise incorporated by reference. Our website address is included for information only.

Available Information

We file or furnish periodic reports, including our annual reports on Form 10-K, our quarterly reports on Form 10-Q and current reports on Form 8-K, proxy statements and other information with the SEC, and amendments to such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange of 1934, as amended, as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Our reports, proxy statements and other information are also made available, free of charge, on our investor relations website at ir.stellarbiotechnologies.com as soon as reasonably practicable after we electronically file such information with the SEC. References to our corporate website address (www.stellarbiotechnologies.com) in this Annual Report on Form 10-K are intended to be inactive textual references only, and none of the information contained on our website is part of this report or incorporated in this report by reference.

Smaller Reporting Company

We are currently a “smaller reporting company” as defined by Rule 12b-2 of the Securities Exchange Act of 1934 (Exchange Act), and are thus allowed to provide simplified executive compensation disclosures in our filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting and have certain other reduced disclosure obligations with respect to our SEC filings.

Item 1A. RISK FACTORS.

Certain factors may have a material adverse effect on our business, financial conditions and results of operations. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes, before deciding to invest in our common shares. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects could be materially and adversely affected.

Risks Related to Our Business

We have a history of net losses and limited cash flow to sustain our operations.

We currently have limited revenue from product sales of Stellar KLH, and anticipate our planned total operating expenses will be greater than our revenues for the foreseeable future. We incurred net losses of \$5.0 million in fiscal 2018 and \$5.0 million in fiscal 2017. As of September 30, 2018, we have an accumulated deficit of \$50.4 million since inception. To date, we have not paid dividends on our common shares and do not anticipate doing so in the foreseeable future. We have historically relied upon the sale of common shares to help fund our operations and meet our obligations. Any future additional equity financing would cause dilution to current shareholders. If we do not have sufficient capital for our operations, management would be forced to reduce or discontinue our activities, which would have a negative effect on our operations and financial condition.

We depend heavily on the success and market acceptance of Stellar KLH and we may never recoup our investment into its research and development.

We have invested a significant portion of our time and financial resources into the development of Stellar KLH. We anticipate that in the near term our ability to generate revenues will depend solely on the commercial success of Stellar KLH, which depends upon its market acceptance by purchasers in the pharmaceutical market and the future market demand and medical need for products and research utilizing KLH. The degree of market acceptance of Stellar KLH depends on a number of factors including: the advantages and disadvantages of Stellar KLH as compared to other KLH sources and carrier molecules; our ability to educate the industry about the high quality, sustainable and traceable qualities of Stellar KLH; product efficacy; customer service; and the price and demonstrated cost-effectiveness of Stellar KLH as compared to our competitors.

Our customers face uncertainties related to regulatory approval, which could reduce the market for our products.

A primary market for our Stellar KLH products is its use as a component of active immunotherapies, which are currently under development. The pharmaceutical industry is subject to significant government regulation, which varies from country to country. None of the products being developed by our customers that utilize our Stellar KLH are approved for commercial sale or have been submitted in a marketing application where our KLH DMF would be reviewed by a regulatory authority. Before regulatory approvals for the commercial sale of any drug is granted, it must be demonstrated through preclinical research and clinical trials to be safe and effective for its intended use in humans. The process to determine safety and efficacy, including clinical trials, is expensive, prolonged and uncertain. The time necessary to complete these processes and clinical trials, and to submit applications for regulatory approvals, is difficult to predict and is subject to numerous factors outside of our customers’ control. Such clinical trials may not be successful. Larger or later stage clinical trials may not produce the same results as earlier trials. Successful results in clinical trials may not result in regulatory approval, due to certain factors including unacceptable side effects or safety issues. If our KLH is referenced in a pending marketing application or regulatory approval is granted for any drug or product that utilizes Stellar KLH, it will be subject to ongoing regulatory requirements, which include registration, manufacturing, labeling, advertising and promotion, packaging, distribution, record keeping and reporting, and storage. Because Stellar’s KLH has not been part of a marketing application where our DMF was reviewed, no regulatory authority has inspected Stellar or its manufacturing operations. Manufacturing facilities, both those operated by us and by our contractors, would be subject to continual review and inspection, and failure to meet these regulatory requirements can interrupt, delay, or shut down these facilities. Previously unknown problems may result in regulatory restrictions on such products, including withdrawal from the marketplace. Delays in obtaining regulatory approvals for products developed by our customers that use Stellar KLH, or failure to obtain or maintain regulatory approvals altogether, would have a negative effect on market demand for our Stellar KLH products, and have a negative effect on our operations and financial condition.

Our business is geographically concentrated and if a catastrophic event, such as a hurricane, an earthquake or coastal flooding, were to impact our facilities, our business may be disrupted which could result in serious harm to our business, results of operations and financial condition.

Our aquaculture operations, research and manufacturing facilities, laboratory space, and executive offices are all located in Port Hueneme, California, a coastal city located along the Pacific Ocean. To date, we have conducted all of our aquaculture operations, research and manufacturing at these facilities and we currently have no active backup facilities or second sites. While we are investigating the establishment of additional aquaculture capabilities in Baja California, Mexico, there can be no assurance that these expansion plans will result in successful development of additional sites of research and manufacturing and KLH production outside of our Port Hueneme location. If a hurricane, an earthquake or other natural disaster, including coastal flooding, or a disease affecting our limpet colony, were to impact our facilities, we may be unable to manufacture our KLH products, which would have a serious disruptive impact on our business and a material adverse effect on our results of operations and financial condition. While we carry personal property insurance, such insurance may not be adequate to compensate us for losses from any damage or interruption of our business operations resulting from a hurricane, an earthquake, coastal flooding or other catastrophic event.

Government and geopolitical changes may impede the implementation of our strategy outside the United States.

Changes in geopolitical policies of the United States, such as changes in U.S. support for existing treaty and trade relationships with other countries, may adversely impact (i) the ability or willingness of non-U.S. companies to transact business in the United States, including with Stellar (ii) regulation and trade agreements affecting U.S. companies, (iii) global stock markets (including The Nasdaq Capital Market on which our common shares are traded), and (iv) general global economic conditions. These factors are outside of our control, but may nonetheless cause us to adjust our strategy in order to compete effectively in global markets.

Our joint venture with Neovacs involves numerous risks that could adversely impact our financial results.

In May 2016, we entered into a strategic relationship with Neovacs S.A. to manufacture and sell conjugated therapeutic vaccines through a newly-formed joint venture entity in France called Neostell S.A.S. This relationship is subject to various risks that could adversely affect the value of our investments and our results of operations. These risks include the following:

- our interests could diverge from those of Neovacs or we may not be able to agree on ongoing manufacturing and operational activities, or on the amount, timing, or nature of further investments in Neostell;
- we may experience difficulties in transferring technology to Neostell;
- we may experience difficulties and delays in manufacturing and production at Neostell;
- as a minority partner, our control over the operations of Neostell is limited;
- Neovacs may be unable to meet its commitments to us or to Neostell, which may pose credit risks for our transactions with them;
- due to differing business models or long-term business goals, we and Neovacs may not participate to the same extent on funding capital investments in Neostell;
- our working capital or cash flows may be inadequate to fund increased capital requirements in Neostell;
- we may experience difficulties or delays in collecting amounts due to us from Neostell and/or Neovacs due to multinational financial regulations or geopolitical forces beyond our control; and
- shifts in the geopolitical landscape may result in tax, legal, or regulatory changes in the United States, France and/or the European Union, thereby necessitating amendments to the agreements with Neovacs and/or the structure of the joint venture.

If our joint venture with Neovacs is unsuccessful, our business, results of operations, or financial condition may be materially adversely affected.

Our expansion plans include the design and development of aquaculture infrastructure and KLH production in Mexico which presents substantial risks to our business and personnel. We may never recoup our investment into this location.

We are investigating the establishment of additional aquaculture capabilities in Baja California, Mexico, including research collaborations with local organizations and companies, site suitability studies, raw material sourcing and the development of regional marine resources, in anticipation of the increased demand for our KLH products, among other considerations. There are certain administrative, legal, governmental and societal risks to operating in Mexico that could adversely impact our ability to expand our operations there. Any one or more of the risks that could adversely affect our ability to successfully implement our expansion and therefore ultimately have a material adverse effect on our business, financial condition and results of operations include, without limitation:

- geopolitical factors could adversely impact the ongoing relationship between the United States and Mexico and/or the continuity of current or future trade agreements;
- regional political and economic instability;
- ability to hire and maintain a significant work force;
- burdensome and evolving government regulations;

- cooperation of various departments of the Mexican government in issuing permits, and inspecting our operations on a timely basis;
- providing adequate security for our employees; and
- change in the value of the Mexican peso.

In addition, our international operations are governed by the U.S. Foreign Corrupt Practices Act and similar anti-corruption laws outside the U.S. Global enforcement of anti-corruption laws has increased substantially in recent years, with more enforcement proceedings by U.S. and foreign governmental agencies and the imposition of significant fines and penalties. While we have implemented policies and procedures to enhance compliance with these laws, our international operations create the risk that there may be unauthorized payments or offers of payments made by employees, consultants, sales agents or distributors. Any alleged or actual violations of these laws may subject us to government investigations, significant criminal or civil sanctions and other liabilities, and negatively affect our reputation.

Our sales in international markets subject us to foreign currency exchange and other risks and costs, which could harm our business.

Substantial portions of our revenues are derived from outside the United States; primarily from Europe and Asia. We anticipate that revenues from international customers will continue to represent a substantial portion of our revenues for the foreseeable future. All our revenues are generated in U.S. dollars. However, if the effective price of our products were to increase as a result of fluctuations in foreign currency exchange rates, demand for our products could decline and adversely affect our results of operations and financial condition.

We compete with other companies in KLH production and manufacturing that may have greater resources than we do.

The immunotherapy industry is rapidly evolving and new competitors with competing technologies and products are regularly entering the market. Our Stellar KLH products are similar to KLH-based products produced by other companies. While we believe we are the only company that offers GMP grade KLH supported by fully traceable production methods, we may not be able to maintain our competitive position against current and potential competitors. We compete directly with Biosyn Corporation, a pharmaceutical and biotechnology company which manufactures KLH starting material and offers clinical and research grade KLH products. We also compete directly with SAFC, a division of Sigma-Aldrich that has historically offered clinical and research grade KLH products. Some of our competitors, both public and private, have greater financial and personnel resources than us, greater experience than us at producing products under GMP conditions suitable for later stage clinical studies, and have greater sales and marketing experience in the industry than us. If they are able to produce and sell comparable KLH products for less than us, it will have a negative effect on our operations and financial position. In addition to competition from current suppliers of KLH, we also face indirect competition from developers of other carrier molecules, adjuvants or therapeutic vaccine platforms. We are unable to predict what effect evolution of the KLH and immunotherapy industries and potential new entrants may have on price, selling strategies, intellectual property or our competitive position.

We may not be able to meet demand for KLH from either internally raised or ocean harvest sources.

We are dependent upon a supply of Giant Keyhole Limpets (*Megathura crenulata*) for KLH production. The range of the Giant Keyhole Limpet in the wild is limited, and due to the lack of a regulated harvest, the wild stocks of Giant Keyhole Limpets are believed to be declining. If the wild stocks are depleted, and our hatchery and aquaculture operations are unable to produce sufficient supplies of captive Giant Keyhole Limpets to meet demand, it would have a negative effect on our operations and financial condition.

We may not be able to manufacture our products in commercial quantities and currently depend on third parties for certain steps in our manufacturing operations, which could prevent us from marketing our products.

The manufacture of pharmaceutical starting materials like KLH requires significant expertise, including the development of advanced manufacturing techniques and process controls that are GMP compliant. We may encounter difficulties in production or meeting GMP standards, particularly in scaling up production or transferring production to a contract manufacturing organization. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations.

We are currently dependent upon a small number of contractors and locations for certain steps in our manufacturing operations, and may be unable to establish and maintain relationships with qualified vendors in order to produce sufficient supplies of our finished products. We do not currently have backup manufacturing capacity for some of our key products. If we are unable to retain our current contractors, or are unable to obtain new contractors to provide manufacturing or testing services in a timely manner and on similar terms, it will have a negative effect on our operations. Further, these contract manufacturers and testing organizations provide services to many biotechnology and research companies, and such third party contractors may not provide acceptable quality, quantity or costs required by us. In addition, they may not be able to provide the services required on a schedule acceptable to us. These issues may result in us being unable to manufacture our products in the required quantities or at an acceptable cost, which would have a negative effect on our operations and financial condition.

We have been, and expect to continue to be in the future, significantly dependent on collaboration and supply agreements for the development and sales of Stellar KLH.

In conducting our research and development and commercialization activities, have relied, and expect to continue to rely, on collaboration and supply agreements with third parties, such as commercial partners, contract manufacturing organizations, contract research and testing organizations, universities, governmental agencies and not-for-profit organizations, for strategic, technological, and financial resources. The inability to secure agreements on acceptable terms, the termination of these relationships, changes in our strategy or development plans or those of third parties, or failure to perform by us or third parties who are subject to regulatory, competitive and other risks, under their respective agreements or arrangements with us, would substantially disrupt or delay our research and development and commercialization activities, including future commercial sales. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

We have limited marketing, sales and distribution experience and capabilities. We will need to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products.

We currently have limited experience in the marketing, sales and distribution of KLH products. Depending on market acceptance of our Stellar KLH products, we may need to expand our capabilities. We may not be able to establish such additional capabilities in-house, and then will need to enter into agreements with third parties to successfully perform these tasks. If we contract or make arrangements with third parties for the sales and marketing of our products, our revenues will be dependent on the efforts of these third parties, whose efforts may not be successful. If we market any of our products directly, we must either internally develop or acquire a marketing and sales force, which would require substantial resources and management attention.

We rely on the significant experience and specialized expertise of our Chief Executive Officer and other members of our senior management team, and we will need to hire and retain other highly skilled personnel to maintain and grow our business.

Our ability to be successful in the highly competitive biotechnology and pharmaceutical industries depends in large part upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and other personnel. Our performance is substantially dependent on the research and development and business development expertise of our executive officers and senior staff. We do not have employment agreements currently in effect with our executive officers, and they are free to leave their employment with us at any time.

There is little possibility that this dependence will decrease in the near term. The loss of the services of our executive officer, or the increased demands placed on our key executives and personnel, could adversely affect our financial performance and our ability to execute our strategies. Our continued success also depends on our ability to attract and retain qualified team members to meet our future growth needs. We may not be able to attract and retain necessary team members to operate our business.

In addition, our future success depends on our ability to identify, attract, hire, train, retain and motivate highly skilled technical, managerial and research personnel in all areas within our organization. We plan to grow our business and will need to hire additional personnel to support this growth. We believe that there are only a limited number of individuals with the requisite skills to serve in many of our key positions, and we compete for key personnel with other biotechnology companies, as well as universities and research institutions. It is often difficult to hire and retain these persons, and we may be unable to timely replace key persons if they leave or be unable to fill new positions, as they become available, requiring key persons with appropriate experience. If we fail to attract, integrate and retain the necessary personnel, our ability to maintain and grow our business could suffer significantly.

We are subject to the risk of product liability claims, for which we may not have, or be able to obtain, adequate insurance coverage.

The pharmaceutical industry is subject to product liability claims in the event of adverse effects, even in respect to products that have received regulatory approval for commercial sale. Such claims might be made directly by consumers, healthcare providers or by pharmaceutical companies, or others selling or utilizing our Stellar KLH products. Although we currently maintain liability insurance for our products, we may not be able to obtain or maintain sufficient and affordable insurance coverage for all claims that may occur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our potential inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition and results of operations.

Our activities are subject to regulation in the United States and in the foreign jurisdictions in which we operate. Failure to comply with applicable laws and regulations could adversely impact our operations.

Our operations, including our aquaculture and harvesting activities, are subject to regulation at the local, state and federal levels in the United States by a number of regulatory agencies including, the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Secretary of the Navy, the Regional Water Quality Control Board, the California Department of Fish and Wildlife, and similar foreign agencies. In addition to regulations in the United States, we may be subject to a variety of foreign regulations related to research, manufacturing, and the commercial sales and distribution of our products, to the extent we choose to manufacture, sell or distribute any products outside of the United States. If we are unable to comply with laws and regulations in the United States and elsewhere, our operations could be restricted, or sanctions could be imposed on us, if we are found to not be in compliance with any such regulation.

We may face environmental risks related to handling regulated substances and hazardous materials.

Our research and clinical development activities, as well as the manufacture of materials and products, are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. We may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and clinical development, both now and in the future, may involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals. We cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources. In addition, in the event of an accident, applicable authorities may curtail our use of hazardous materials and interrupt our business operations.

Risks Related to Intellectual Property

The inability to protect our intellectual property rights could result in competitive harm to our Company.

Our success and ability to maintain our competitive position depends on our ability to protect our intellectual property, including by obtaining patent protection in the United States and other countries, or through protection of our trade secrets, including unpatented know-how, technology and other proprietary information. When appropriate, we seek to protect our proprietary position by filing patent applications in the United States and other countries. If we are unable to protect our intellectual property, whether by obtaining patents or through trade secret protection, our competitors could develop and commercialize products similar or identical to ours.

We may not have adequate remedies for any infringement or funds to take action against those infringing any of our intellectual property rights, or if our trade secrets otherwise become known or independently developed by competitors. There can be no assurance that any current or future patents held, licensed by or applied for by us will be upheld, if challenged, or that the protections afforded will not be circumvented by others. The patent positions of biotechnology and pharmaceutical companies, which often involve licensing agreements, are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patents, patent applications and licensed rights may not provide protection against competitive technologies or may be held invalid if challenged or could be circumvented. If we enter litigation in regards to our business or to protect or enforce our patents, it may involve substantial expenditures and require significant management attention, even if we ultimately prevail.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited.

In addition, some of our technologies are not covered by any patent application and we rely instead on confidentiality agreements and trade secret law to protect such intellectual property rights. We require all of our employees and consultants to sign confidentiality agreements. The agreements also oblige our employees, and to the extent practicable, our consultants, and advisors, to assign to us ideas, developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that these agreements will maintain confidentiality, will prevent disclosure, or will protect our proprietary information or intellectual property, or that others will not independently develop substantially equivalent proprietary information or intellectual property.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our success depends, in part, on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the “freedom to operate.” The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, interference proceedings and related legal and administrative proceedings, both in the United States and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming, and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the United States are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to a product or method similar to ours may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our products, methods or other claims, we may have to participate in an adversarial proceeding, such as an interference or derivation proceeding in the USPTO or similar proceedings in other countries, to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be subject to injunctions or damage awards.

In the future, the USPTO or a foreign patent office may grant patent rights to our claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further use, develop or commercialize such products or methods. Any required licenses may not be available to us on acceptable terms, if at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and compelled to pay significant damages, including punitive damages, which could harm our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

Certain of our employees were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, consultants, independent contractors or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, we may lose our rights to such information, in addition to paying monetary damages. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related Ownership of Our Securities

The price of our common shares may be subject to substantial volatility.

Although our common shares are listed on The Nasdaq Capital Market in the United States, there can be no assurance that an active trading market for our common shares will be maintained on Nasdaq, or that the volume of trading will be sufficient to allow for timely trades. Investors may not be able to sell our common shares quickly or at the latest market price if trading in our shares is not active or if trading volume is limited. In addition, if trading volume in our common shares is limited, trades of relatively small numbers of shares may have a disproportionate effect on the market price of our common shares.

