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

OR

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

For the transition period from January 1, 2019 to September 30, 2019

Commission file number: 001-37619

EDESA BIOTECH, 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.)
100 Spy Court **Markham, ON, Canada** (Address of principal executive offices)	**L3R 5H6** (Zip Code)

Registrant's telephone number, including area code: (289) 800-9600

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Shares, without par value	EDSA	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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

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

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

As of March 29, 2019, 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 $5,757,940, which was calculated based on 888,454 common shares outstanding as of that date, of which 880,419 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. These amounts reflect the one for six reverse split of the registrant's outstanding common shares effected June 7, 2019.

As of December 12, 2019, the registrant had 7,504,468 common shares issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

EDESA BIOTECH, INC.
ANNUAL REPORT ON FORM 10-K
Nine-month Period Ended September 30, 2019

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FORWARD-LOOKING STATEMENTS AND OTHER MATTERS

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 about, among other things: the status, progress and results of our clinical programs; our ability to obtain regulatory approvals for or successfully commercialize any of our product candidates; our business plans, strategies and objectives, including plans to pursue collaboration, licensing or other similar arrangements or transactions; our expectations regarding our liquidity and performance, including our expense levels, sources of capital and ability to maintain our operations; the competitive landscape of our industry; and general market, economic and political conditions.

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 discussed in this report in the Part I, Item 1A. Risk Factors and elsewhere in this report. Risks and uncertainties include, among others,

- our ability to obtain funding for our operations;
- our estimates regarding our expenses, revenues, anticipated capital requirements and our needs for additional financing;
- the timing of the commencement, progress and receipt of data from any of our preclinical and clinical trials;
- the expected results of any preclinical or clinical trial and the impact on the likelihood or timing of any regulatory approval;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- changes in our strategy or development plans;
- the volatility of our common share price;
- the rate and degree of market acceptance and clinical utility of any future products;
- the effect of competition;
- our ability to protect our intellectual property as well as comply with the terms of license agreements with third parties;
- our ability to identify, develop and commercialize additional products or product candidates;
- reliance on key personnel; 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, "Edesa," "the Company," "we," "us," and "our" refer to Edesa Biotech, Inc. and our consolidated subsidiaries, except where the context otherwise requires.

Our logo and other trademarks or service marks of Edesa Biotech, Inc. appearing in this Annual Report on Form 10-K are the property of Edesa Biotech, 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 June 7, 2019 and the related exercise prices in this Form 10-K have been adjusted to reflect the effect of the one for six reverse split, effected at the close of market on June 7, 2019.

PART I

Item 1. BUSINESS.

Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing clinical-stage drugs for dermatological and gastrointestinal indications with clear unmet medical needs. Our lead product candidate, EB01, is an $sPLA_2$ inhibitor for the topical treatment of chronic allergic contact dermatitis (ACD), a common, potentially debilitating condition and occupational illness. EB01 employs a novel, non-steroidal mechanism of action and in two clinical studies has demonstrated statistically significant improvement of multiple symptoms in ACD patients. Our investigational new drug (IND) application for EB01 was accepted by the U.S. Food and Drug Administration (FDA) in November 2018 and we initiated patient enrollment for a Phase 2B clinical study evaluating EB01 in October 2019.

We also intend to expand the utility of our $sPLA_2$ inhibitor technology, which forms the basis for EB01, across multiple indications. For example, in September 2019, we received approval from Health Canada to begin a proof-of-concept clinical study of EB02, an $sPLA_2$ inhibitor, as a potential treatment for patients with hemorrhoids disease (HD). In addition to EB01 and EB02, we plan to expand our portfolio with drug candidates to treat other skin and gastrointestinal conditions.

Competitive Strengths

We believe that we possess a number of competitive strengths that position us to become a leading biopharmaceutical company focused on dermatological and gastrointestinal diseases, including:

- *Novel pipeline addressing large underserved markets.* Our product candidates are novel clinical-stage compounds that have significant scientific rationale for effectiveness. By initially targeting large markets that have significant unmet medical needs, we believe that we can drive adoption of new products and improve our competitive position. For example, we believe that the novel, non-steroidal mode of action of our lead product candidates will be an appealing alternative for managing the symptoms of ACD and HD. These diseases impact millions of people in the United States and Canada, and can have significant effects on patients' quality of life and, in the case of many chronic ACD patients and their employers, significant workplace-related costs and limitations.