Furthermore, the stock market is subject to significant price and volume fluctuations, and the price of our common shares has been in the past, and may continue in the future to be subject to wide fluctuations in response to several factors, including:

- our quarterly or annual operating results;
- our cash and cash equivalents position;
- changes in our earnings estimates;
- investment recommendations by securities analysts following our business or our industry;
- additions or departures of key personnel;
- changes in the business, earnings estimates or market perceptions of our competitors;
- our failure to achieve operating results consistent with securities analysts' projections;
- announcements or the expectation of raising additional financing;
- sales of our common shares by us, our insiders or other shareholders;
- the status of our listing on the Nasdaq;
- changes in industry, general market or economic conditions; and
- announcements of legislative or regulatory changes in the United States and in other countries where we transact business.

The stock markets in general, and the small-cap biotech market, in particular, have experienced extreme price and volume fluctuations in recent years that have significantly affected the quoted prices of the securities of many companies, including companies in our industry. The changes often appear to occur without regard to specific operating performance. The price of our common shares could fluctuate based upon factors that have little or nothing to do with our company and these fluctuations could materially reduce our share price.

If we cannot meet Nasdaq's continuing listing requirements and Nasdaq rules, Nasdaq may delist our securities, which could negatively affect our Company and the price of our securities.

Although our shares are currently listed on Nasdaq, in the future, we may not be able to meet the continued listing requirements of Nasdaq, which require, among other things, a minimum bid price of \$1.00 per share for common shares listed on the exchange. If we are unable to satisfy the Nasdaq criteria for maintaining our listing, our securities could be subject to delisting. Without a Nasdaq listing, shareholders may have a difficult time getting a quote for the sale or purchase of our shares, the sale or purchase of our shares would likely be made more difficult, and the trading volume and liquidity of our shares could decline. Delisting from Nasdaq could also result in negative publicity and could make it more difficult for us to raise additional capital. If our common shares are delisted by Nasdaq, our common shares may be eligible to trade on an over-the-counter quotation system where an investor may find it more difficult to sell our shares or obtain accurate quotations as to the market value of our common shares. We cannot assure you that our common shares, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the-counter quotation system.

We may require additional financing or financings, which would result in substantial dilution to existing shareholders.

While the Company plans to finance company operations for at least the next twelve months with cash on hand and product sales, management expects to continue incurring losses for the foreseeable future and may need to raise additional capital to pursue our business plan. In addition, we may decide to expand operations, undertake strategic acquisitions or determine some other business need. Financing could include debt and/or equity financings, including transactions with strategic customers and partners that may include debt and/or equity arrangements. Such sources of financing may not be available on acceptable terms, if at all. Failure to obtain such financing may cause us to curtail or cease operations and/or result in delay or indefinite postponement of research and development of our Stellar KLH, expansion initiatives, capital expenditures and other operational priorities. Any transaction involving the issuance of previously authorized but unissued common shares, or securities convertible into common shares, could result in dilution, possibly substantial, to present and prospective holders of common shares and may be on terms less favorable to us.

We could be deemed a “passive foreign investment company” in the future, which could have negative consequences for U.S. investors.

We would be designated as a “passive foreign investment company”, or a PFIC, under the meaning of Section 1297 of the United States Internal Revenue Code of 1986, as amended, or the Code, if (a) 75% or more of our gross income is “passive income” (generally, dividends, interest, rents, royalties and gains from the disposition of assets producing passive income) in any taxable year, or (b) at least 50% of the average value of our assets produce, or are held for the production of, passive income. If we are designated a PFIC for any taxable year during which a U.S. shareholder holds our common shares, it would likely result in materially adverse U.S. federal income tax consequences for such U.S. shareholder, including, but not limited to, any gain from the sale of our common shares would be taxed as ordinary income, as opposed to capital gain, and such gain and certain distributions on our common shares would be subject to an interest charge, except in certain circumstances. In addition, U.S. shareholders should be aware that there can be no assurances that we would be able to satisfy the record keeping requirements that apply to a PFIC, or that we would supply U.S. shareholders with the information that such U.S. shareholders require to make certain elections available under the Code that are intended to mitigate the adverse tax consequences of the PFIC rules. The PFIC rules are extremely complex. A U.S. shareholder of our common shares is encouraged to consult a tax advisor regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of our common shares.

We are governed by the corporate laws in British Columbia, Canada which in some cases have a different effect on shareholders than the corporate laws in Delaware.

The material differences between the British Columbia Business Corporations Act (BCBCA) as compared to the Delaware General Corporation Law (DGCL) which may be of most interest to shareholders include the following: (i) for material corporate transactions (such as amalgamations, other extraordinary corporate transactions, amendments to the notice of articles and amendments to the Articles), the BCBCA generally requires a two-thirds majority vote by shareholders (and, in addition, especially where the holders of a class of shares are being affected differently from others, approval will be required by holders of two-thirds of the shares of such class voting in a meeting called for that purpose), whereas the DGCL generally only requires a majority vote of shareholders for similar material corporate transactions; (ii) quorum for shareholders meetings is not prescribed under the BCBCA and is 33-1/3% under our Articles (to assure compliance with Nasdaq corporate governance requirements); whereas, under the DGCL, quorum requires the holders of a majority of the shares entitled to vote to be present; and (iii) our Articles require a two-thirds majority vote of shareholders to pass a resolution for one or more directors to be removed, whereas the DGCL requires only the affirmative vote of a majority of the shareholders. Accordingly, certain provisions of our corporate governance under the laws of British Columbia may be disadvantageous to our shareholders.

Risks Related to an Emerging Growth and Smaller Reporting Company

We are an “emerging growth company” under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common shares less attractive to investors.

We are an “emerging growth company” (EGC) as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act), and as a result, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies.” We will remain an EGC until the expiration of this status as provided by the JOBS Act or we meet other criteria. We may choose to take advantage of some but not all of these reduced reporting burdens. As EGC we are exempt from Sarbanes-Oxley requirements that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting, certain executive compensation and discussion reporting requirements and certain other reduced disclosure obligations with respect to our SEC filings. We have elected not to take advantage of the extended transition period for complying with new or revised accounting standards.

If we take advantage of any of these reduced reporting burdens in future filings, the information that we provide our security holders may be different than information such security holders might receive from other public companies in which they hold equity interests. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

As a smaller reporting company, we cannot be certain if such reduced disclosure will make our common stock less attractive to investors.

We are currently a “smaller reporting company” as defined in the Exchange Act, and are thus allowed to provide simplified executive compensation disclosures in our filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting and have certain other reduced disclosure obligations with respect to our SEC filings. We will remain a “smaller reporting company” until the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our recently completed second fiscal quarter is over \$250 million or we have over \$100 million in annual revenues. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Item 1B. UNRESOLVED STAFF COMMENTS.

None.

Item 2. PROPERTIES.

We currently lease 4,300 square feet of executive office and laboratory space in Port Hueneme, California under a lease which expires in July 2020, with options to renew for three successive two-year terms.

Our aquaculture and KLH manufacturing operations are located on approximately 37,000 square feet of oceanfront land in the Port Hueneme Aquaculture Business Park. Our facilities here include specialized aquaculture infrastructure, seawater supply and discharge systems, laboratories, manufacturing and administrative offices. We have two sublease agreements which expire in September and October 2020, respectively, with options to extend the leases for two additional five-year terms.

We currently lease undeveloped land in Baja California, Mexico under a lease agreement which expires in June 2020, with an option to extend the lease for 30 years. In February 2018, the lease term was extended for two years without further rent payments. We have made certain leasehold improvements, including power-generating equipment and structures, and are holding the undeveloped land for potential future expansion of production. In Mexico, we also have a short-term lease for administrative office space in a business center located in Ensenada, Baja California.

Item 3. LEGAL PROCEEDINGS.

From time to time, we may be involved in legal proceedings, claims and litigation arising in the ordinary course of business, including contract disputes, employment matters and intellectual property disputes. We are not currently a party to any material legal proceedings or claims outside the ordinary course of business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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.

Market Information

Our common shares trade on The Nasdaq Capital Market in the United States under the symbol “SBOT”.

Holders

As of November 28, 2018, we had 5,330,715 common shares outstanding, with 9 shareholders of record. The number of record shareholders was determined from the records of our stock transfer agent and does not reflect persons or entities that hold their shares in nominee or “street” name through various brokerage firms.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12 “*Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*” of this report.

Dividends

We have not declared any dividends on our common shares since our incorporation and do not anticipate that we will do so in the foreseeable future. Our present policy is to retain future earnings, if any, for use in our operations and the expansion of our business.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

None.

Purchase of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. SELECTED FINANCIAL DATA.

We are a smaller reporting company and are not required to provide the information under this item.

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

This discussion contains forward-looking statements that involve risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by such forward-looking statements as a result of many important factors, including those set forth in Part I of this Annual Report on Form 10-K under the caption "Risk Factors." Please see "Special Note Regarding Forward-Looking Statements" in Part I above. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.

Operating and Financial Review and Prospects

Overview

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and include the accounts of the Company and our wholly-owned subsidiaries, Stellar Biotechnologies, Inc. and BioEstelar S.A. de C.V.

In the past, operations of the Company have primarily been funded by the issuance of common shares, exercise of warrants, grant revenues, contract services revenue and product sales. In May and June 2018, we completed equity financings and warrant exercises resulting in net cash proceeds of \$8.8 million. Management believes the Company's working capital is sufficient to support the Company's operations for at least the next 12 months. Management also seeks to expand the customer base for existing marketed products, and may seek additional financing through debt and/or equity financings, including transactions with strategic customers and partners that may include debt and/or equity arrangements.

Results of Operations

Fiscal Year Ended September 30, 2018 Compared to the Fiscal Year Ended September 30, 2017

Our total revenues decreased by \$0.02 million to \$0.21 million for fiscal 2018 compared to \$0.23 million for fiscal 2017 due to a decrease in contract services revenue which was partially offset by an increase in product sales. Contract services revenue in fiscal 2017 was related to a technology transfer that was completed in March 2017. Product sales volumes are subject to variability associated with the rate of development and progression of clinical studies of third-party products that utilize Stellar KLH. The rate of progression toward later stage studies is expected to continue to affect the timing and volume of future product sales. During both years, product mix was similar, consisting of various grades of KLH for clinical and pre-clinical studies and immune system assays.

Our total expenses decreased by \$0.16 million to \$5.29 million for fiscal 2018 compared to \$5.45 million for fiscal 2017:

- Our cost of sales and contract services decreased by \$0.12 million to \$0.13 million for fiscal 2018 compared to \$0.25 million for fiscal 2017 primarily due to reduced expenses related to sales of KLH that was produced as a byproduct of our research and development activities.
- Our costs of aquaculture increased by \$0.03 million to \$0.31 million for fiscal 2018 compared to \$0.28 million for fiscal 2017 primarily due to increased testing expenses related to new state regulatory requirements.
- Our research and development expenses increased by \$0.11 million to \$2.09 million for fiscal 2018 compared to \$1.97 million for fiscal 2017. The increase was primarily due to an increase in research and development activities intended to increase the scalability and throughput capacity of existing manufacturing systems, including engineering lots of KLH produced under our optimization initiative, as well as a non-cash item related to our share of operational expenses of the Neostell joint venture. An increase in contracted research services and additional research and development in aquaculture, analytics and product formulation also contributed to the increase.
- Our general and administrative expenses decreased by \$0.19 million to \$2.76 million for fiscal 2018 compared to \$2.94 million for fiscal 2017 primarily due to reduced professional fees and travel expenses.

Our total other income (loss) decreased by \$0.15 million to an overall gain of \$0.04 million for fiscal 2018 compared to an overall gain of \$0.19 million for fiscal 2017 primarily due to fluctuations in Canadian exchange rates.

Our net loss for fiscal 2018 was \$5.04 million, or \$1.76 per basic share, compared to a net loss of \$5.03 million, or \$3.44 per basic share, for fiscal 2017. The weighted average number of shares used in the calculation of net loss per share for fiscal years 2018 and 2017 were 2,869,374 and 1,462,459, respectively.

Capital Expenditures

Our capital expenditures, which primarily consist of scientific, manufacturing, and aquaculture equipment, and facility leasehold improvements for the previous two fiscal years are as follows:

2018	\$ 382,810
2017	302,733

The increase in fiscal 2018 over fiscal 2017 was due primary to an increase in construction in progress related to the construction of renovated ocean-front space for aquaculture production and related activities at our facility located at the Port of Hueneme. We expect to continue investing in capital expenditures in the future as we prepare our core aquaculture infrastructure for expanded capacity as we deem appropriate based on third party clinical milestones and market conditions. Capital expenditures include \$330,057 of construction in progress, primarily for aquaculture site improvements and installation of lab equipment.

Liquidity and Capital Resources

Our operations have historically been funded by the issuance of common shares, exercise of warrants, grant revenues, contract services revenue and product sales. For the fiscal years 2018 and 2017, the Company reported net losses of approximately \$5.0 million and \$5.0 million, respectively. As of September 30, 2018, the Company had an accumulated deficit of approximately \$50.4 million and working capital of approximately \$10.2 million. We plan to finance company operations for at least the next twelve months with cash and investments on hand and product sales. Management has flexibility to adjust planned expenditures based on a number of factors including the size and timing of capital expenditures, staffing levels, inventory levels, and the status of customer clinical trials. Management also seeks to expand the customer base for existing marketed products, and may seek additional financing through debt and/or equity financings, including transactions with strategic customers and partners that may include debt and/or equity arrangements.

On May 15, 2018, we completed a registered public offering resulting in net proceeds of \$4.64 million. On May 29, 2018, we closed an offering with certain holders of our warrants, pursuant to a warrant exercise agreement, resulting in net proceeds of \$2.49 million. During May and June 2018, other warrant exercises resulted in net proceeds of \$1.64 million.

At September 30, 2018, we had cash, cash equivalents and short-term investments in U.S. Treasury Bills of \$10.3 million, working capital of \$10.2 million, shareholders' equity of \$11.3 million and an accumulated deficit of \$50.4 million.

Research and Development

Our core business is developing and commercializing Keyhole Limpet Hemocyanin for use in immunotherapy and immunodiagnostic applications. Our internal research has included, among other activities, improvement of methods for the culture and growth of Giant Keyhole Limpet, developing proprietary formulated limpet diets, innovations in aquaculture systems and infrastructure, biophysical and biochemical characterization of the KLH molecule, analytical processes to enhance performance of our products, KLH manufacturing process improvements, new KLH formulations and KLH-related technologies, and new uses for KLH in immunotherapy and immunodiagnostic applications.

Research and development costs, including (i) materials, (ii) KLH designated for internal research use only and (iii) salaries of employees directly involved in research and development efforts, are expensed as incurred. From time to time, we produce saleable KLH as a byproduct of our research and development activities. The cost of this KLH is not assigned to inventory.

The following table includes our research and development costs for each of the most recent two fiscal years:

2018	\$ 2,087,402
2017	1,973,400

The increase in fiscal 2018 over fiscal 2017 was primarily due to research and development activities intended to increase the scalability and throughput capacity of existing manufacturing systems, including engineering lots of KLH produced under our optimization initiative

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Foreign Exchange Risk

Our exposure to foreign exchange risk is primarily related to fluctuations between the Canadian dollar and the U.S. dollar. Funds held in Mexican pesos are nominal. We incur operating expenses and capital expenditures mostly in U.S. dollars, with some operating expenses incurred in Canadian dollars which are subject to foreign currency fluctuations. The fluctuation of the U.S. dollar in relation to the Canadian dollar will have an impact upon our profitability and may also affect the value of our assets and the amount of shareholders' equity. We have not entered into any agreements or purchased any instruments to hedge possible currency risks. At September 30, 2018, we held approximately CDN\$0.7 million in cash and cash equivalents in Canadian dollars and the U.S. dollar was equal to 1.2918 Canadian dollars. Based on the exposure at September 30, 2018, a 10% annual change in the Canadian/U.S. exchange rate over the prior year would impact our net loss by \$0.05 million.

Concentration of Credit Risk

We are potentially subject to financial instrument concentration of credit risk through our cash equivalents, US Treasury bills and accounts receivables. We place our cash and cash equivalents in 4 week US Treasury bills or financial institutions believed to be credit worthy and perform periodic evaluations of their relative credit standing. We place short-term investments in 13 to 52 week US Treasury bills. Accounts receivable can be potentially exposed to a concentration of credit risk with our major customers. We assess the collectability of our accounts receivable through a review of our current aging, as well as an analysis of our historical collection rate, general economic conditions and credit status of our customers. As of September 30, 2018 and 2017, all outstanding accounts receivable were deemed to be fully collectible, and therefore, no allowance for doubtful accounts was recorded. We determine terms and conditions for our customers primarily based on the volume purchased by the customer, customer creditworthiness and past transaction history. Management works to mitigate our concentration of credit risk with respect to accounts receivable through our credit evaluation policies, reasonably short payment terms and geographical dispersion of sales. Revenue includes export sales to foreign companies located principally in Europe and Asia.

Significant Accounting Policies and Estimates

Our consolidated financial statements, which are indexed under Item 15 of this Annual Report on Form 10-K, have been prepared in accordance with accounting principles generally accepted in the United States, which require that the management make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 3 in the Notes to Consolidated Financial Statements. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment or may otherwise be more relevant to our financial condition and results of operations.

Investments

Investments at September 30, 2018 and 2017 consisted of U.S. Treasury bills with original maturities between 13 and 52 weeks. They are classified as held-to-maturity and are reported at amortized cost, which approximates fair value. We regularly review these investments to determine whether any decline in fair value below the amortized cost basis has occurred that is other than temporary. If a decline in fair value has occurred that is determined to be other than temporary, the cost basis of the investment is written down to fair value.

Inventory

We record inventory at the lower of cost or market, with market not in excess of net realizable value. Raw materials are measured using FIFO (first-in first-out) cost. Work in process and finished goods are measured using average cost. Raw materials include inventory of manufacturing supplies. Work in process includes manufacturing supplies, direct and indirect labor, contracted manufacturing and testing, and allocated manufacturing overhead for inventory in process at the end of the year. Finished goods include products that are complete and available for sale. The Company recorded work in process and finished goods inventory only for those products with recent sales levels to evaluate net realizable value.

Revenue Recognition

Product Sales

The Company recognizes product sales when KLH product is shipped (for which the risk is typically transferred upon delivery to the shipping carrier) and there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collectability is reasonably assured. The Company documents arrangements with customers with purchase orders and sales agreements.

Product sales include sales made under supply agreements with customers for a fixed price per gram of KLH products based on quantities ordered. Supply agreements are typically on a non-exclusive basis except within that customer's field of use.

Contract services revenue

The Company recognizes contract services revenue when contract services have been performed and reasonable assurance exists regarding measurement and collectability. An appropriate amount will be recognized as revenue in the period that the Company is assured of fulfilling the contract requirements. Amounts received in advance of performance of contract services are recorded as deferred revenue.

Contract services include services performed under collaboration agreements and technology transfer and purchase agreement.

Share-Based Compensation

We grant options to buy common shares of the Company to our directors, officers, employees and consultants, and grant other equity-based instruments to non-employees.

The fair value of share-based compensation is measured on the date of grant, using the Black-Scholes option valuation model and is recognized over the vesting period net of estimated forfeitures for employees or the service period for non-employees. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying shares, risk-free interest rate, dividend yield, and expected life of the option.

Foreign Exchange

Items included in the financial statements of our subsidiaries are measured using the currency of the primary economic environment in which the entity operates (the functional currency). Our functional currency and the functional currency of our subsidiaries is the U.S. dollar.

Transactions in currencies other than the U.S. dollar are recorded at exchange rates prevailing on the dates of the transactions.

Recent Accounting Pronouncements

Recent accounting pronouncements are contained in Note 3 to the financial statements, which are indexed under Item 15 of this this Annual Report on Form 10-K.

CERTAIN INCOME TAX CONSIDERATIONS

The following discussion is a summary of certain U.S. federal income tax issues that may be relevant to a U.S. Holder (as defined herein) and non-U.S. Holder (as defined herein), holding and disposing of the Ordinary Shares. Additional tax issues may exist that are not addressed in this discussion and that could affect the U.S. federal income tax treatment of the acquisition, holding and disposition of the Common Shares.

This section is based on the U.S. Tax Code, its legislative history, existing and proposed regulations, published rulings by the IRS and court decisions, all as currently in effect. These laws are subject to change, possibly on a retroactive basis. The discussion applies, unless indicated otherwise, only to U.S. Holders and certain non U.S. Holders who hold Common Shares as capital assets within the meaning of Section 1221 of the U.S. Tax Code (generally, as property held for investment) and use the U.S. dollar as their functional currency. It does not address special classes of holders that may be subject to different treatment under the U.S. Tax Code, such as:

- certain financial institutions;
- insurance companies;
- dealers and traders in securities;
- persons holding Common Shares as part of a hedge, straddle, conversion or other integrated transaction;
- partnerships or other entities classified as partnerships for U.S. federal income tax purposes;
- persons liable for the alternative minimum tax;
- tax-exempt organizations;
- certain U.S. expatriates; or
- persons holding Common Shares that own or are deemed to own 10 per cent or more (by vote or value) of the Company's shares.

United States Federal Income Taxation

As used below, a "U.S. holder" is a beneficial owner of a common share that is, for U.S. federal income tax purposes, (i) a citizen or resident alien individual of the United States, (ii) a corporation (or an entity treated as a corporation) created or organized under the law of the United States, any State thereof or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax without regard to its source or (iv) a trust if (1) a court within the United States is able to exercise primary supervision over the administration of the trust, and one or more United States persons have the authority to control all substantial decisions of the trust, or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person. For purposes of this discussion, a "non-U.S. holder" is a beneficial owner of a common share that is (i) a nonresident alien individual, (ii) a corporation (or an entity treated as a corporation) created or organized in or under the law of a country other than the United States or a political subdivision thereof or (iii) an estate or trust that is not a U.S. Holder. If a partnership (including for this purpose any entity treated as a partnership for U.S. federal tax purposes) is a beneficial owner of a common share, the U.S. federal tax treatment of a partner in the partnership generally will depend on the status of the partner and the activities of the partnership. A holder of a common share that is a partnership and partners in that partnership should consult their own tax advisers regarding the U.S. federal income tax consequences of holding and disposing of common shares. We have not sought a ruling from the Internal Revenue Service (IRS) or an opinion of counsel as to any U.S. federal income tax consequence described herein. The IRS may disagree with the description herein, and its determination may be upheld by a court. This discussion does not address U.S. federal tax laws other than those pertaining to U.S. federal income taxation (such as estate or gift tax laws), nor does it address any aspects of U.S. state or local or non-U.S. taxation.

This summary is based upon certain understandings and assumptions with respect to the business, assets and holders, including that the Company is not, does not expect to become, nor at any time has been a controlled foreign corporation as defined in Section 957 of the U.S. Tax Code ("CFC"). The Company believes that it is not and has never been a CFC, and does not expect to become a CFC. In the event that one or more of such understandings and assumptions proves to be inaccurate, the following summary may not apply and material adverse U.S. federal income tax consequences may result to U.S. Holders.

GIVEN THE COMPLEXITY OF THE TAX LAWS AND BECAUSE THE TAX CONSEQUENCES TO ANY PARTICULAR SHAREHOLDER MAY BE AFFECTED BY MATTERS NOT DISCUSSED HEREIN, SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE SPECIFIC TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF COMMON SHARES, INCLUDING THE APPLICABILITY AND EFFECT OF STATE, LOCAL AND NON-U.S. TAX LAWS, AS WELL AS U.S. FEDERAL TAX LAWS.

Taxation of Dividends

U.S. Holders. In general, subject to the passive foreign investment company rules discussed below, a distribution on a common share will constitute a dividend for U.S. federal income tax purposes to the extent that it is made from a corporation's current or accumulated earnings and profits as determined under U.S. federal income tax principles. If a distribution exceeds the current and accumulated earnings and profits of the distributing corporation, it will generally be treated as a non-taxable reduction of basis to the extent of the U.S. holder's tax basis in the common share on which it is paid, and to the extent it exceeds that basis it will be treated as capital gain. The Company has not and does not plan to maintain calculations of earnings and profits under U.S. federal income tax principles. Accordingly, it is unlikely that U.S. holders will be able to establish that a distribution by the Company is in excess of its current and accumulated earnings and profits (as computed under U.S. federal income tax principles). Therefore, a U.S. holder should expect that a distribution by the Company will generally be taxable in its entirety as a dividend to U.S. holders for U.S. federal income tax purposes even though the distribution may be treated in whole or in part as a non-taxable distribution for Canadian tax purposes.

The gross amount of any dividend on a common share (which will include the amount of any Canadian taxes withheld with respect to such dividend) generally will be subject to U.S. federal income tax as foreign source dividend income, and will not be eligible for the corporate dividends received deduction. The amount of a dividend paid in Canadian dollars will be its value in U.S. dollars based on the prevailing spot market exchange rate in effect on the day the U.S. holder receives the dividend. A U.S. holder will have a tax basis in any distributed Canadian dollars equal to their U.S. dollar value on the date of receipt, and any gain or loss realized on a subsequent conversion or other disposition of such Canadian dollars generally will be treated as U.S. source ordinary income or loss. If dividends paid in Canadian dollars are converted into U.S. dollars on the date they are received by a U.S. holder, the U.S. holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend income.

Subject to certain exceptions for short-term and hedged positions, as well as the passive foreign investment rules, a dividend that a non-corporate holder receives on a common share will generally be subject to a maximum federal income tax rate of 20% if the dividend is a “qualified dividend.” A dividend on a common share will be a qualified dividend if (i) either (a) the common shares are readily tradable on an established market in the United States or (b) we are eligible for the benefits of a comprehensive income tax treaty with the United States that the Secretary of the Treasury determines is satisfactory for purposes of these rules and that includes an exchange of information program, and (ii) we were not, in the year prior to the year the dividend was paid, and are not, in the year the dividend is paid, a passive foreign investment company (PFIC). The common shares are listed on The Nasdaq Capital Market which should be treated as an established securities market in the United States. In any event, the U.S. Canada Income Convention (the Treaty) satisfies the requirements of clause (i)(b), the Company is incorporated in and tax resident of Canada and should be entitled to the benefits of the Treaty. Based on our audited financial statements, income tax returns and relevant market and shareholder data, we believe that we likely will not be classified as a PFIC in the September 30, 2018 taxable year. There can be no assurance, however, that the Company will not be considered to be a PFIC for any particular year in the future because PFIC status is factual in nature, depends upon factors not wholly within the Company’s control, generally cannot be determined until the close of the taxable year in question, and is determined annually. Accordingly, no assurance can be made that a dividend paid, if any, would be a “qualified dividend.” In addition, as described in the section below entitled “Passive Foreign Investment Company Rules,” if we were a PFIC in a year while a U.S. holder held a common share, and if the U.S. holder has not made a qualified electing fund election effective for the first year the U.S. holder held the common share, the common share remains an interest in a PFIC for all future years or until such an election is made. The IRS takes the position that such rule will apply for purposes of determining whether a common share is an interest in a PFIC in the year a dividend is paid or in the prior year, even if we do not satisfy the tests to be a PFIC in either of those years. Even if dividends on the common shares would otherwise be eligible for qualified dividend treatment, in order to qualify for the reduced qualified dividend tax rates, a non-corporate holder must hold the common share on which a dividend is paid for more than 60 days during the 120-day period beginning 60 days before the ex-dividend date, disregarding for this purpose any period during which the non-corporate holder has an option to sell, is under a contractual obligation to sell or has made (and not closed) a short sale of substantially identical stock or securities, is the grantor of an option to buy substantially identical stock or securities or, pursuant to U.S. Treasury regulations, has diminished such holder’s risk of loss by holding one or more other positions with respect to substantially similar or related property. In addition, to qualify for the reduced qualified dividend tax rates, the non-corporate holder must not be obligated to make related payments with respect to positions in substantially similar or related property. Payments in lieu of dividends from short sales or other similar transactions will not qualify for the reduced qualified dividend tax rates.

A non-corporate holder that receives an extraordinary dividend (generally, any dividend that is in excess of 10% of the holder's adjusted basis in the common share on which the dividend is paid) that is eligible for the reduced qualified dividend rates must treat any loss on the sale of the common share as a long-term capital loss to the extent of the dividend. For purposes of determining the amount of a non-corporate holder’s deductible investment interest expense, a dividend is treated as investment income only if the non-corporate holder elects to treat the dividend as not eligible for the reduced qualified dividend tax rates. Special limitations on foreign tax credits with respect to dividends subject to the reduced qualified dividend tax rates apply to reflect the reduced rates of tax.

The U.S. Treasury has announced its intention to promulgate rules pursuant to which non-corporate holders of stock of non-U.S. corporations, and intermediaries through which the stock is held, will be permitted to rely on certifications from issuers to establish that dividends are treated as qualified dividends. Because those procedures have not yet been issued, it is not clear whether we will be able to comply with them.

Non-corporate holders of common shares are urged to consult their own tax advisers regarding the availability of the reduced qualified dividend tax rates with respect to dividends, if any, received on the common shares in the light of their own particular circumstances.

Any Canadian withholding tax imposed on dividends received with respect to the common shares will be treated as a foreign income tax eligible for credit against a U.S. holder’s U.S. federal income tax liability, subject to generally applicable limitations under U.S. federal income tax law. For purposes of computing those limitations separately under current law for specific categories of income, a dividend generally will constitute foreign source “passive category income” or, in the case of certain holders, “general category income.” A U.S. holder will be denied a foreign tax credit with respect to Canadian income tax withheld from dividends received with respect to the common shares to the extent the U.S. holder has not held the common shares for at least 16 days of the 30-day period beginning on the date which is 15 days before the ex-dividend date or to the extent the U.S. holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a U.S. holder has substantially diminished its risk of loss on the common shares are not counted toward meeting the 16-day holding period required by the statute. The rules relating to the determination of the foreign tax credit are complex, and U.S. holders are urged to consult with their own tax advisers to determine whether and to what extent they will be entitled to foreign tax credits as well as with respect to the determination of the foreign tax credit limitation. Alternatively, any Canadian withholding tax may be taken as a deduction against taxable income, provided the U.S. holder takes a deduction and not a credit for all foreign income taxes paid or accrued in the same taxable year. In general, special rules will apply to the calculation of foreign tax credits in respect of dividend income that is subject to preferential rates of U.S. federal income tax.

Non-U.S. Holders. A dividend paid to a non-U.S. holder of a common share will generally not be subject to U.S. federal income tax unless the dividend is effectively connected with the conduct of trade or business by the non-U.S. holder within the United States (and is attributable to a permanent establishment or fixed base the non-U.S. holder maintains in the United States if an applicable income tax treaty so requires as a condition for the non-U.S. holder to be subject to U.S. taxation on a net income basis on income from the common share). A non-U.S. holder generally will be subject to tax on an effectively connected dividend in the same manner as a U.S. holder. A corporate non-U.S. holder under certain circumstances may also be subject to an additional “branch profits tax,” the rate of which may be reduced pursuant to an applicable income tax treaty.

Taxation of Capital Gains

U.S. Holders. Subject to the passive foreign investment company rules discussed below, on a sale or other taxable disposition of a common share, a U.S. holder will recognize capital gain or loss in an amount equal to the difference between the U.S. holder’s adjusted basis in the common share and the amount realized on the sale or other disposition, each determined in U.S. dollars. Such capital gain or loss will be long-term capital gain or loss if at the time of the sale or other taxable disposition the common share has been held for more than one year. In general, any adjusted net capital gain of an individual is subject to a maximum federal income tax rate of 20%. Capital gains recognized by corporate U.S. holders generally are subject to U.S. federal income tax at the same rate as ordinary income. The deductibility of capital losses is subject to limitations.

Any gain a U.S. holder recognizes generally will be U.S. source income for U.S. foreign tax credit purposes, and, subject to certain exceptions, any loss will generally be a U.S. source loss. If a Canadian tax is paid on a sale or other disposition of a common share, the amount realized will include the gross amount of the proceeds of that sale or disposition before deduction of the Canadian tax. The generally applicable limitations under U.S. federal income tax law on crediting foreign income taxes may preclude a U.S. holder from obtaining a foreign tax credit for any Canadian tax paid on a sale or other disposition of a common share. The rules relating to the determination of the foreign tax credit are complex, and U.S. holders are urged to consult with their own tax advisers regarding the application of such rules. Alternatively, any Canadian tax paid on the sale or other disposition of a common share may be taken as a deduction against taxable income, provided the U.S. holder takes a deduction and not a credit for all foreign income taxes paid or accrued in the same taxable year.

Non-U.S. Holders. A non-U.S. holder will not be subject to U.S. federal income tax on gain recognized on a sale or other disposition of a common share unless (i) the gain is effectively connected with the conduct of trade or business by the non-U.S. holder within the United States (and is attributable to a permanent establishment or fixed base the non-U.S. holder maintains in the United States if an applicable income tax treaty so requires as a condition for the non-U.S. holder to be subject to U.S. taxation on a net income basis on income from the common share), or (ii) in the case of a non-U.S. holder who is an individual, the holder is present in the United States for 183 or more days in the taxable year of the sale or other disposition and certain other conditions apply. Any effectively connected gain of a corporate non-U.S. holder may also be subject under certain circumstances to an additional “branch profits tax,” the rate of which may be reduced pursuant to an applicable income tax treaty.

Passive Foreign Investment Company Rules

A special set of U.S. federal income tax rules applies to a foreign corporation that is a PFIC for U.S. federal income tax purposes. As noted above, based on our audited financial statements, income tax returns, and relevant market and shareholder data, we believe that we likely will not be classified as a PFIC in the September 30, 2018 taxable year. There can be no assurance, however, that the Company will not be considered to be a PFIC for any particular year in the future because PFIC status is factual in nature, depends upon factors not wholly within the Company’s control, generally cannot be determined until the close of the taxable year in question, and is determined annually.

In general, a non-US corporation is a PFIC if in any taxable year either (i) at least 75% of its gross income is “passive income” or (ii) at least 50% of the quarterly average value of its assets is attributable to assets that produce or are held to produce “passive income.” In applying these tests, the Company generally is treated as holding its proportionate share of the assets and receiving its proportionate share of the income of any other corporation in which the Company owns at least 25% by value of the shares. Passive income for this purpose generally includes dividends, interest, royalties, rent and capital gains, but generally does not include certain royalties derived in an active business. Passive assets are those assets that are held for production of passive income or do not produce income at all. Thus cash will be a passive asset. Interest, including interest on working capital, is treated as passive income for purposes of the income test. Without taking into account the value of its goodwill, more than 50% of the Company’s assets by value would be passive so that the Company would be a PFIC under the asset test. Based upon its current operations, its goodwill (the value of which is based on our belief of the estimated fair market value of the Company in excess of book value) will likely be attributable to its activities that will generate active income and to such extent, should be treated as an active asset. The determination of whether a foreign corporation is a PFIC is a factual determination made annually and is therefore subject to change. Subject to exceptions pursuant to certain elections that generally require the payment of tax, once stock in a foreign corporation is stock in a PFIC in the hands of a particular shareholder that is a United States person, it remains stock in a PFIC in the hands of that shareholder.

If we are treated as a PFIC, contrary to the tax consequences described in “Taxation of Dividends” and “Taxation of Capital Gains” above, a U.S. holder that does not make an election described in the succeeding two paragraphs would be subject to special rules with respect to (i) any gain realized on a sale or other disposition of a common share (for purposes of these rules, a disposition of a common share includes many transactions on which gain or loss is not realized under general U.S. federal income tax rules) and (ii) any “excess distribution” by the Company to the U.S. holder (generally, any distribution during a taxable year in which distributions to the U.S. holder on the common share exceed 125% of the average annual taxable distributions (whether actual or constructive and whether or not out of earnings and profits) the U.S. holder received on the common share during the preceding three taxable years or, if shorter, the U.S. holder’s holding period for the common share). Under those rules, (i) the gain or excess distribution would be allocated ratably over the U.S. holder’s holding period for the common share, (ii) the amount allocated to the taxable year in which the gain or excess distribution is realized would be taxable as ordinary income in its entirety and not as capital gain, would be ineligible for the reduced qualified dividend rates, and could not be offset by any deductions or losses, and (iii) the amount allocated to each prior year, with certain exceptions, would be subject to tax at the highest tax rate in effect for that year, and the interest charge generally applicable to underpayments of tax would be imposed in respect of the tax attributable to each of those years.

The special PFIC rules described above will not apply to a U.S. holder if the U.S. holder makes a timely election, which remains in effect, to treat the Company as a “qualified electing fund” (QEF) in the first taxable year in which the U.S. holder owns a common share and the Company is a PFIC and if the Company complies with certain requirements. Instead, a shareholder of a QEF generally is currently taxable on a pro rata share of the Company’s ordinary earnings and net capital gain as ordinary income and long-term capital gain, respectively. Neither that ordinary income nor any actual dividend from the Company would qualify for the 20% maximum federal income tax rate on dividends described above if the Company is a PFIC in the taxable year the ordinary income is realized or the dividend is paid or in the preceding taxable year. A QEF election cannot be made unless the Company provides U.S. Holders the information and computations needed to report income and gains pursuant to a QEF election. The Company expects that will not provide this information. It is, therefore, likely that U.S. holders would not be able to make a QEF election in any year we are a PFIC.

In lieu of a QEF election, a U.S. holder of stock in a PFIC that is considered marketable stock could elect to mark the stock to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the stock and the U.S. holder’s adjusted basis in the stock. Losses would be allowed only to the extent of net mark-to-market gain previously included in income by the U.S. holder under the election for prior taxable years. A U.S. holder’s adjusted basis in the common shares will be adjusted to reflect the amounts included or deducted with respect to the mark-to-market election. If the mark-to-market election were made, the rules set forth in the second preceding paragraph would not apply for periods covered by the election. A mark-to-market election will not apply during any later taxable year in which the Company does not satisfy the tests to be a PFIC. In general, the common shares will be marketable stock if the common shares are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter on a national securities exchange that is registered with the SEC or on a designated national market system or on any exchange or market that the Treasury Department determines to have rules sufficient to ensure that the market price accurately represents the fair market value of the stock. Under current law, the mark-to-market election may be available to U.S. holders of common shares because the common shares are listed on The Nasdaq Capital Market and the TSX Venture Exchange (at least one of which should constitute a qualified exchange for this purpose), although there can be no assurance that the common shares will be “regularly traded” for purposes of the mark-to-market election.