- *Intellectual property protection and market exclusivity.* We have opportunities to develop our competitive position through patents, trade secrets, technical know-how and continuing technological innovation. We have exclusive license rights in our target indications to multiple patents and pending patent applications in the United States and in various foreign jurisdictions. In addition to patent protection, we intend to utilize trade secrets and market exclusivity afforded to a New Chemical Entity, where applicable, to enhance or maintain our competitive position.

- *Experienced management and drug development capabilities.* Our leadership team possesses core capabilities in dermatology, gastrointestinal medicine, drug development and commercialization, chemistry, manufacturing and controls, public company management and finance. Our founder, Chief Executive Officer, Pardeep Nijhawan, MD, FRCPC, AGAF, is a board-certified gastroenterologist and hepatologist with a successful track record of building life science businesses, including Medical Futures, Inc., which was sold to Tribute Pharmaceuticals in 2015. In addition to our internal capabilities, we have also established a network of key opinion leaders, contract research organizations, contract manufacturing organizations and consultants. As a result, we believe we are well positioned to efficiently develop novel dermatological and gastrointestinal treatments.

Our Business Strategy

Our business strategy is to develop and commercialize innovative drug products that address unmet medical needs for large, underserved markets where there is limited competition. Key elements of our strategy include:

- *Establish EB01 as the leading treatment for chronic ACD.* Our primary goal is to obtain regulatory approval for EB01 and commercialize EB01 for use in the treatment of ACD. Based on promising clinical trial results in which patients treated with EB01 experienced statistically significant improvements of their symptoms with minimal side effects, we initiated a Phase 2B clinical study evaluating EB01 in the United States.

- *Selectively targeting additional indications within the areas of dermatology and gastroenterology.* In addition to our ACD program, we plan to efficiently generate proof-of-concept data for other programs where the inhibition of $sPLA_2$ activity may have a therapeutic benefit. For example, given sufficient funding, we are planning a clinical study to evaluate EB02 for internal hemorrhoids.

- *In-license promising product candidates.* We are applying our cost-effective development approach to advance and expand our pipeline. Our current product candidates are in-licensed from academic institutions or other pharmaceutical companies, and we plan to continue to identify, evaluate and potentially obtain rights to and develop additional assets. Our objective is to maintain a well-balanced portfolio with product candidates across various stages of development. In general, we seek to identify product candidates and technology that represent a novel therapeutic approach to dermatological and gastrointestinal diseases, are supported by compelling science, target an unmet medical need, and provide a meaningful commercial opportunity. We do not currently intend to invest significant capital in basic research, which can be expensive and time-consuming.

- *Capture the full commercial potential of our product candidates.* If our product candidates are successfully developed and approved, we may build commercial infrastructure capable of directly marketing the products in North America and potentially other major geographies of strategic interest. We also plan to evaluate strategic licensing arrangements with pharmaceutical companies for the commercialization of our drugs, where applicable, such as in territories where a partner may contribute additional resources, infrastructure and expertise.

Allergic Contact Dermatitis

Contact dermatitis is one of the most common occupational and work-related skin conditions in the United States. The disease can be either irritant contact dermatitis or ACD. Together, these conditions have been estimated to cost up to $2 billion annually as a result of lost work, reduced productivity, medical care and disability payments. Based on published reports and U.S. insurance claims data, we estimate that there are more than 2.5 million people in the United States with ACD, including more than 1 million people who have chronic ACD. Since primary care physicians do not always distinguish between irritant and allergic contact dermatitis, a potentially larger undiagnosed patient population may also be present.

ACD is caused by an allergen interacting with skin and usually occurs on areas of the body that have been directly exposed to the environment, with a high prevalence on the hands and face. Common allergens associated with ACD include plants, metals, plastics and resins, rubber additives, dyes, biocides, and various cosmetics. The disease is characterized by inflammation, erythema (redness), pruritus (itchiness), and blistering of the skin. Inflammation can vary from mild irritation and redness to open sores, depending on the type of irritant, the body part affected and the degree of sensitivity. ACD can become chronic if not treated or if the causative allergen is not removed. In many chronic cases, the causative allergen is unknown or difficult to avoid (as an example, the allergen is present in the workplace).