If we are treated as a PFIC, each U.S. holder generally will be required to file a separate annual information return with the United States Internal Revenue Service (IRS) with respect to the Company (and any lower-tier PFICs). A failure to file this return will suspend the statute of limitations with respect to any tax return, event, or period to which such report relates (potentially including with respect to items that do not relate to a U.S. holder’s investment in the common shares). Given the complexities of the PFIC rules and their potentially adverse tax consequences, U.S. holders of common shares are urged to consult their tax advisers about the PFIC rules.

Medicare Surtax on Net Investment Income

Non-corporate U.S. Holders whose income exceeds certain thresholds generally will be subject to 3.8% surtax on their “net investment income” (which generally includes, among other things, dividends on, and capital gain from the sale or other taxable disposition of, the common shares). Absent an election to the contrary, if a QEF election is available and made, QEF inclusions will not be included in net investment income at the time a U.S. Holder includes such amounts in income, but rather will be included at the time distributions are received or gains are recognized. Non-corporate U.S. Holders should consult their own tax advisers regarding the possible effect of such tax on their ownership and disposition of the common shares, in particular the applicability of this surtax with respect to a non-corporate U.S. Holder that makes a QEF or mark-to-market election in respect of their common shares.

Information Reporting and Backup Withholding

Dividends paid on, and proceeds from the sale or other disposition of, a common share to a U.S. holder generally may be subject to information reporting requirements and may be subject to backup withholding unless the U.S. holder provides an accurate taxpayer identification number or otherwise establishes an exemption. The amount of any backup withholding collected from a payment to a U.S. holder will be allowed as a credit against the U.S. holder's U.S. federal income tax liability and may entitle the U.S. holder to a refund, provided certain required information is furnished to the Internal Revenue Service. A non-U.S. holder generally will be exempt from these information reporting requirements and backup withholding tax but may be required to comply with certain certification and identification procedures in order to establish its eligibility for exemption.

Under U.S. federal income tax law and U.S. Treasury Regulations, certain categories of U.S. holders must file information returns with respect to their investment in, or involvement in, a foreign corporation. U.S. holders are urged to consult with their own tax advisors concerning such reporting requirements.

Reporting Obligations of Individual Owners of Foreign Financial Assets

Section 6038D of the Code generally requires U.S. individuals (and possibly certain entities that have U.S. individual owners) to file IRS Form 8938 if they hold certain "specified foreign financial assets," the aggregate value of which exceeds \$50,000 on the last day of the year or \$75,000 at any time during the year. The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also, unless held in accounts maintained by a financial institution, any stock or security issued by a non-US. person, any financial instrument or contract held for investment that has an issuer or counterparty other than a U.S. person and any interest in a foreign entity. Persons who are required to report foreign financial assets and fail to do so may be subject to substantial penalties.

Foreign Account Tax Compliance Act

Under certain circumstances, the Company or its paying agent may be required, pursuant to the Foreign Account Tax Compliance Act and the regulations promulgated thereunder ("FATCA"), to withhold U.S. tax at a rate of 30% on all or a portion of payments of dividends or other corporate distributions to U.S. Holders which are treated as "foreign pass-thru payments" made on or after the later of January 1, 2019 or when final treasury regulations providing a definition of foreign pass-thru payments are published, if such payments are not in compliance with FATCA. The rules regarding FATCA and "foreign pass-thru payments," including the treatment of proceeds from the disposition of the Ordinary Shares, are not completely clear, and further guidance is expected from the IRS that would clarify how FATCA might apply to dividends or other amounts paid on or with respect to the Common Shares.

Canadian Federal Income Tax Consequences

The following summary of the material Canadian federal income tax consequences is stated in general terms and is not intended to be legal or tax advice to any particular shareholder. Each shareholder or prospective shareholder is urged to consult his or her own tax advisor regarding the tax consequences of his or her purchase, ownership and disposition of common shares. The tax consequences to any particular holder of common shares will vary according to the status of that holder as an individual, trust, corporation or member of a partnership, the jurisdiction in which that holder is subject to taxation, the place where that holder is resident and, generally, according to that holder's particular circumstances.

This summary is applicable only to holders who are resident in the United States for income tax purposes, have never been resident in Canada for income tax purposes, deal at arm's length with the Company, hold their common shares as capital property and who will not use or hold the common shares in carrying on business in Canada. Special rules, which are not discussed in this summary, may apply to a United States holder that is an issuer that carries on business in Canada and elsewhere.

This summary is based upon the provisions of the Income Tax Act (Canada) and the regulations thereunder (collectively, the Tax Act or ITA) and the Canada-United States Tax Convention (the Tax Convention) at the date of this Annual Report and the current administrative practices of the Canada Revenue Agency. This summary does not take into account provincial income tax consequences. The comments in this summary that are based on the Tax Convention are applicable to U.S. holders only if they qualify for benefits under the Tax Convention. Management urges each holder to consult his own tax advisor with respect to the income tax consequences applicable to him in his own particular circumstances.

Non-Resident Holders

The summary below is restricted to the case of a holder (a Holder) of one or more common shares who for the purposes of the Tax Act is a non-resident of Canada, holds his common shares as capital property and deals at arm's length with the Company.

Dividends

A Holder will be subject to Canadian withholding tax (Part XIII Tax) equal to 25%, or such lower rates as may be available under an applicable tax treaty, of the gross amount of any dividend paid or deemed to be paid on his common shares. The Company will be required to withhold the applicable amount of Part XIII Tax from each dividend so paid and remit the withheld amount directly to the Receiver General for Canada for the account of the Holder.

Disposition of Common Shares

A Holder who disposes of common shares, including by deemed disposition on death, will not be subject to Canadian tax on any capital gain thereby realized unless the common share constituted “taxable Canadian property” as defined by the Tax Act. Generally, a common share of a public corporation will not constitute taxable Canadian property of a Holder unless he held the common share as capital property used by him carrying on a business in Canada, or he, persons with whom he did not deal at arm’s length or partnerships in which he or persons with whom he did not deal at arm’s length held an interest, alone or together held or held options to acquire, at any time within the 60 months preceding the disposition, 25% or more of the issued shares of any class of the capital shares of the Company and at any time during the 60 months preceding the disposition more than 50% of the value of the common shares is derived from, or from an interest in, Canadian real estate, including Canadian resource or timber resource properties.

Holders Resident in the United States

A Holder who is a resident of the United States and realizes a capital gain on disposition of common shares that was taxable Canadian property will, if qualified for benefits under the Tax Convention, generally be exempt from Canadian tax thereon unless (a) more than 50% of the value of the common shares is derived from, or from an interest in, Canadian real estate, including Canadian natural resource properties, (b) the common shares formed part of the business property of a permanent establishment that the Holder has or had in Canada within the 12 months preceding disposition, or (c) the Holder (i) was a resident of Canada at any time within the ten years immediately preceding the disposition, and for a total of 120 months during any period of 20 consecutive years, preceding the disposition, (ii) owned the common shares when he ceased to be resident in Canada, and (iii) the common shares were not subject to a deemed disposition on the Holder’s departure from Canada.

Inclusion in Taxable Income

A Holder who is subject to Canadian tax in respect of a capital gain realized on disposition of common shares must include one half of the capital gain (“taxable capital gain”) in computing his taxable income earned in Canada. The Holder may, subject to certain limitations, deduct one half of any capital loss (“allowable capital loss”) arising on disposition of taxable Canadian property from taxable capital gains realized in the year of disposition in respect to taxable Canadian property and, to the extent not so deductible, from such taxable capital gains of any of the three preceding years or any subsequent year.

Subject to certain exceptions, a non-resident person who disposes of taxable Canadian property must notify the Canada Revenue Agency either before or after the disposition (within ten days of the disposition).

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are a smaller reporting company and are not required to provide the information under this item.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements and related financial information required to be filed hereunder are indexed under Item 15 of this Annual Report on Form 10-K and are incorporated herein by reference.

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

There were no reportable events under this item during the past two fiscal years.

Item 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining disclosure controls and procedures to provide reasonable assurance that material information related to our Company, including our consolidated subsidiaries, is made known to senior management, including our Chief Executive Officer and the Chief Financial Officer, by others within those entities on a timely basis so that appropriate decisions can be made regarding public disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and our Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Securities and Exchange Act of 1934, as amended) as of September 30, 2018. Our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures as of September 30, 2018, were effective.

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for designing, establishing and maintaining a system of internal controls over financial reporting (as defined in Exchange Act Rule 13a-15(f)) to provide reasonable assurance that the financial information prepared by us for external purposes is reliable and has been recorded, processed and reported in an accurate and timely manner in accordance with accounting principles generally accepted in the United States. The Board of Directors is responsible for ensuring that management fulfills its responsibilities. The Audit Committee fulfills its role of ensuring the integrity of the reported information through its review of the interim and annual financial statements. Management reviewed the results of their assessment with our Audit Committee.

Because of its inherent limitations, our internal control over financial reporting may not prevent or detect all possible misstatements or frauds. 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 policies or procedures may deteriorate.

Management has used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in “Internal Control — Integrated Framework (2013)” to evaluate the effectiveness of our internal control over financial reporting. Management has assessed the effectiveness of our internal control over financial reporting and concluded that such internal control over financial reporting was effective as of September 30, 2018.

Attestation Report of Our Registered Public Accounting Firm

This Annual Report does not include an attestation report from our independent registered public accounting firm. We are an “emerging growth company,” as defined under the JOBS Act and a “smaller reporting company” as defined by Rule 12b-2 of the Exchange Act, and are subject to reduced public company reporting requirements. We are not required to have the effectiveness of our internal control over financial reporting audited by our external auditors.

Limitations on the Effectiveness of Controls

Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal controls will prevent all error and all fraud. A control system, no matter how well designed 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 our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is also based, in part, upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION.

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Directors

Our directors and their ages as of November 30, 2018 are set forth below.

Name	Age	Position(s) Held	Director Since
Deborah F. Aghib, Ph.D. (1)(3)	60	Director	January 23, 2018
Tessie M. Che, Ph.D.	68	Director	September 25, 2013
Paul Chun (1)(3)	37	Director	December 8, 2016
David L. Hill, Ph.D. (2)(3)	67	Director	May 17, 2011
Frank R. Oakes	68	President, Chief Executive Officer and Chairman of Board of Directors	April 9, 2010
Charles V. Olson, D.Sc. (2)	61	Director	December 8, 2016
Mayank D. Sampat (1)(2)	63	Director	August 15, 2012

- (1) Member of Audit Committee.
- (2) Member of Compensation Committee.
- (3) Member of Nominating and Corporate Governance Committee.

There are no family relationships between any of our directors or executive officers.

Biographies and Qualifications. The biographies of our directors and certain information regarding each director's experience, attributes, skills and/or qualifications that led to the conclusion that the director should be serving as a director of our Company are as follows:

Deborah F. Aghib, Ph.D. has been a director of Stellar since January 2018. She has more than 24 years of executive and consulting experience for biotechnology and healthcare-related companies and organizations. She is currently a business development executive for CellPly S.r.L., a biomedical company, a position she has held since August 2017. She also currently serves as an advisor to the boards and management of BrainDTech S.r.L., a company that develops diagnostic approaches to the early detection of brain diseases (since January 2016), Sanipedia S.r.L, a company that operates in the very early stage of product/service development, (since October 2014) and Neuro-Zone S.r.L., a company that provides managerial and strategic support to researchers (since January 2007). Previously, from February 2014 to September 2014, she was a private equity consultant for CRG LP, a healthcare-focused investment firm. From 2013 to 2014 she was Business Development and Strategy executive under a consulting arrangement for Theravance Inc, a biopharmaceutical company that develops medicines for serious illnesses. From February 2012 to December 2012, she served as Stellar's chief business development executive under a consulting arrangement. From 2007 to 2012, she was the Vice President of Business Development and Strategy for Neuro-Zone Since October 2015, Dr. Aghib has served on the Advisory Board of Open Common Consortium, a cloud computing and data commons infrastructure that supports cancer medical research from the University of Chicago. Dr. Aghib holds a Ph.D. in Molecular and Cellular Biology from the University of Milan and a Ph.D. in Human Genetics from the University of Pavia. Dr. Aghib has broad scientific knowledge and significant international experience in developing long-term strategies for business development, licensing and asset spinoffs for drug discovery, medical device and companion diagnostics companies.

Tessie M. Che, Ph.D. has been a director of Stellar since September 2013. Dr. Che is currently General Manager and Chair of the Board of Directors of Amaran Biotechnology Inc., a privately-held biopharmaceuticals manufacturer based in Taiwan, a position she has held since 2012. She is also a director of OBI Pharma USA, a wholly-owned subsidiary of OBI Pharma, Inc., a publicly traded biotechnology corporation in Taiwan. From 1998 to 2011 she served as COO and Sr. V.P., Corporate Affairs of Optimer Pharmaceuticals Inc., a company she co-founded. At Optimer, Dr. Che guided the company's CMC team to the successful registration and commercialization of Difigid™ in the U.S., Canada and Europe. Prior to Optimer, Dr. Che's experience includes 20 years in research, operations and management at global companies, including Exxon Mobil Corp., Aventis Pharmaceuticals Inc., and EniChem SpA. Dr. Che holds bachelor degrees in chemistry from Illinois State University and Fu-Jen Catholic University (Taiwan) and a PhD in physical-inorganic chemistry from Brandeis University. She has authored numerous scientific publications and holds over 20 U.S. patents. Dr. Che has extensive scientific, operational, manufacturing, quality assurance, product development and senior management experience in the pharmaceutical and biotechnology industries, as well as experience serving on a board of directors within our industry.

Paul Chun has been a director of Stellar since December 2016 and serves as the chair of the Nominating and Governance Committee. He is a Managing Partner of Eldred Advisors LLC, a life sciences advisory firm he founded in May 2016. From November 2015 to April 2016, he served as Director of Strategy and Corporate Development at Kiromic, LLC. From May 2011 to October 2015, Mr. Chun served as a life sciences principal with Westwicke Partners, LLC, a capital markets advisory firm. During his tenure at Westwicke, he supported the capital markets and investor engagement objectives of private and public biopharma companies, including the support of multiple initial public offerings and other strategic transactions. Prior to Westwicke, he held various roles in investment research and corporate finance, including at Amgen, Inc., Tavistock Life Sciences and Goldman, Sachs & Co. He received his bachelors in biological sciences from Columbia University. Mr. Chun has broad experience in therapeutics development and commercialization, valuation, corporate development and finance.

David L. Hill, Ph.D. has been a director of Stellar since May 2011. Since January 2018 he has operated the California Central Coast IVF Laboratory, a healthcare company he founded in San Luis Obispo, California. He previously served as Scientific Director for the ART Reproductive Center, Beverly Hills, California, from December 1999 until December 2016. He is also an Assistant Clinical Professor in the Dept. of Obstetrics and Gynecology at the David Geffen School of Medicine, University of California, Los Angeles, and a Research Assistant IV at Cedars-Sinai Medical Center, Los Angeles, California. Dr. Hill received his Ph.D. in Biological Sciences from the Department of Pathology, School of Life Sciences, University of Connecticut and completed a Postdoctoral Fellowship at the Dana Farber Cancer Institute through an appointment by the Department of Physiology and Biophysics, Harvard Medical School, Boston, Massachusetts. Dr. Hill has extensive scientific and clinical research experience in our industry.

Frank R. Oakes was appointed our President and Chief Executive Officer and Chairman of our Board of Directors in April 2010. Prior to that time, he served as founder and Chief Executive Officer of Stellar’s California subsidiary since 1999. He has more than 40 years of management experience in aquaculture including a decade as Chief Executive Officer of The Abalone Farm, Inc., during which he led the company through the R&D, capitalization, and commercialization phases of development to become the largest abalone producer in the United States. Mr. Oakes is the inventor of our patented method for non-lethal extraction of hemolymph from a live gastropod mollusk. He was the principal investigator on our Small Business Innovation Research (SBIR) grant from the National Science Foundation and was principal investigator on our Phase I and II SBIR grants from the NIH’s Center for Research Resources, and a California Technology Investment Partnership (CalTIP) grant from the Department of Commerce. Mr. Oakes has consulted and lectured for the aquaculture industry around the world. He received his Bachelor of Science degree from California State Polytechnic University, San Luis Obispo and is a graduate of the Los Angeles Regional Technology Alliance University’s management-training program. Mr. Oakes is a valuable member of our Board due to his depth of operating, strategic, and senior management experience in our industry, specifically as related to aquaculture. Additionally, Mr. Oakes holds an intimate knowledge of Stellar due to his longevity in the industry and with us.

Charles V. Olson, D.Sc. has been a director of Stellar since December 2016 and a member of our scientific advisory board since June 2014, and serves as the chair of the Compensation Committee. Since September 2017, he has served at Applied Molecular Transport Inc., as the Vice President of Biologics. He has also been a Principal Biotechnology Consultant for Compass Biotechnology LLC since 2006. Dr. Olson previously held senior and executive management positions at Anthera Pharmaceuticals Inc. from April 2010 to August 2017, NGM Biopharmaceuticals Inc., a clinical stage biopharmaceutical company, Coherus BioSciences Inc., a company focused on biosimilar therapeutics, Nexbio Inc., a drug development company, Cell Genesys, Inc., a biotechnology company, Biomarin Pharmaceuticals, Inc., a company that develops and commercializes therapies for serious and life-threatening rare diseases, and Onyx Pharmaceuticals, Inc., a biopharmaceutical company. After graduate school, Dr. Olson was a Research Scientist at Kaiser Hospitals, followed by Scientist and Senior Scientist positions at Genentech and Bayer, respectively. He holds a B.A. in biology and chemistry from Westmont College, an M.A. in chemistry from the University of California at Santa Barbara and a D.Sc. in biochemistry. Dr. Olson has extensive scientific, manufacturing operations, process development, and senior management experience in the biopharmaceutical industry.

Mayank (Mike) D. Sampat has been a director of Stellar since August 2012, and serves as the chair of the Audit Committee. Mr. Sampat is an independent consultant providing business services to companies seeking expertise in financial planning and analysis, accounting and financial reporting, M&A transactions support and financial system implementation. He previously held the positions of controller at Precision Toxicology, LLC, a healthcare focused clinical laboratory specializing in providing quantitative drug testing, from February 2015 to May 2016, Zpower, LLC, an emerging manufacturer in the microbattery industry, from June 2012 to September 2014, and Imaging Advantage LLC, which develops and provides cloud based technology for healthcare facilities, from September 2010 to June 2012, and the position of Chief Financial Officer for Gamma Medica-Ideas, a supplier of imaging equipment to the medical industry, from September 2007 to June 2010. Mr. Sampat received a BBA in accounting from Bombay University and his MBA in Finance at Mercer University. Mr. Sampat is a seasoned finance and accounting executive, having worked with multiple companies ranging from startups to large Fortune 100 companies.

Executive Officers

Set forth below is certain information with respect to the names, ages, and positions of our executive officers as of November 30, 2018. Biographical information pertaining to Mr. Oakes, who is a director and an executive officer, may be found in the above section entitled “Directors.” The executive officers serve at the pleasure of our Board of Directors.

Name	Age	Position(s) Held	Date of Appointment
Frank R. Oakes	68	President, Chief Executive Officer and Chairman of our Board of Directors	April 9, 2010
Kathi Niffenegger, CPA	61	Chief Financial Officer and Corporate Secretary	November 1, 2013
Gregory T. Baxter, Ph.D.	59	Executive Vice President of Corporate Development	December 1, 2016

Kathi Niffenegger, CPA was appointed Chief Financial Officer in November 2013 and Corporate Secretary in June 2013. She initially joined Stellar in May 2012 as Controller, after previously serving as the company's outside Certified Public Accountant for more than 12 years. Ms. Niffenegger has more than 30 years of experience in accounting and finance in a range of industries. She held positions of increasing responsibility in the audit division of Glenn Burdette CPAs from 1988 to 2012 and served most recently as technical partner. She obtained CFO experience at Martin Aviation, and began her career at Peat, Marwick, Mitchell & Co. (now KPMG LLP). Ms. Niffenegger has held leadership roles for audits of manufacturing, aquaculture, pharmaceutical and governmental grant clients, and developed specific expertise in cost accounting systems and internal controls. Ms. Niffenegger holds a B.S. degree in Business Administration, Accounting from California State University, Long Beach and is a member of the American Institute of Certified Public Accountants (AICPA).

Gregory T. Baxter, Ph.D. joined Stellar's executive management team in December 2016 following his service on the company's Board of Directors, which he joined in August 2012. Dr. Baxter has served as an executive and scientist for several biotechnology corporations and foundations. Since 2001, Dr. Baxter has been a Senior Scientist in the Department of Clinical Drug Development for CCS Associates Inc., a scientific research consulting firm specializing in technical and support services for clinical research, design strategies for preclinical studies, chemical information sciences and research and development support for translational science. His prior experience includes serving as Program Director for the National Science Foundation (NSF) Division of Industrial Innovation and Partnerships, Founder and CSO of Hurel Corporation, Founder and CEO of Aegen Biosciences and Research Scientist for Molecular Device Corporation. He also serves as Adjunct Associate Professor at Cornell University in the College of Chemical Engineering and on the Founders Board of Stanford University's StartX Med Program. Dr. Baxter received his B.A. and Ph.D. in Biochemistry/Molecular Biology from University of California, Santa Barbara.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act, requires that our directors, executive officers, and greater-than-10% shareholders file reports with the SEC on their initial beneficial ownership of our common shares and any subsequent changes. To our knowledge, based solely on a review of copies of such reports furnished to us by our officers and directors during the fiscal year ended September 30, 2018, we believe that all such filings met all applicable Section 16(a) requirements, except that due to an administrative error, one late Form 4, reporting four late transactions, was filed on March 14, 2018 for Daniel E. Morse, Ph.D., a former member of our Board of Directors.

Code of Ethics

We have adopted a Code of Ethics and Business Conduct that applies to all of our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of our Code of Ethics and Business Conduct is available on the Investor Relations section of our website at <http://ir.stellarbiotechnologies.com>, in the Corporate Governance section, under the Governance Docs tab. We intend to satisfy the SEC's disclosure requirements regarding amendments to, or waivers of, our Code of Ethics and Business Conduct by posting such information on our website. Copies of our Code of Ethics and Business Conduct may be obtained, free of charge, by writing to our Corporate Secretary, Stellar Biotechnologies, Inc., 332 East Scott Street, Port Hueneme, California 93041.

Information about our Board Committees

Our Board of Directors has appointed an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The Board of Directors has determined that each director who serves on these committees is "independent," as that term is defined by the listing rules of Nasdaq and rules of the Securities and Exchange Commission. The Board of Directors has adopted written charters for its Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee. Copies of these charters are available on our website at <http://ir.stellarbiotechnologies.com>. In addition, our board of directors appointed a Strategic Investments Committee to approve actions related to potential strategic investments and to approve actions related to our capital raising transactions. There was no requirement for directors who served on these committees to be "independent".

Audit Committee

Our Audit Committee is composed of Deborah Aghib, Paul Chun, and Mayank Sampat (chair). The purpose of the Audit Committee is to oversee our accounting and financial reporting processes and the audits of our financial statements. In that regard, the Audit Committee assists the Board in monitoring: (a) the integrity of our financial statements; (b) our independent auditor's qualifications, independence, and performance; (c) the performance of our system of internal controls, financial reporting, and disclosure controls; and (d) our compliance with legal and regulatory requirements. To fulfill this obligation and perform its duties, the Audit Committee maintains effective working relationships with the Board, management, and our independent auditor.

Mayank Sampat is the Chair of our Audit Committee and has extensive financial experience. He received an MBA in Finance from Mercer University, and has served in several financial positions with other companies, including several years as Chief Financial Officer for a medical equipment manufacturer. Mr. Sampat is considered to be "independent" as defined pursuant to the listing rules of the Nasdaq. The Board has determined that Mr. Sampat is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K.

Compensation Committee

Our Compensation Committee is composed of David Hill, Charles Olson (chair), and Mayank Sampat. The purpose of the Compensation Committee is to oversee the Board's responsibilities relating to compensation, including (i) the approval of compensation for our Company's Chief Executive Officer and (ii) the review of compensation for our other executive officers. It has overall responsibility for approving and evaluating all of our compensation plans, policies and programs as such plans, policies and programs affect executive officers.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee is composed of Deborah Aghib, Paul Chun (chair), and David Hill. The purpose of the Nominating and Corporate Governance Committee is to identify individuals qualified to become Board members; recommend to the Board individuals to serve as directors; advise the Board with respect to Board composition, procedures and committees; develop, recommend to the Board and annually review a set of corporate governance principles applicable to the Company; and oversee any related matters required by the federal securities laws.

Item 11. EXECUTIVE COMPENSATION.

Executive Compensation

Our named executive officers for 2018 were Frank R. Oakes, Chief Executive Officer, President and Executive Chairman of our Board of Directors; Kathi Niffenegger, CPA, Chief Financial Officer and Corporate Secretary; and Gregory T. Baxter, Ph.D., Executive Vice President of Corporate Development.

Summary Compensation Table

The following table sets forth information regarding the compensation awarded to, earned by or paid to the named executive officers.

Name and Principal Position	Fiscal Year	Salary (\$)	Bonus (\$)	Stock Awards (\$ (1))	Option Awards (\$ (2))	All Other Compensation (\$)	Total (\$)
Frank R. Oakes President, Chief Executive Officer and Chairman of our Board of Directors	2018	\$ 264,813	\$ 50,000	\$ -	\$ 32,443	\$ 28,297(4)	\$ 343,110
	2017	257,100	25,000	296,969(3)	-	23,669	602,738
Kathi Niffenegger, CPA Chief Financial Officer and Corporate Secretary	2018	208,637	60,512	-	28,387	19,039(5)	288,188
	2017	202,560	20,000	-	19,744	18,526	260,830
Gregory T. Baxter, Ph.D. Executive Vice President of Corporate Development	2018	152,438	-	-	24,332	17,179(6)	169,617
	2017	157,372	500	-	15,605	18,406(7)	191,883

- (1) The amounts shown in this column represent the aggregate grant date fair value of the share awards based on the closing price on Nasdaq, not the actual amounts paid to or realized by the named executive officer during the covered fiscal year. It differs from the amounts recorded in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification 718, which were based on the share value at the inception of the performance share plan in April 2010 expensed over the estimated vesting period ended August 31, 2012. The vesting requirements of these awards are set forth in Note 8 to our audited consolidated financial statements for the year ended September 30, 2018 included in this Annual Report.
- (2) The amounts shown in this column represent the aggregate grant date fair value of the share option awards computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification 718, not the actual amounts paid to or realized by the named executive officers during the covered fiscal year. The assumptions used in determining grant date fair value of these awards are set forth in Note 8 to our audited consolidated financial statements for the year ended September 30, 2018 included in this Annual Report.
- (3) 33,670 shares were issued under our Performance Share Plan.
- (4) Represents (i) \$20,197 in health insurance and (ii) \$8,100 in 401(k) Company contributions.
- (5) Represents (i) \$12,962 in health insurance and (ii) \$6,077 in 401(k) Company contributions.
- (6) Represents (i) \$12,679 in health insurance and (ii) \$4,500 in 401(k) Company contributions.
- (7) Dr. Baxter's employment with the Company began December 1, 2016. Dr. Baxter was a director of the Company from August 15, 2012 until December 1, 2016. Other compensation includes \$1,050 in director fees in fiscal 2017.

Employment Agreements

We do not have employment agreements currently in effect with any of our named executive officers. Like our other employees, our executives are eligible for annual salary increases and discretionary equity grants.

Performance Share Plan

Under the merger agreement between our Company and our California subsidiary, we allotted 142,857 common shares (the Performance Shares) under a performance share plan (the Plan). The performance shares were reserved for issuance to certain officers, directors and employees of the Company upon achievement of three milestones related to completion of method development for commercial-scale manufacture of KLH, compilation and regulatory submittal of all required chemistry, manufacturing and control data and completion of preclinical toxicity and immunogenicity testing of products. Share-based compensation was recorded over the estimated vesting period ending in August 2012.

As each milestone was met as determined by our Board of Directors, one third of the Performance Shares were available to be released to the Plan participants. The three milestones were met on or before August 2012, and all Performance Shares had been issued to non-director employees by August 2012. In December 2013, the Board issued 21,645 Performance Shares to a former director of the Company. The Board issued the remaining Performance Shares in June 2017, of which (a) 1,924 Performance Shares were issued to a former director of the Company, (b) 33,670 Performance Shares were issued to Mr. Oakes, the Company's current President, CEO and Chairman and an eligible participant in the Plan, and (c) 19,240 Performance Shares were issued to Dr. Morse, a former director of the Company effective September 28, 2018 and an eligible participant in the Plan. Since all Performance Shares under the Plan have been issued, the Plan was terminated.

Outstanding Equity Awards at 2018 Fiscal Year-End

The following table summarizes the equity awards made to our named executive officers that were outstanding at September 30, 2018.

Name	Award grant date	Option Awards			
		Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable (1)	Option exercise prices (\$)	Option expiration date
Frank R. Oakes	4/13/12	5,366	-	\$ CDN29.40	4/13/19
	3/12/18	1,905	3,809(2)	US5.88	3/12/25
Kathi Niffenegger, CPA	6/18/12	1,286	-	CDN20.30	6/18/19
	12/19/12	714	-	CDN17.50	12/19/19
	5/14/13	1,286	-	CDN40.60	5/14/20
	11/1/13	1,429	-	US128.10	11/1/20
	11/12/14	1,286	-	CDN106.40	11/12/21
	12/22/15	1,429	-	US50.68	12/22/22
	12/20/16	1,429	-	US14.21	12/20/23
3/12/18	1,667	3,333(3)	US5.88	3/12/25	
Gregory T. Baxter, Ph.D.	8/16/12	1,000	-	CDN25.90	8/16/19
	11/12/14	179	-	CDN106.40	11/12/21
	3/28/17	476	953(4)	US11.20	3/28/24
	3/12/18	1,429	2,857(5)	US5.88	3/12/25

(1) Our options vesting policy is described in the Outstanding Equity Awards Narrative Disclosure section.

(2) The options for past service will vest 1,905 at 3/12/19 and 1,904 at 9/12/19.

(3) The options for past service will vest 1,667 at 3/12/19 and 1,666 at 9/12/19.

(4) The options for future service will vest 476 at 3/28/19 and 477 at 3/28/20.

(5) The options for past service will vest 1,429 at 3/12/19 and 1,428 at 9/12/19.

Outstanding Equity Awards Narrative Disclosure

Incentive Compensation Plan

We adopted an Incentive Compensation Plan in 2017 (the 2017 Plan) administered by the Board of Directors, which amended and restated the 2013 fixed share option plan (the 2013 Plan). Options, restricted shares and restricted share units are eligible for grant under the 2017 Plan. The number of shares available for issuance under the 2017 Plan is 228,143, including shares available for the exercise of outstanding options under the 2013 Plan. The purpose of the 2017 Plan is to advance the interests of the Company by encouraging equity participation through the acquisition of common shares of the Company. Our Board is responsible for the general administration of the 2017 Plan and the proper execution of its provisions, its interpretation and the determination of all questions arising thereunder. Specifically, the Board has the power to, among other things:

- allot common shares for issuance in connection with the exercise of options;
- grant options, restricted shares or restricted share units;
- amend, suspend, terminate or discontinue the plan; and
- delegate all or a portion of its administrative powers as it may determine to one or more committees.

Options, restricted shares or restricted share units may be awarded to our directors, officers, employees and consultants.

Options to purchase 70,498 common shares at prices ranging from CDN\$17.50 to CDN\$130.90 and \$5.88 to \$128.10 are outstanding at September 30, 2018. No restricted shares or restricted share units have been granted as of September 30, 2018.

Options granted during fiscal 2018 to employees and consultants under the 2017 Plan totaled 28,902 options to purchase common shares, at exercise prices ranging from \$5.88 to \$6.51.

Options granted for past service are subject to the following vesting schedule: (a) one-third of the option shall vest on the date of grant; (b) one-third of the option shall vest 12 months from the date of grant; and (c) the remaining one-third of the option shall vest 18 months from the date of grant. Options granted for future service are subject to the following vesting schedule: (x) one-third shall vest at 12 months from the date of grant, (y) one-third shall vest at 24 months from the date of grant and (z) one-third shall vest at 36 months from the date of grant.

Retirement Benefits

We have established a 401(k) plan to provide retirement benefits to eligible executive officers and employees. Employees may enter the plan after they have been employed by us for at least three consecutive months. Under the plan, we contribute a flat non-elective contribution of 3% of eligible compensation for each plan participant at the end of the calendar year. Any Company contributions we made to the plan for our named executive officers are reflected in the "All Other Compensation" column of the Summary Compensation Table above.

Other than the funds contributed under our 401(k) plan, no other funds were set aside or accrued by us during fiscal 2018 or 2017 to provide pension, retirement or similar benefits for our named executive officers.

Director Compensation

The following table sets forth information regarding the compensation of our non-employee directors for the fiscal year ended September 30, 2018.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
Deborah F. Aghib, Ph.D.	\$ 5,850	\$ 4,267(2)	\$ -	\$ 10,117
Tessie M. Che, Ph.D.	4,450	2,028(3)	-	6,478
Paul Chun	8,300	2,028(3)	-	10,328
David L. Hill, Ph.D.	6,200	2,028(3)	-	8,228
Daniel E. Morse, Ph.D.	1,700	2,028(3)	-	3,728
Charles V. Olson, D.Sc.	6,200	2,028(3)	4,025(4)	12,253
Mayank D. Sampat	9,700	2,028(3)	-	11,728

- (1) The amounts shown in this column represent the aggregate grant date fair value of the share option awards computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification 718, not the actual amounts paid to or realized by the directors during the fiscal year. The assumptions used in determining grant date fair value of these awards are set forth in Note 8 to our audited consolidated financial statements for the year ended September 30, 2018 included in this Annual Report.
- (2) The option awards were issued under our 2017 Incentive Compensation Plan, with 357 options for future service vesting in thirds beginning January 2019 and 357 options for past service vesting in thirds beginning March 2018. See footnote 5 below for Outstanding Equity Awards at Fiscal Year-End.
- (3) The option awards were issued under our 2017 Incentive Compensation Plan for past service, with 357 options vesting in thirds beginning March 2018. See footnote 5 below for Outstanding Equity Awards at Fiscal Year-End.
- (4) Represents (i) \$2,625 in consultant fees and (ii) \$1,400 for service as member of our Scientific Advisory Board.
- (5) Outstanding Equity Awards at 2018 Fiscal Year-End

The following table summarizes the equity awards made to our directors that were outstanding at September 30, 2018.

Name	Outstanding Options (#)
Deborah F. Aghib, Ph.D.	714
Tessie M. Che, Ph.D.	2,071
Paul Chun	1,071
David L. Hill, Ph.D.	2,142
Daniel E. Morse, Ph.D.	3,149
Charles V. Olson, D.Sc.	1,250
Mayank D. Sampat	2,071

Narrative to Director Compensation Table

Non-Employee Director Compensation Policy

Pursuant to our non-employee director compensation policy, non-employee directors receive \$1,000 for each Board meeting attended in person and \$350 for each Board meeting attended by telephone. Members of Board committees also receive \$350 for each committee meeting attended. Non-executive directors may also receive share option awards at the discretion of the Board of Directors.

Non-Employee Directors on our Scientific Advisory Board

Dr. Morse (through September 28, 2018) and Dr. Olson are members of our Scientific Advisory Board. As compensation for their services, the members of our Scientific Advisory Board receive certain advisory fees and expense reimbursements. Amounts for their services as members of our Scientific Advisory Board are reflected in the Director Compensation table above.

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

Equity Compensation Plan Information

The following table provides certain information as of September 30, 2018 about our common shares that may be issued under our equity compensation plans, which consists of our 2017 Incentive Compensation Plan:

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders	70,498	\$ 25.42	157,645
Equity compensation plans not approved by security holders	N/A	N/A	N/A
Total	70,498	\$ 25.42	157,645

Security Ownership of Certain Beneficial Owners and Management

The following tables sets forth certain information as of November 28, 2018, with respect to the beneficial ownership of our common shares by: (1) all of our directors; (2) our named executive officers listed in the Summary Compensation Table; (3) all of directors and executive officers as a group; and (4) each person known by us to beneficially own more than 5% of our outstanding common shares.

We have determined beneficial ownership in accordance with the rules of the SEC, based on a review of filings with the SEC and information known to us. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common shares that they beneficially own, subject to applicable community property laws.

Common shares subject to options or warrants currently exercisable or exercisable within 60 days of November 28, 2018 are deemed outstanding for computing the share ownership and percentage of the person holding such options and warrants, but are not deemed outstanding for computing the percentage of any other person. The percentage ownership of our common shares of each person or entity named in the following table is based on 5,330,715 common shares outstanding as of November 28, 2018.

Directors and Officers

Name and Address of Beneficial Owner (1)	Amount and Nature of Beneficial Ownership	Percent of Shares Beneficially Owned
Frank R. Oakes	59,195(2)	1.1%
Kathi Niffenegger, CPA	10,526(3)	*
Gregory T. Baxter, Ph.D.	3,084(4)	*
Deborah F. Aghib, Ph.D.	238(5)	*
Tessie M. Che, Ph.D.	1,833(6)	*
Paul Chun	714(7)	*
David L. Hill, Ph.D.	2,190(8)	*
Charles V. Olson, D.Sc.	1,012(9)	*
Mayank D. Sampat	1,833(10)	*
All directors and executive officers as a group (9 persons)	80,626(11)	1.5%

* Percentage of shares beneficially owned does not exceed one percent.