The immune mechanisms involved in ACD are well documented. During the initial contact with the offending allergen, the immune system is sensitized. Upon subsequent contact, a delayed-type hypersensitivity reaction (Type IV) occurs at the point of contact between the skin and the allergen. As a cell-mediated response, the immune reaction primarily involves the interaction of T cells with antigens rather than an antibody response. More specifically, ACD involves an exogenous substance binding a cell surface protein to form a hapten that is recognized as a foreign antigen by the immune system. Haptens are known to signal through toll-like receptors, a family of receptors involved in the innate immune system recognizing pathogens, leading to the induction of pro-inflammatory cytokines such as interleukin (IL)-1b. EB01 has been shown in preclinical studies to inhibit the production of pro-inflammatory cytokines induced via toll-like receptor signaling (IL-1b, IL-6, IL-8, MIP-1a, and TNFa), suggesting that EB01 may address the underlying disease mechanism of ACD.

Current Treatments

Diagnosis of ACD is typically based upon the appearance of the skin and the history of exposure to an allergen. Currently, patch testing is the standard for identifying the allergen causing the reaction; however, it is a lengthy procedure that only identifies the offending allergen approximately half of the time according to our market research.

Generally, dermatologists view chronic ACD from both a duration and recurrence perspective, considering how often and how long symptoms persist. Chronic disease affects patients over a prolonged period, typically greater than six months or even years. These chronic patients have either frequent intermittent exposure or continuous exposure. Since inflammation in ACD is driven by external exposure to an allergen, the severity of ACD does not necessarily correlate with body surface area, as is often the case with other dermatological diseases.

The current mainstay of treatment is to identify and remove exposure to the allergen. However, in approximately 70% of cases, allergen exposure cannot be eliminated, according to our market research. To our knowledge, there are no drug treatment options specifically indicated for ACD. As such, physicians must utilize agents approved for other dermatological conditions. Topical corticosteroids are the most commonly used therapeutic intervention for ACD but cannot be used continuously since they have well-known side-effects including skin thinning, stretch marks, acne, testicular atrophy, nosebleeds, stinging, burning and dryness. Other topical treatments for ACD include immunomodulators such as topical calcineurin inhibitors. However, these are less efficacious than topical corticosteroids and have an FDA “black box warning” for risk of malignancies. Systemic corticosteroids can be used for acute control of severe cases of ACD but have safety concerns including hypothalamic-pituitary-adrenal axis suppression, growth suppression and loss of bone-density, thereby limiting the utility of steroids for treating chronic disease. The last resort for patients is systemic immunomodulators which have a series of “black box warnings” and associated safety issues. Systemic therapies also need to be tapered off each time the physician wants to patch test allergens to identify the source of a patient’s ACD.

EB01

Overview and Status

Our lead product candidate, EB01, is a topical vanishing cream containing a novel, non-steroidal anti-inflammatory compound. EB01 exerts its anti-inflammatory activity through the inhibition of certain pro-inflammatory enzymes known as secretory phospholipase 2, or $sPLA_2$. These enzymes are secreted by immune cells upon their activation and produce arachidonic acid via phospholipid hydrolysis, which, in turn, initiates a broad inflammatory cascade. The $sPLA_2$ enzyme family plays a key role in initiating inflammation associated with many diseases, and we believe that targeting the $sPLA_2$ enzyme family with enzyme inhibitors will have a superior anti-inflammatory therapeutic effect because the inflammatory process will be inhibited at its inception rather than after inflammation has occurred.

In October 2019, we initiated patient enrollment for a multi-center Phase 2B clinical study evaluating EB01 as a monotherapy for patients with moderate to severe chronic ACD. In the first cohort, ACD patients will be treated for 28 days with EB01cream. The double-blind, vehicle-controlled study will primarily evaluate the safety and efficacy of EB01 in ACD patients. Investigators will also evaluate symptom reduction, quality of life and dose-relationships among various strengths of EB01 cream as secondary and exploratory measures. We plan to perform a blinded interim analysis following the completion of the first cohort to determine the total number of patients for the second part of the study. The sample size adaptive protocol contemplates up to 166 total subjects.

Previous Results

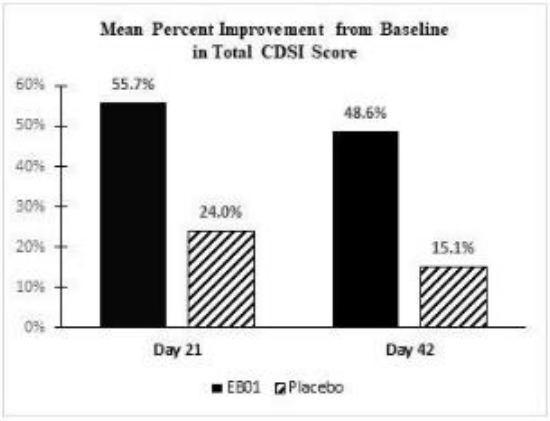
EB01 has demonstrated anti-inflammatory activity in a variety of *in vitro* and *in vivo* preclinical pharmacology models. In addition, EB01 has demonstrated efficacy for the treatment of ACD in two previous clinical trials.