- (1) Unless otherwise indicated, the address of each beneficial owner is c/o Stellar Biotechnologies, Inc., 332 E. Scott Street, Port Hueneme, California 93041.
- (2) This amount includes (i) 7,271 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018; and excludes (ii) 791 common shares issuable upon the exercise of outstanding options currently exercisable or exercisable within 60 days of November 28, 2018 which are held by Mr. Oakes' spouse who has sole voting and dispositive power over the securities, and as to which Mr. Oakes disclaims beneficial ownership. Mr. Oakes does not have the power to vote or dispose of, or to direct the voting or disposition of, the shares held by his spouse, or with respect to any shares acquired under her outstanding options.
- (3) Represents 10,526 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.
- (4) Represents 3,084 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.
- (5) Represents 238 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.
- (6) Represents 1,833 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.
- (7) Represents 714 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.
- (8) This amount includes 1,904 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.
- (9) Represents 1,012 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.
- (10) Represents 1,833 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.
- (11) This amount includes 28,415 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of November 28, 2018.

Shareholders Known by Us to Own 5% or More of Our Common Shares

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Shares Beneficially Owned
Intracoastal Capital, LLC (1) 245 Palm Trail Delray Beach, FL 33483	1,274,300	9.99%

(1) Voting and investment power over the shares held by Intracoastal Capital, LLC ("Intracoastal") is exercised by the co-managers of Intracoastal, Mitchell P. Kopin and Daniel P. Asher. Intracoastal holds 1,274,300 common shares issuable upon exercise of warrants, which, pursuant to their terms, may not be exercised to the extent such exercise would cause the holder, together with its affiliates and attribution parties, to beneficially own a number of common shares which would exceed 4.99 or 9.99% of our then outstanding common shares following such exercise, excluding for purposes of such determination common shares issuable upon exercise of such warrants which have not been exercised.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Related Party Transactions

Patent Royalty Agreement

On August 14, 2002, through our California subsidiary, we entered into an agreement with Frank Oakes, our Chief Executive Officer, where he would receive royalty payments in exchange for the assignment of his rights to U.S. Patent No. 6,852,338 to us. The royalty is 5% of gross receipts from products using this invention in excess of \$500,000 annually. Our current operations utilize this invention. No patent royalties were paid for the years ended September 30, 2018 and 2017.

Director Independence

In evaluating the independence of our Board members and the composition of the committees of our Board of Directors, the Board of Directors utilizes the definition of “independence” as that term is defined by the Securities Exchange Act of 1934, and the Nasdaq Listing Rules. Using this standard, the Board of Directors has determined that Paul Chun, David Hill, Charles Olson and Mayank Sampat are “independent directors.” This means that our Board of Directors is composed of a majority of independent directors as required by the rules of Nasdaq.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The following table shows the aggregate fees paid or accrued for audit and other services provided for the years ended September 30, 2018 and 2017 rendered by Moss Adams LLP.

Principal Accountant Fees and Services

<u>Type of Service</u>	<u>Fiscal Year 2018</u>	<u>Fiscal Year 2017</u>
Audit Fees	\$ 235,000	\$ 190,000
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total	\$ 235,000	\$ 190,000

Audit Fees consisted of fees incurred for professional services rendered for audits of the years ended September 30, 2018 and 2017 and include procedures related to registrations and offerings.

Pre-Approval Policies and Procedures

The Audit Committee is directly responsible for the appointment, compensation and oversight of our auditors. It has established procedures for the receipt, retention, and treatment of complaints received by us regarding accounting, internal accounting controls, or auditing matters, and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters. The Audit Committee also has the authority and the funding to engage independent counsel and other outside advisors.

The Audit Committee pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year, and any pre-approval is detailed as to the particular service or category of services and is generally subject to an amount or range of estimated fees. All proposed engagements of the auditor for audit and permitted non-audit services are submitted to the Audit Committee for approval prior to the beginning of any such services. Our auditors are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with the pre-approval, and the fees for the services performed to date. The Audit Committee may also pre-approve particular services on a case-by-case basis. The Audit Committee pre-approved 100% of the audit services performed by our independent registered public accounting firm for the fiscal year ended September 30, 2018.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) The following documents are filed as a part of this Annual Report:

(1) Financial Statements

The list of consolidated financial statements and notes required by this Item 15 (a) (1) is set forth in the “Index to Financial Statements” on page F-1 of this Annual Report.

(2) Financial Statement Schedules

All schedules have been omitted because the required information is included in the financial statements or notes thereto.

(b) Exhibits

The exhibits listed on the Exhibit Index below are filed as part of this Annual Report.

EXHIBIT INDEX

Exhibit No. Description

- [3.1](#) [Certificate of Incorporation of the Company, dated June 12, 2007 \(included as Exhibit 1\(a\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [3.2](#) [Certificate of Amendment of the Company, dated April 15, 2008 \(included as Exhibit 1\(b\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [3.3](#) [Certificate of Continuation of the Company, dated November 25, 2009 \(included as Exhibit 1\(c\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [3.4](#) [Certificate of Change of Name of the Company, dated April 7, 2010 \(included as Exhibit 1\(f\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [3.5](#) [Amended and Restated Articles of the Company, dated April 9, 2018 \(included as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 11, 2018, and incorporated herein by reference\).](#)
- [3.6](#) [Notice of Articles of the Company, dated April 13, 2018 \(filed herewith\).](#)
- [4.1](#) [Form of Warrant dated June 30, 2016 \(included as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 30, 2016, and incorporated herein by reference\).](#)
- [4.3](#) [Form of Warrant \(included as Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed on May 8, 2018, and incorporated herein by reference\).](#)
- [4.4](#) [Form of Pre-Funded Warrant \(included as Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed on May 8, 2018, and incorporated herein by reference\).](#)
- [4.5](#) [Form of Placement Agent Warrant \(included as Exhibit 4.4 to the Company's Registration Statement on Form S-1 filed on May 8, 2018, and incorporated herein by reference\).](#)
- [4.6](#) [Form of Series A Common Share Purchase Warrant \(included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 29, 2018, and incorporated herein by reference\).](#)
- [4.7](#) [Form of Series B Common Share Purchase Warrant \(included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on May 29, 2018, and incorporated herein by reference\).](#)
- [4.8](#) [Form of Placement Agent Warrant \(included as Exhibit 10.4 to the Company's Current Report on Form 8-K filed on May 29, 2018, and incorporated herein by reference\).](#)
- [10.1](#) [Patent Assignment and Royalty Agreement between the Company and Frank Oakes, dated August 6, 2002 \(included as Exhibit 4\(a\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [10.2](#) [Sublease Agreement \(Units 3, 4 and 5\) between the Company and the Port Hueneme Surplus Property Authority, dated October 2, 2000 \(included as Exhibit 4\(j\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [10.3](#) [Sublease Agreement \(Unit 7\) between the Company and the Port Hueneme Surplus Property Authority, dated March 21, 2005 \(included as Exhibit 4\(k\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [10.4](#) [Lease Agreement between the Company and Beachport Center, dated March 29, 2011 \(included as Exhibit 4\(l\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [10.5](#) [Research Collaboration Agreement between the Company and Bayer Innovation GmbH, dated August 27, 2009 \(included as Exhibit 4\(16\) to the Company's Amendment No. 2 to its Registration Statement on Form 20-F filed on July 5, 2012, and incorporated herein by reference\).](#)
- [10.6 #](#) [Joint Venture Agreement, dated May 11, 2016, by and among the Company and Neovacs, S.A. \(included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 17, 2016, and incorporated herein by reference\).](#)
- [10.7](#) [License Agreement between the Company and University of Guelph, dated July 24, 2013 \(included as Exhibit 99.1 to the Company's Report on Form 6-K filed on August 30, 2013, and incorporated herein by reference\).](#)

- [10.8 @ Fixed Share Option Plan dated December 18, 2013 \(included as Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on November 14, 2014, and incorporated herein by reference\).](#)
- [10.9 @ 2017 Incentive Compensation Plan \(included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 29, 2017, and incorporated herein by reference\).](#)
- [10.10 @ Performance Share Plan dated April 9, 2010 \(included as Exhibit 10\(d\) to the Company's Registration Statement on Form 20-F filed on February 3, 2012, and incorporated herein by reference\).](#)
- [10.11 Advance Notice Policy, adopted October 31, 2013 \(included as Exhibit 10.14 to the Company's Annual Report on Form 10-K filed on November 14, 2014, and incorporated herein by reference\).](#)
- [10.12 Amendment One to Lease Agreement between the Company and Beachport Center, dated June 24, 2014 \(included as Exhibit 10.15 to the Company's Annual Report on Form 10-K filed on November 14, 2014, and incorporated herein by reference\).](#)
- [10.13 Sublease Amendment No. 2 \(Units 4 and 5\) to Sublease Agreement between the Company and the Port Hueneme Surplus Property Authority, dated October 2, 2010 \(included as Exhibit 10.16 to the Company's Annual Report on Form 10-K filed on November 14, 2014, and incorporated herein by reference\).](#)
- [10.14 Sublease Amendment No. 1 \(Unit 7\) to Sublease Agreement between the Company and the Port Hueneme Surplus Property Authority, dated March 21, 2010 \(included as Exhibit 10.17 to the Company's Annual Report on Form 10-K filed on November 14, 2014, and incorporated herein by reference\).](#)
- [10.15 Collaboration Agreement by and between Stellar Biotechnologies, Inc. and Amaran Biotechnology dated December 7, 2013 \(included as Exhibit 10.18 to Amendment No. 2 of the Company's Annual Report on Form 10-K filed on September 9, 2015, and incorporated herein by reference\).](#)
- [10.16 Collaboration Agreement, dated July 27, 2015, by and between Stellar Biotechnologies, Inc. and Ostiones Guerrero SA de CV \(included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 30, 2015, and incorporated herein by reference\).](#)
- [10.17 Sublease Amendment No. 1 \(Units 4 and 5\) to Sublease Agreement between the Company and the Port Hueneme Surplus Property Authority, and establishment of new commencement date for Sublease Agreement \(Unit 7\) between the Company and the Port Hueneme Surplus Property Authority, dated October 31, 2005 \(included as Exhibit 10.20 to the Company's Annual Report on Form 10-K filed on December 14, 2015, and incorporated herein by reference\).](#)
- [10.18 Sublease Amendment No. 3 \(Units 4 and 5\) to Sublease Agreement between the Company and the Port Hueneme Surplus Property Authority, dated June 4, 2015 \(included as Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on December 14, 2015, and incorporated herein by reference\).](#)
- [10.19 Sublease Amendment No. 2 \(Unit 7\) to Sublease Agreement between the Company and the Port Hueneme Surplus Property Authority, dated June 4, 2015 \(included as Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on December 14, 2015, and incorporated herein by reference\).](#)
- [10.20 Form of Securities Purchase Agreement, dated June 30, 2016 \(included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 30, 2016, and incorporated herein by reference\).](#)
- [10.21 Form of Securities Purchase Agreement \(included as Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed on May 8, 2018, and incorporated herein by reference\).](#)
- [10.22 Form of Warrant Exercise Agreement, dated May 24, 2018 \(included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 29, 2018, and incorporated herein by reference\).](#)
- [14.1 Code of Ethics and Business Conduct \(included as Exhibit 14.1 to the Company's Annual Report on Form 10-K filed on December 1, 2017, and incorporated herein by reference\).](#)
- [21 Subsidiaries of Stellar Biotechnologies, Inc. \(included as Exhibit 21 to the Company's Annual Report on Form 10-K filed on December 1, 2017, and incorporated herein by reference\).](#)
- [23.1 Consent of Moss Adams LLP \(filed herewith\).](#)

- [31.1](#) [Certification of the Chief Executive Officer pursuant to Rule 13a-14\(a\) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 \(filed herewith\).](#)
- [31.2](#) [Certification of the Chief Financial Officer pursuant to Rule 13a-14\(a\) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 \(filed herewith\).](#)
- [32.1](#) [^] [Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 \(filed herewith\).](#)
- [32.2](#) [^] [Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 \(filed herewith\).](#)
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Label Linkbase Document
- 101.PRE XBRL Taxonomy Presentation Linkbase Document
- @ Management contract or compensatory plan or arrangement.
- # Confidential treatment has been granted for certain portions of this exhibit. Original copies have been filed separately with the Securities and Exchange Commission pursuant to Rule 24B-2 of the Securities Exchange Act of 1934, as amended.
- [^] A signed original of this written statement required by Section 906 has been provided and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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: November 30, 2018

STELLAR BIOTECHNOLOGIES, INC.

/s/ Frank R. Oakes

Frank R. Oakes
President and Chief Executive Officer
(Principal Executive Officer)

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ FRANK R. OAKES</u> Frank R. Oakes	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	November 30, 2018
<u>/s/ KATHI NIFFENEGGER</u> Kathi Niffenegger	Chief Financial Officer (Principal Financial and Accounting Officer)	November 30, 2018
<u>/s/ DEBORAH F. AGHIB</u> Deborah F. Aghib	Director	November 30, 2018
<u>/s/ TESSIE M. CHE</u> Tessie M. Che	Director	November 30, 2018
<u>/s/ PAUL CHUN</u> Paul Chun	Director	November 30, 2018
<u>/s/ DAVID L. HILL</u> David L. Hill	Director	November 30, 2018
<u>/s/ CHARLES V. OLSON</u> Charles V. Olson	Director	November 30, 2018
<u>/s/ MAYANK D. SAMPAT</u> Mayank D. Sampat	Director	November 30, 2018

STELLAR BIOTECHNOLOGIES, INC.
INDEX TO FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
Stellar Biotechnologies, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Stellar Biotechnologies, Inc. (the “Company”) as of September 30, 2018 and 2017, the related consolidated statements of operations, changes in equity and cash flows for the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of September 30, 2018 and 2017, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Moss Adams LLP
Los Angeles, California
November 30, 2018

We have served as the Company’s auditor since 2014.

Stellar Biotechnologies, Inc.
Consolidated Balance Sheets

	<u>September 30,</u> <u>2018</u>	<u>September 30,</u> <u>2017</u>
Assets:		
Current assets:		
Cash and cash equivalents	\$ 4,225,521	\$ 4,570,951
Accounts receivable	41,246	1,287
Short-term investments	6,078,031	1,994,401
Inventory	224,267	68,114
Prepaid and other assets	86,919	123,694
Total current assets	<u>10,655,984</u>	<u>6,758,447</u>
Noncurrent assets:		
Equity investment in joint venture	46,456	66,695
Property, plant and equipment, net	1,062,195	879,523
Deposits	15,340	15,340
Total noncurrent assets	<u>1,123,991</u>	<u>961,558</u>
Total Assets	<u>\$ 11,779,975</u>	<u>\$ 7,720,005</u>
Liabilities and Shareholders' Equity:		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 493,385	\$ 320,947
Total Current Liabilities	<u>493,385</u>	<u>320,947</u>
Commitments (Note 7)		
Shareholders' equity:		
Common shares, unlimited common shares authorized, no par value, 5,330,715 and 1,502,870 issued and outstanding at September 30, 2018 and 2017, respectively	56,652,957	48,351,701
Accumulated share-based compensation	5,064,625	4,439,400
Accumulated deficit	<u>(50,430,992)</u>	<u>(45,392,043)</u>
Total Shareholders' Equity	<u>11,286,590</u>	<u>7,399,058</u>
Total Liabilities and Shareholders' Equity	<u>\$ 11,779,975</u>	<u>\$ 7,720,005</u>

The accompanying notes are an integral part of these consolidated financial statements.

Stellar Biotechnologies, Inc.
Consolidated Statements of Operations

	Years Ended	
	September 30, 2018	September 30, 2017
Revenues:		
Product sales	\$ 211,849	\$ 178,287
Contract services revenue	-	50,000
	<u>211,849</u>	<u>228,287</u>
Expenses:		
Cost of sales and contract services	133,316	250,042
Costs of aquaculture	312,004	284,411
Research and development	2,087,402	1,973,400
General and administrative	2,757,377	2,944,980
	<u>5,290,099</u>	<u>5,452,833</u>
Loss from Operations	(5,078,250)	(5,224,546)
Other Income (Loss)		
Foreign exchange gain (loss)	(35,059)	162,028
Investment income	75,160	32,670
	<u>40,101</u>	<u>194,698</u>
Loss Before Income Tax	(5,038,149)	(5,029,848)
Income tax expense	800	800
Net Loss	\$ (5,038,949)	\$ (5,030,648)
Loss per common share:		
Basic and diluted	\$ (1.76)	\$ (3.44)
Weighted average number of common shares outstanding:		
Basic and diluted	<u>2,869,374</u>	<u>1,462,459</u>

The accompanying notes are an integral part of these consolidated financial statements.

Stellar Biotechnologies, Inc.
Consolidated Statements of Cash Flows

	Years Ended	
	September 30, 2018	September 30, 2017
Cash Flows Used In Operating Activities:		
Net loss	\$ (5,038,949)	\$ (5,030,648)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	188,372	179,322
Share-based compensation	154,313	115,546
Foreign exchange (gain) loss	35,059	(162,028)
Transfer equipment to research and development	12,419	-
Change in equity investment in joint venture	20,239	-
Changes in working capital items:		
Accounts receivable	(40,004)	84,573
Inventory	(156,153)	181,316
Prepaid and other assets	36,748	235,001
Accounts payable and accrued liabilities	172,451	(302,731)
Net cash used in operating activities	<u>(4,615,505)</u>	<u>(4,699,649)</u>
Cash Flows From Investing Activities:		
Purchase of property, plant and equipment	(382,810)	(302,733)
Purchase of short-term investments	(9,083,630)	(5,005,607)
Proceeds on sales and maturities of short-term investments	5,000,000	7,000,000
Net cash provided by (used in) investing activities	<u>(4,466,440)</u>	<u>1,691,660</u>
Cash Flows From Financing Activities:		
Proceeds from issuance of common shares, net	4,520,319	-
Payments for issuance costs	(398,811)	-
Proceeds from exercise of warrants	4,650,659	-
Net cash provided by financing activities	<u>8,772,167</u>	<u>-</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(35,652)</u>	<u>162,036</u>
Net change in cash and cash equivalents	<u>(345,430)</u>	<u>(2,845,953)</u>
Cash and cash equivalents - beginning of year	4,570,951	7,416,904
Cash and cash equivalents - end of year	<u>\$ 4,225,521</u>	<u>\$ 4,570,951</u>
Cash (demand deposits)	\$ 3,719,041	\$ 3,847,655
Cash equivalents	<u>506,480</u>	<u>723,296</u>
Cash and cash equivalents	<u>\$ 4,225,521</u>	<u>\$ 4,570,951</u>
Supplemental cash flow information:		
Cash paid during the period for taxes	\$ 800	\$ 800
Supplemental disclosure of non-cash transactions:		
Issuance costs withheld from escrow proceeds	\$ 972,811	\$ -
Fair value of placement agent warrants	470,912	-

The accompanying notes are an integral part of these consolidated financial statements.

Stellar Biotechnologies, Inc.

Consolidated Statements of Changes in Equity

	Shares	Common Shares	Accumulated Share-Based Compensation	Accumulated Deficit	Total Shareholders' Equity
Balance - September 30, 2016	1,448,036	\$ 47,280,792	\$ 5,394,763	\$ (40,361,395)	\$ 12,314,160
Issuance of performance shares	54,834	1,070,909	(1,070,909)	-	-
Share-based compensation	-	-	115,546	-	115,546
Net loss	-	-	-	(5,030,648)	(5,030,648)
Balance - September 30, 2017	1,502,870	\$ 48,351,701	\$ 4,439,400	\$ (45,392,043)	\$ 7,399,058
Issuance of common shares in equity offering	1,388,396	5,493,130	-	-	5,493,130
Issuance costs including fair value of placement agent warrants	-	(1,842,533)	470,912	-	(1,371,621)
Issuance of common shares upon exercise of warrants	2,439,449	4,650,659	-	-	4,650,659
Share-based compensation	-	-	154,313	-	154,313
Net loss	-	-	-	(5,038,949)	(5,038,949)
Balance - September 30, 2018	5,330,715	\$ 56,652,957	\$ 5,064,625	\$ (50,430,992)	\$ 11,286,590

The accompanying notes are an integral part of these consolidated financial statements.

Stellar Biotechnologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended September 30, 2018 and 2017

1. Nature of Operations

Stellar Biotechnologies, Inc. (the Company) is organized under the laws of British Columbia, Canada. The Company's business is the aquaculture, research and development, manufacture and commercialization of Keyhole Limpet Hemocyanin (KLH). The Company markets and distributes its KLH products to biotechnology and pharmaceutical companies, academic institutions, clinical research organizations and research centers primarily in Europe, North American and Asia. The Company's common shares have been listed for trading on The Nasdaq Capital Market in the United States under the symbol SBOT since November 5, 2015.

In April 2010, the Company changed its name from CAG Capital, Inc. to Stellar Biotechnologies, Inc. and completed a reverse merger transaction with Stellar Biotechnologies, Inc., a California corporation, which was founded in September 1999, and remains the Company's wholly-owned subsidiary and principal operating entity. In January 2017, the California subsidiary and the Company established a wholly-owned Mexican subsidiary under the name BioEstelar, S.A. de C.V. in Ensenada, Baja California to perform aquaculture research and development activities in Mexico. The Company's executive offices are located at 332 E. Scott Street, Port Hueneme, California, 93041, USA, and its registered and records office is 1500 Royal Centre, 1055 West Georgia Street, Vancouver, BC, V6E 4N7, Canada.

Functional Currency

The consolidated financial statements of the Company are presented in U.S. dollars, which is the Company's functional currency, unless otherwise stated.

Management Plans

Company operations have historically been funded by the issuance of common shares, exercise of warrants, grant revenues, contract services revenue and product sales. For the fiscal years 2018 and 2017, the Company reported net losses of approximately \$5.0 million and \$5.0 million, respectively. As of September 30, 2018, the Company had an accumulated deficit of approximately \$50.4 million and working capital of approximately \$10.2 million. The Company expects to incur additional losses as it continues to invest in its research and development programs, manufacturing platform and market development activities.

The Company plans to finance company operations over the course of at least the next twelve months with cash and investments on hand and product sales. Management has flexibility to adjust planned expenditures based on a number of factors including the size and timing of capital expenditures, staffing levels, inventory levels, and the status of customer clinical trials. Management also seeks to expand the customer base for existing marketed products, and may seek additional financing through debt and/or equity financings, including transactions with strategic customers and partners that may include debt and/or equity arrangements. The Company has historically relied upon the sale of common shares to help fund its operations and meet its obligations and presently expects to continue to do so in the future as and when it considers appropriate, subject to market conditions and the availability of favorable terms.

2. Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and include the accounts of the Company, its wholly-owned subsidiaries, Stellar Biotechnologies, Inc., a California corporation in the U.S. and BioEstelar, S.A. de C.V. a Baja California corporation in Mexico. All significant intercompany balances and transactions have been eliminated in consolidation.

3. Significant Accounting Policies

a) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reported periods. These estimates include warrant liabilities, share-based compensation, intangible assets, valuation of accounts receivable, valuation of inventory, and income taxes. Actual outcomes could differ from these estimates. These consolidated financial statements include estimates, which by their nature are uncertain. The impacts of such estimates are pervasive throughout the consolidated financial statements, and may require accounting adjustments based on future periods if the revision affects both current and future periods. These estimates are based on historical experience, current and future economic conditions and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

b) Cash and Cash Equivalents

Cash and cash equivalents consist of demand deposits with financial institutions and highly liquid investments which are readily convertible into cash with maturities of three months or less when purchased.

c) Investments

Investments at September 30, 2018 and 2017 consisted of U.S. Treasury bills with original maturities between 13 and 52 weeks. They are classified as held-to-maturity and are reported at amortized cost, which approximates fair value. The Company regularly reviews these investments to determine whether any decline in fair value below the amortized cost basis has occurred that is other than temporary. If a decline in fair value has occurred that is determined to be other than temporary, the cost basis of the investment is written down to fair value.

d) Allowance for Doubtful Accounts Receivable

The Company assesses the collectability of its accounts receivable through a review of its current aging, as well as an analysis of its historical collection rate, general economic conditions and credit status of its customers. As of September 30, 2018 and 2017, all outstanding accounts receivable were deemed to be fully collectible, and therefore, no allowance for doubtful accounts was recorded.

e) Inventory

The Company records inventory at the lower of cost or market, with market not in excess of net realizable value. Raw materials are measured using FIFO (first-in first-out) cost. Work in process and finished goods are measured using average cost.

f) Property, Plant and Equipment

Property, plant and equipment are recorded at cost less accumulated depreciation and accumulated impairment losses, if any. Depreciation is recorded on the straight-line method over useful lives ranging from 1.5 to 15 years. Leasehold improvements are depreciated over the shorter of the useful life of the improvement or remaining term of lease. Maintenance and repairs are charged to operations as incurred.

g) Impairment of Long-Lived Assets

If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the amount of such impairment is measured by comparing the carrying value of the asset to the fair value of the asset and the Company records the impairment as a reduction in the carrying value of the related asset and a charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment, and assumptions could differ materially from actual results.

h) Fair Value of Financial Instruments

The Company uses the fair value measurement framework for valuing financial assets and liabilities measured on a recurring basis in situations where other accounting pronouncements either permit or require fair value measurements. See Note 10 for fair value measurements.

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i) Revenue Recognition

Product Sales

The Company recognizes product sales when KLH product is shipped (for which the risk is typically transferred upon delivery to the shipping carrier) and there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collectability is reasonably assured. The Company documents arrangements with customers with purchase orders and sales agreements.

Product sales include sales made under supply agreements with customers for a fixed price per gram of KLH products based on quantities ordered. Supply agreements are typically on a non-exclusive basis except within that customer's field of use.

Contract services revenue

The Company recognizes contract services revenue when contract services have been performed and reasonable assurance exists regarding measurement and collectability. An appropriate amount will be recognized as revenue in the period that the Company is assured of fulfilling the contract requirements. Amounts received in advance of performance of contract services are recorded as deferred revenue.

Contract services include services performed under a technology transfer and purchase agreement.

j) Research and Development

Research and development expenses principally consist of personnel costs related to the Company's research and development staff as well as depreciation of research and development assets. Research and development expenses also include costs incurred for laboratory supplies, KLH designated for internal research use only, reimbursable costs associated with collaborative agreements, third-party contract payments, consultants, facility and related overhead costs. Research and development costs are expensed as incurred.

k) Share-Based Compensation

The Company grants options to buy common shares of the Company to its directors, officers, employees and consultants, and grants other equity-based instruments to non-employees.

The fair value of share-based compensation is measured on the date of grant, using the Black-Scholes option valuation model and is recognized over the vesting period net of estimated forfeitures for employees or the service period for non-employees. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option.

l) Foreign Exchange

Items included in the financial statements of the Company's subsidiaries are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The functional currency of the parent and its subsidiaries is the U.S. dollar.

Transactions in currencies other than the U.S. dollar are recorded at exchange rates prevailing on the dates of the transactions.

m) Income Taxes

Income tax expense comprises current and deferred tax. Income tax is recognized in income or loss except to the extent that it relates to items recognized directly in equity. Current tax expense is the expected tax payable on taxable income for the year, using tax rates enacted or substantively enacted at year-end, adjusted for amendments to tax payable with regards to previous years.

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Notes to Consolidated Financial Statements

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Deferred tax is recorded using the liability method, providing for temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Temporary differences are not provided for relating to goodwill not deductible for tax purposes. The amount of deferred tax provided is based on the expected manner of realization or settlement of the carrying amount of assets and liabilities, using tax rates enacted or substantively enacted at the balance sheet date.

A deferred tax asset is recognized only to the extent that it is more likely than not that future taxable profits will be available against which the asset can be utilized. To the extent that the Company does not consider it more likely than not that a deferred tax asset will be recovered, it provides a valuation allowance against that excess.

The Company periodically evaluates its tax positions to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities. The Company has not incurred any interest or penalties as of September 30, 2018 with respect to uncertain income tax matters. The Company does not expect that there will be unrecognized tax benefits of a significant nature that will increase or decrease within 12 months of the reporting date.

The Company files income tax returns in the U.S. federal and state jurisdictions and in Canada on a fiscal year basis. Mexico tax returns are on a calendar year basis. Management believes that there are no material uncertain tax positions that would impact the accompanying consolidated financial statements. The Company's policy is to recognize interest and penalties related to unrecognized tax benefits in income tax expense. The Company may be subject to examination by the Internal Revenue Service for tax years 2014 through 2017 and by the Canada Revenue Agency for tax years 2014 through 2018. The Company may also be subject to examination on certain state, local and other foreign jurisdictions for the tax years 2013 through 2018.

n) Earnings (Loss) Per Share

Basic earnings (loss) per share is calculated by dividing income available to common shareholders by the weighted average number of common shares outstanding during the period.

The computation of diluted earnings (loss) per share assumes the conversion, exercise or contingent issuance of securities only when such conversion, exercise or issuance would have a dilutive effect on earnings (loss) per share. The dilutive effect of convertible securities is reflected in diluted earnings per share by application of the "if converted" method. The dilutive effect of outstanding options and warrants and their equivalents is reflected in diluted earnings per share by application of the treasury stock method. Conversion of outstanding warrants, broker units and options would have an antidilutive effect on loss per share for the years ended September 30, 2018 and 2017 and are therefore excluded from the computation of diluted loss per share.

o) Segments

The Company operates in one reportable segment and, accordingly, no segment disclosures have been presented. All equipment, leasehold improvements and other fixed assets owned by the Company are physically located within the United States (except for insignificant leasehold improvements under evaluation in Baja California, Mexico), and all supply, collaboration and licensing agreements are denominated in U.S. dollars.

p) Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued guidance codified in Accounting Standards Codification (ASC) 606 *Revenue Recognition – Revenue from Contracts with Customers*. The standard, including subsequently issued amendments, will replace most existing revenue recognition guidance and industry-specific guidance when it becomes effective. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity applies a five-step approach outlined in the standard. We plan to adopt ASC 606 using the modified retrospective method at the effective date for the Company, during the first quarter of fiscal 2019.

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Notes to Consolidated Financial Statements

For the Years Ended September 30, 2018 and 2017

Management has completed a review of existing revenue arrangements following the five-step approach. No material differences have been identified that impact the amount or timing of product sales or contract services revenue between the new revenue recognition guidance as compared to the current guidance. The Company continues to assess disclosures required by the new guidance to determine what additional information will be disclosed.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, which primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, ASU 2016-01 clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The guidance is effective for public entities for fiscal years beginning after December 15, 2017, including interim periods within those years, with early adoption permitted. These standards are effective for the Company during the fiscal year ending September 30, 2019. Management believes ASU 2016-01 will not have a significant impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which establishes a new lease accounting model for lessees. The updated guidance, including subsequently issued amendments, requires an entity to recognize assets and liabilities on the balance sheet arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. The amended guidance is effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within those years, with early adoption permitted. These standards are effective for the Company during the fiscal year ending September 30, 2020. We anticipate adoption of ASU 2016-02, will result in lease liabilities and right-of-use assets on the Company's consolidated financial statements for three operating leases with terms ending in July 2020, October 2020 and November 2020. Management will continue to assess the impact of ASU 2016-02 on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which includes provisions that require financial assets measured at amortized cost basis to be presented at the net amount expected to be collected and credit losses relating to available-for-sale debt securities to be recorded through an allowance for credit losses, which requires recognition of an estimate of all current expected credit losses. The guidance is effective for public entities for fiscal years beginning after December 15, 2019, including interim periods within those years, with early adoption permitted for fiscal years beginning after December 15, 2018. These standards are effective for the Company during the fiscal year ending September 30, 2021. Management is in the process of assessing the impact of ASU 2016-13 on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Scope of Modification Accounting*, which provides new guidance on changes to the terms or conditions of share-based payment awards that would be required to apply modification accounting under ASC 718, *Compensation-Stock Compensation*. The amendments are effective for annual reporting periods beginning after December 15, 2017 with early adoption permitted. These standards are effective for the Company during the fiscal year ending September 30, 2019. Management believes ASU 2017-09 will not have a significant impact on the Company's consolidated financial statements.

4. Investments

Short-term investments consisted of the following:

	<u>September 30,</u> <u>2018</u>	<u>September 30,</u> <u>2017</u>
U.S. Treasury Bills	\$ 6,078,031	\$ 1,994,401

U.S. Treasury Bills are carried at amortized cost which approximates fair value and are classified as held-to-maturity investments.

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Notes to Consolidated Financial Statements

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5. Inventory

Raw materials include inventory of manufacturing supplies. Work in process includes manufacturing supplies, direct and indirect labor, contracted manufacturing and testing, and allocated manufacturing overhead for inventory in process at the end of the year. Finished goods include products that are complete and available for sale. At September 30, 2018 and 2017, the Company recorded work in process and finished goods inventory only for those products with recent sales levels to evaluate net realizable value.

Inventory consisted of the following:

	<u>September 30,</u> <u>2018</u>	<u>September 30,</u> <u>2017</u>
Raw materials	\$ 46,670	\$ 21,761
Work in process	83,297	-
Finished goods	94,300	46,353
	<u>\$ 224,267</u>	<u>\$ 68,114</u>

6. Property, Plant and Equipment, net

Property, plant and equipment, net consisted of the following:

	<u>September 30,</u> <u>2018</u>	<u>September 30,</u> <u>2017</u>
Aquaculture system	\$ 126,257	\$ 126,257
Laboratory facilities	62,033	62,033
Computer and office equipment	125,859	117,840
Manufacturing and laboratory equipment	1,042,993	982,439
Vehicles	77,994	77,994
Leasehold improvements	347,360	337,060
	<u>1,782,496</u>	<u>1,703,623</u>
Less: accumulated depreciation	<u>(1,146,566)</u>	<u>(969,418)</u>
Depreciable assets, net	635,930	734,205
Construction in progress	426,265	145,318
	<u>\$ 1,062,195</u>	<u>\$ 879,523</u>

Depreciation expense amounted to approximately \$188,000 and \$179,000 for the years ended September 30, 2018 and 2017, respectively.

7. Commitments*Operating leases*

The Company leases buildings and facilities used in its operations under two sublease agreements. In June 2015, the Company exercised its option to extend these sublease agreements for an additional five-year term beginning in October and November 2015. The Company negotiated an option to extend the leases for two additional five-year terms.

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Notes to Consolidated Financial Statements

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The Company leases facilities used for executive offices and laboratories and pays a portion of the common area maintenance. In July 2018, the Company extended this lease for a two-year term, with options to renew for three successive two-year terms.

The Company leases undeveloped land in Baja California, Mexico to assess the potential development of an additional aquaculture locale and expansion of production. The lease term was three years from June 2015 with options to extend the lease for 30 years. In February 2018, the lease term was extended for two years without further rent payments. The Company may terminate early with 30 days' notice. The Company had a related collaboration agreement with the lessor, which expired in June 2018, pursuant to which the Company and the lessor would collaborate on the design, expansion and development of marine aquaculture resources and KLH production facilities on the leased property. Under that agreement, the Company was responsible for certain leasehold improvements including construction of structures and a power-generating facility, which are owned by the Company. The Company was also responsible for reimbursing the lessor for local operational support.

Aggregate future minimum lease payments at September 30, 2018 are approximately as follows:

For The Year Ending September 30,	
2019	\$ 185,000
2020	167,000
2021	6,000
	<u>\$ 358,000</u>

Rent expense on these lease agreements amounted to approximately \$237,000 and \$238,000 for the years ended September 30, 2018 and 2017, respectively.

Purchase obligations

The Company has commitments totaling approximately \$201,000 at September 30, 2018, for signed agreements with contract research organizations, consultants and construction contractors.

Supply agreements

The Company has commitments under supply agreements with customers for fixed prices per gram of KLH in connection with clinical trials on a non-exclusive basis except within that customer's field of use. The expiration dates of these supply agreements range from October 2019 to February 2022, and are generally renewable upon written request of the customer.

Joint venture agreement

In May 2016, the Company entered into a joint venture agreement with another party for the formation of a joint venture company to manufacture and sell conjugated therapeutic vaccines. The joint venture is organized as a French simplified corporation.

The Company holds a 30% equity interest in the joint venture in exchange for an initial capital contribution of €120,000. One-half of the initial contribution, approximately \$67,000, was paid during the year ended September 30, 2016 with the balance due upon the occurrence of certain defined future events. The Company will also provide the joint venture additional financing as may be required, on a pro rata basis in line with our equity interest. According to the joint venture agreement, as amended February 2018, if certain milestones are not achieved by December 31, 2018, the joint venture will be dissolved, unless (i) the parties mutually agree to pursue the joint venture arrangement, or (ii) either party decides to purchase the equity interests of the other party. Each of the parties is entitled, upon the occurrence of certain defined events, to acquire the interest of the other party. Except as described herein, the joint venture has an initial ten-year term, renewable for successive five-year terms. If either party provides notice at least six months prior to the expiration date of an applicable term that it does not wish to continue its participation in the joint venture, the other party will have a right to acquire all of such terminating party's equity interests in the joint venture.

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Licensing agreement and technology transfer agreement

In July 2013, the Company acquired the exclusive, worldwide license to certain patented technology for the development of human immunotherapies against *Clostridium difficile* infection (C. diff) under a written agreement (the License Agreement) with a University (the Licensor) which required payments of license fees, patent cost reimbursements and other contingent fees. In March 2017, (i) the Company entered into an agreement to terminate the License Agreement, (ii) the Company concurrently entered into a technology transfer and purchase agreement (the Transfer Agreement) with a vaccine biotechnology company (the Transferee), and (iii) the Licensor and Transferee entered into a direct licensing arrangement relating to the patented C. diff technology. Under the Transfer Agreement, the Company transferred to the Transferee its proprietary rights and know-how of immunogens and vaccine technology for C. diff, in exchange for an upfront payment and a percentage of future fees, milestone payments, sublicensing income and royalties, if any, paid by the Transferee or its assigns to the Licensor.

As a result of the termination of the License Agreement, there are no early termination penalties and no further annual licensing fees, contingent milestone payments, royalties, sub-licensing fees or other financial obligations payable by the Company to the Licensor.

Retirement savings plan 401(k) contributions

The Company sponsors a 401(k) retirement savings plan that requires an annual non-elective safe harbor employer contribution of 3% of eligible employee wages. All employees over 21 years of age are eligible beginning the first payroll after 3 consecutive months of employment. Employees are 100% vested in employer contributions and in any voluntary employee contributions. Contributions to the 401(k) plan were approximately \$75,000 and \$62,000 for the years ended September 30, 2018 and 2017, respectively.

*Related party commitments:**Patent royalty agreement*

On August 14, 2002, through its California subsidiary, the Company entered into an agreement with a director and officer of the Company, where he would receive royalty payments in exchange for assignment of his patent rights to the Company. The royalty is 5% of gross receipts from products using this invention in excess of \$500,000 annually. The Company's current operations utilize this invention. There was no royalty expense incurred during the years ended September 30, 2018 and 2017.

8. Share Capital

The Company had the following transactions in share capital:

	Years Ended	
	September 30, 2018	September 30, 2017
Number of common shares issued	3,827,845	54,834
Issuance of common shares	\$ 5,493,130	\$ -
Issuance of common shares upon exercise of warrants	4,650,659	-
Issuance of performance shares	-	1,070,909
Share issuance costs	(1,371,621)	
Fair value of placement agent warrants	(470,912)	

Equity Offerings

On May 15, 2018, the Company completed a registered public offering of 1,388,396 units, with each unit consisting of (i) one common share, no par value, or common share equivalent, and (ii) one warrant to purchase one common share at a price of \$2.65 per unit. The registered public offering also included 687,076 pre-funded units, offered to certain purchasers in lieu of units that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or at the election of a purchaser, 9.99%) of outstanding common shares. The purchase price of each pre-funded unit was equal to the price per unit being sold to the public, minus \$0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit was \$0.01 per common share. Net proceeds were \$4.6 million, after deducting underwriting discounts and commissions and estimated offering expenses. The warrants were immediately exercisable at an aggregate price of \$2.65 and expire five years from the date of issuance. In connection with the offering, the Company also issued warrants to purchase an aggregate of 145,283 common shares, at an exercise price of \$3.3125, to certain affiliated designees of the placement agent as part of the placement agent's compensation.

On May 24, 2018, the Company entered into a warrant exercise agreement with certain holders of our warrants, pursuant to which the holders agreed to exercise their warrants to purchase 1,122,076 common shares, in the aggregate, resulting in net proceeds of \$2.5 million. In consideration, the Company agreed to issue to the holders new Series A Common Share Purchase Warrants to purchase up to 1,122,076 common shares at an exercise price of \$2.65 per share, with an exercise period of five years, and new Series B Common Share Purchase Warrants to purchase up to 2,244,152 common shares at an exercise price of \$2.65 per share, with an exercise period of seven months. In connection with the agreement, the Company also issued warrants to purchase an aggregate of 78,545 common shares to certain affiliated designees of the placement agent as part of the placement agent's compensation, at an exercise price of \$3.3125.

Reverse Share Split

On May 4, 2018, the Company effected a share consolidation (reverse split) of the Company's common shares at a ratio of 1-for-7. As a result of the reverse split, every seven shares of the issued and outstanding common shares, without par value, consolidated into one newly-issued outstanding common share, without par value. Each fractional share remaining after the reverse split that was less than one-half of a share was cancelled and each fractional share that was at least one-half of a share was changed to one whole share. The reverse split reduced the number of common shares outstanding from 10,520,096 to 1,502,870 after fractional share rounding. The number of warrants and options were proportionately adjusted by the split ratio and the exercise prices correspondingly increased by the same split ratio. All shares and exercise prices are presented on a post-split basis in these consolidated financial statements.

Performance Shares

Pursuant to a performance share plan approved by shareholders in 2010, 142,857 common shares were reserved for issuance to certain officers, directors and employees of the Company upon achievement of certain milestones related to completion of method development for commercial-scale manufacture of KLH, compilation and regulatory submittal of all required chemistry, manufacturing and control data and completion of preclinical toxicity and immunogenicity testing of products. Share-based compensation was recorded over the estimated vesting period ending in August 2012.

At September 30, 2017, all vested performance shares under the plan had been issued, and the performance share plan was terminated.

Black-Scholes option valuation model

The Company uses the Black-Scholes option valuation model to determine the fair value of warrants, broker units and share options. Option valuation models require the input of highly subjective assumptions including the expected price volatility. The Company has used historical volatility to estimate the volatility of the share price. Changes in the subjective input assumptions can materially affect the fair value estimates, and therefore the existing models do not necessarily provide a reliable single measure of the fair value of the Company's warrants, broker units and share options.

Warrants

A summary of the Company's warrants activity is as follows:

	<u>Number of Warrants</u>	<u>Weighted Average Exercise Price</u>
Balance - September 30, 2017	180,805	\$ 31.50
Granted	5,665,528	2.68
Granted pre-funded warrants	687,076	.01
Exercised	(1,752,373)	2.65
Exercised pre-funded warrants	(687,076)	.01
Balance - September 30, 2018	<u>4,093,960</u>	<u>\$ 3.96</u>

The weighted average contractual life remaining on the outstanding warrants at September 30, 2018 is 28 months.

The following table summarizes information about the warrants outstanding at September 30, 2018:

<u>Exercise Price</u>	<u>Number of Warrants</u>	<u>Expiry Date</u>
\$ 2.65	2,044,152	December 2018
31.50	180,805	January 2022
2.65	1,645,175	May 2023
3.31	223,828	May 2023
	<u>4,093,960</u>	

The fair value of placement agent warrants granted was determined using the Black-Scholes option valuation model, using the following weighted average assumptions at the date of the grant:

	<u>Year Ended September 30, 2018</u>
Risk free interest rate	2.21%
Expected life (years)	5.0
Expected share price volatility	173%
Expected dividend yield	0%

The weighted average fair value of placement agent warrants granted during the year ended September 30, 2018 was \$1.98.

Share Options

The Company adopted an incentive compensation plan in 2017 (the Incentive Plan), which amended and restated the 2013 fixed share option plan and is administered by the Board of Directors. Options, restricted shares and restricted share units are eligible for grants under the Incentive Plan. The number of shares available for issuance under the Incentive Plan is 228,143, including shares available for the exercise of outstanding options under the 2013 fixed share option plan. No restricted shares or restricted share units have been granted as of September 30, 2018.

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The exercise price of an option is set at the closing price of the Company's common shares on the date of grant. Share options granted to directors, officers, employees and certain individual consultants for past service are subject to the following vesting schedule: (a) one-third shall vest immediately, (b) one-third shall vest at 12 months from the date of grant and (c) one-third shall vest at 18 months from the date of grant.

Share options granted to directors, officers, employees and certain individual consultants for future service are subject to the following vesting schedule: (x) one-third shall vest at 12 months from the date of grant, (y) one-third shall vest at 24 months from the date of grant and (z) one-third shall vest at 36 months from the date of grant.

Share options granted to certain individual investor relations consultants are subject to the following vesting schedule: (aa) 25% shall vest at 3 months from the date of grant, (bb) 25% shall vest at 6 months from the date of grant, (cc) 25% shall vest at 12 months from the date of grant and (dd) 25% shall vest at 15 months from the date of grant.

Options have been granted under the Incentive Plan allowing the holders to purchase common shares of the Company as follows:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>	
Balance - September 30, 2017	58,711	\$ 40.18	
Granted	29,426	5.88	
Expired	(2,266)	84.87	
Expired	<u>(15,373)</u>	<u>42.07</u>	CDN \$
Balance - September 30, 2018	70,498	\$ 25.42	

The weighted average contractual life remaining on the outstanding options is 49 months.

The following table summarizes information about the options under the Incentive Plan outstanding and exercisable at September 30, 2018:

<u>Number of Options</u>	<u>Exercisable at September 30, 2018</u>	<u>Range of exercise prices</u>	<u>Expiry Dates</u>
13,479	13,479	CDN\$15.00 - 35.00	Apr 2019-Dec 2019
40,046	17,326	\$5.00 - 20.00	Sep 2023-Mar 2025
7,571	7,571	CDN\$40.00 - 70.00	May 2020-Jun 2022
2,114	2,114	\$50.00 - 60.00	Dec 2022
3,073	3,073	CDN\$105.00 - 140.00	Nov 2018-Nov 2021
4,215	4,215	\$120.00 - 130.00	Nov 2020
<u>70,498</u>	<u>47,778</u>		

The estimated fair value of the share options granted was determined using a Black-Scholes option valuation model with the following weighted average assumptions:

	<u>Years Ended</u>	
	<u>September 30, 2018</u>	<u>September 30, 2017</u>
Risk free interest rate	2.13%	1.44%
Expected life (years)	7.00	7.00
Expected share price volatility	155%	166%
Expected dividend yield	0%	0%

The weighted average fair value of share options granted during the years ended September 30, 2018 and 2017 was \$5.67, and \$12.88, respectively.

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As of September 30, 2018, the Company had approximately \$72,000 of unrecognized share-based compensation expense, which is expected to be recognized over a period of 28 months.

There were no options exercised during the years ended September 30, 2018 and 2017. There was no intrinsic value of the vested options at September 30, 2018.

9. Income Taxes

The breakdown of loss before income tax by jurisdiction is as follows:

	Years Ended	
	September 30,	September 30,
	2018	2017
U.S.	\$ (4,306,650)	\$ (4,540,094)
Canadian	(623,835)	(464,990)
Other foreign	(107,664)	(24,764)
Total Loss Before Income Tax	\$ (5,038,149)	\$ (5,029,848)

Deferred income tax assets and liabilities of the Company are as follows:

	September 30,	September 30,
	2018	2017
Deferred income tax assets:		
Non-capital loss carry-forwards	\$ 10,646,900	\$ 12,164,100
Research and development tax credits	1,117,100	947,300
Deferred expenses	36,400	34,300
Property, plant and equipment	-	2,200
Share issuance costs	981,800	142,600
Deferred income tax liabilities:		
U.S. federal benefit (liability) of state deferred taxes	(666,700)	(923,700)
Property, plant and equipment	(1,800)	-
Valuation allowance	(12,113,700)	(12,366,800)
Net deferred income tax asset (liability)	\$ -	\$ -

Realization of the deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

As of September 30, 2018, the Company had federal net operating loss (NOL) carryforwards of approximately \$29.6 million expiring 2030 through 2038, California NOL carryforwards of approximately \$29.2 million expiring 2030 through 2038, and Canadian federal and provincial NOL carryforwards of approximately CDN\$8.7 million expiring 2028 through 2038. Portions of these NOL carryforwards may be used to offset future taxable income, if any.

As of September 30, 2018, the Company also has federal and California research and development tax credit carryforwards of approximately \$0.53 million and \$0.58 million, respectively, available to offset future taxes. The federal credits begin expiring in 2028 and continue expiring through 2038. The state tax credits do not expire.

Stellar Biotechnologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended September 30, 2018 and 2017

Under the provisions of Section 382 of the Internal Revenue Code, substantial changes in the Company's ownership limit the amount of net operating loss carryforwards and tax credit carryforwards that can be utilized annually in the future to offset taxable income. A valuation allowance has been established to reserve the potential benefits of these carryforwards in the Company's consolidated financial statements to reflect the uncertainty of future taxable income required to utilize available tax loss carryforwards and other deferred tax assets.

The income tax expense shown in the consolidated statements of operations differs from the amounts obtained by applying statutory rates to the loss before provision for income taxes due to the following:

	Years Ended	
	September 30, 2018	September 30, 2017
Combined Canadian federal and provincial tax rates	27.0%	26.0%
Expected income tax (recovery)/expense	\$ (1,360,300)	\$ (1,307,800)
Nondeductible share-based payments	41,700	30,000
Deductible share issuance costs	(287,300)	(66,300)
Effect of income tax rate differences in the U.S. and Mexico	(33,500)	(624,400)
Impact of tax rate changes	2,906,100	-
Foreign currency differences	9,500	(42,200)
Other	(143,100)	(108,200)
Change in valuation allowance on deferred tax assets	(1,132,300)	2,119,700
Income tax expense	\$ 800	\$ 800

On December 22, 2017, the Tax Cuts and Jobs Act (the Tax Act) was enacted into law in the U.S. The Tax Act contains a broad range of tax reform measures, including a reduction in the U.S. federal corporate tax rate from 35% to 21% effective January 1, 2018. The Company remeasured certain tax assets and liabilities at September 30, 2018 based on expected lower future U.S. federal tax rates expected to apply when temporary differences reverse in the future. SEC Staff Accounting Bulletin No. 118, "Income Tax Accounting Implications of the Tax Cuts and Jobs Act" (SAB 118), allows provisional amounts to be recorded for the tax effects of the Tax Act when the necessary information is not available, prepared, or analyzed in reasonable detail to finalize its accounting for the changes in the tax law during a measurement period not to extend beyond one year of the enactment date. The Company has provisionally recorded a \$2.95 million reduction of deferred tax assets with a corresponding reduction in the valuation allowance for our U.S. subsidiary. Certain aspects of the Tax Act are still being analyzed which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts. Potential adjustments are not expected to have a material impact since any adjustments would be fully offset by a valuation allowance. The Company expects to finalize its analysis within the measurement period in accordance with SAB 118 after completing reviews of additional guidance issued by the Internal Revenue Service.

On November 2, 2017, Bill 2-2017, Budget Measures Implementation Act (the Budget Act) came into force in British Columbia, increasing the provincial corporate tax rate from 11% to 12% effective January 1, 2018. The Company remeasured certain tax assets and liabilities at September 30, 2018 based on the provincial tax rates expected to apply when temporary differences reverse in the future. The Company has recorded a \$0.04 million increase in deferred tax assets with a corresponding increase in the valuation allowance.

Stellar Biotechnologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended September 30, 2018 and 2017

The components of income tax provision (benefits) are as follows:

	Years Ended	
	September 30, 2018	September 30, 2017
Current tax provision		
U.S. federal	\$ -	\$ -
Canadian	-	-
Other foreign	-	-
State	800	800
Deferred tax provision		
U.S. federal	2,059,300	(1,447,100)
Canadian	(446,700)	(199,100)
Other foreign	(22,600)	(5,200)
State	(457,700)	(468,300)
Change in valuation allowance on deferred tax assets	(1,132,300)	2,119,700
Total	\$ 800	\$ 800

10. Fair Value of Financial Instruments

The Company uses the fair value measurement framework for valuing financial assets and liabilities measured on a recurring basis in situations where other accounting pronouncements either permit or require fair value measurements.

Fair value of a financial instrument is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The carrying value of certain financial instruments such as accounts receivable, accounts payable, accrued liabilities, and deferred revenue approximates fair value due to the short-term nature of such instruments. Short-term investments in U.S. Treasury Bills are recorded at amortized cost, which approximates fair value.

The Company follows the fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

Level 1:	Quoted prices in active markets for identical or similar assets and liabilities.
Level 2:	Quoted prices for identical or similar assets and liabilities in markets that are not active or observable inputs other than quoted prices in active markets for identical or similar assets and liabilities.
Level 3:	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company reports its short-term investments in U.S. Treasury Bills at fair value using Level 1 inputs in the fair value hierarchy.

The following table summarizes fair values for those assets and liabilities with fair value measured on a recurring basis.

	Fair Value Measurements Using			Total Fair Value
	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
September 30, 2018				
Assets				
Short-term investments in U.S. Treasury Bills	\$ 6,078,031	\$ -	\$ -	\$ 6,078,031
September 30, 2017				
Assets				
Short-term investments in U.S. Treasury Bills	\$ 1,994,401	\$ -	\$ -	\$ 1,994,401

Stellar Biotechnologies, Inc.

Notes to Consolidated Financial Statements

For the Years Ended September 30, 2018 and 2017

11. Concentrations of Credit Risk

Credit risk is the risk of an unexpected loss if a customer or third party to a financial instrument fails to meet its contractual obligations. Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents, U.S Treasury Bills, and accounts receivable. The Company estimates its maximum credit risk at the amount recorded on the balance sheet.

Management's assessment of the Company's credit risk for cash and cash equivalents is low as they are held in major financial institutions believed to be credit worthy or U.S. Treasury Bills with maturities of 90 days or less. The Company limits its exposure to credit loss for short-term investments by holding U.S. Treasury Bills with maturities of 1 year or less. Based on credit monitoring and history, the Company considers the risk of credit losses due to customer non-performance on accounts receivable to be low.

The Company had the following concentrations of revenues by customers, each of which accounted for more than 10% of revenues in the applicable period:

The Company had the following concentrations of revenues by customers, each of which accounted for more than 10% of revenues in the applicable period:

	Years Ended	
	September 30, 2018	September 30, 2017
Product sales and contract services revenue	59% from 2 customers	79% from 2 customers

The Company had the following concentrations of revenues by geographic areas:

	Years Ended	
	September 30, 2018	September 30, 2017
Europe	51%	64%
North America	45%	33%
Asia	4%	3%

The Company had the following concentrations of accounts receivable from its customers, each of which accounted for more than 10% in the applicable period:

	September 30, 2018
Accounts receivable	87% from 2 customers

There were no customer accounts receivable at September 30, 2017.



BC Registry Services

Mailing Address: PO Box 9431 Stn Prov Govt Victoria BC V8W 9V3 www.corporateonline.gov.bc.ca

Location: 2nd Floor - 940 Blanshard Street Victoria BC 1 877 528-1526

CERTIFIED COPY Of a Document filed with the Province of British Columbia Registrar of Companies

Notice of Articles

BUSINESS CORPORATIONS ACT

CAROL PREST

This Notice of Articles was issued by the Registrar on: April 13, 2018 01:42 PM Pacific Time

Incorporation Number: C0867178

Recognition Date and Time: Continued into British Columbia on November 25, 2009 03:15 PM Pacific Time

NOTICE OF ARTICLES

Name of Company:

STELLAR BIOTECHNOLOGIES, INC.

REGISTERED OFFICE INFORMATION

Mailing Address:

1055 WEST GEORGIA STREET 1500 ROYAL CENTRE, P.O. BOX 11117 VANCOUVER BC V6E 4N7 CANADA

Delivery Address:

1055 WEST GEORGIA STREET 1500 ROYAL CENTRE, P.O. BOX 11117 VANCOUVER BC V6E 4N7 CANADA

RECORDS OFFICE INFORMATION

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PORT HUENEME CA 93041
UNITED STATES

RESOLUTION DATES:

Date(s) of Resolution(s) or Court Order(s) attaching or altering Special Rights and Restrictions attached to a class or a series of shares:

March 27, 2018

AUTHORIZED SHARE STRUCTURE

1.	No Maximum	Common Shares	Without Par Value
			Without Special Rights or Restrictions attached

2.	No Maximum	Preferred Shares	Without Par Value
			With Special Rights or Restrictions attached

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-217480) of Stellar Biotechnologies, Inc. of our report dated November 30, 2018, relating to the consolidated financial statements of Stellar Biotechnologies, Inc., which report appears in this Annual Report on Form 10-K for the year ended September 30, 2018.

/s/ Moss Adams LLP
Los Angeles, California
November 30, 2018

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)**

I, Frank R. Oakes, certify that:

1. I have reviewed this Annual Report on Form 10-K of Stellar Biotechnologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 30, 2018

By: /s/ Frank R. Oakes
Frank R. Oakes
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)**

I, Kathi Niffenegger, certify that:

1. I have reviewed this Annual Report on Form 10-K of Stellar Biotechnologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 30, 2018

By: /s/ Kathi Niffenegger
Kathi Niffenegger
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Stellar Biotechnologies, Inc. (the Company) on Form 10-K for the year ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Frank R. Oakes, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 30, 2018

By: /s/ Frank R. Oakes
Frank R. Oakes
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Stellar Biotechnologies, Inc. (the Company) on Form 10-K for the year ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Kathi Niffenegger, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 30, 2018

By: /s/ Kathi Niffenegger
Kathi Niffenegger
Chief Financial Officer
(Principal Financial Officer)