A variety of *in vitro* and in *vivo* preclinical pharmacology models were used to assess the anti-inflammatory activity of EB01. Using a model for hapten signaling indicative of ACD, lipopolysaccharide-stimulated peripheral blood mononuclear cells were treated with EB01 and shown to inhibit pro-inflammatory cytokines including IL-1b, IL-6, IL-8, MIP-1a, and TNFa at the protein and mRNA expression levels. Additionally, the safety of EB01 has been established in several Good Laboratory Practice toxicology studies, including an eight-week study involving topical application of 2.0% EB01 cream to minipigs and a 6-week continuous infusion study in rats. Overall, EB01 was well-tolerated and systemic exposure was negligible (below the limit of detection). No genotoxicity has been demonstrated in bacterial reverse mutation and micronucleus testing.

Clinical experience with EB01 includes five clinical studies involving a total of 176 subjects. No serious adverse reactions were encountered during these clinical studies. Healthy volunteers were treated with EB01 under occlusion. EB01 was classified as a weak sensitizer by maximization assay (Grade 1) and is, therefore, considered safe to use under any conditions. EB01 has demonstrated efficacy for the treatment of ACD in two separate clinical trials. Both studies were double-blind, vehicle-controlled bilateral comparison studies to assess the safety, tolerability and efficacy of EB01 cream applied twice daily for the treatment of ACD of the hand and forearm as determined by the Contact Dermatitis Severity Index (CDSI), a physician’s visual assessment. The CDSI is a composite endpoint, which grades each symptom of the disease (dryness, scaling, redness, pruritus, and fissures) scored from 0 (none) to 3 (severe), with a maximum severity score of 15. A diagnosis of ACD was confirmed by a positive patch test deemed to be clinically relevant by the investigator.

The first study (*n*=11) was a double-blind, placebo-controlled clinical study to assess the safety and efficacy of topical 1.0% EB01 cream for the treatment of ACD. Subjects selected for inclusion had bilateral ACD. Prior to randomization, subjects were patch tested. Patch tests were applied to the upper part of each subjects' back for 2 days and were read on Days 2 and 4. Only "++" reactions were considered clinically relevant and positive for the study. The study was bilateral in design with one lesion treated with 1.0% EB01 cream twice daily, while a comparable lesion was treated with placebo cream. Disease severity was assessed before treatment (Day 0) and at Day 30 by the investigator using the CDSI. For each individual patient, the change in disease score in the drug-treated hand was compared to that in the placebo-treated hand, thus making the latter an internal control for each patient. The mean change from baseline for 1.0% EB01 cream treated lesions was 69.9%, compared to 36.5% in the placebo cream lesions (p = 0.0024). No serious adverse events were reported.

A second, larger (n=30) bilateral study was conducted to assess 2.0% EB01 cream applied twice daily for 21 consecutive days in connection with the treatment of ACD. To be included in the study, patients had to have bilateral ACD with a CDSI score of at least 10 on each side, with no more than a 1-point difference between lesions. At Day 21, EB01-treated lesions had a mean improvement from baseline of 56%, compared to 24% for those treated with placebo cream ($p < 0.001$). Efficacy of the 2.0% EB01 cream was maintained through Day 42 (21-days after ending treatment) with a 49% decrease in total CDSI score for 2.0% EB01 cream-treated hands, compared to 15% in the vehicle-treated hands ($p < 0.001$).



Within the total CDSI score, EB01 demonstrated statistically significant reductions for each of the individual CDSI components (dryness, scaling, redness, pruritus, and fissures), as shown in the following table:

Mean Percent Reduction in Individual Symptoms from Baseline to Day 21

	EB01	Vehicle/Placebo	P-Value
Scaling	-48%	-20%	<0.001
Redness	-47%	-20%	<0.001
Pruritis	-62%	-25%	<0.001
Fissures	-81%	-46%	<0.001
Dryness	-45%	-15%	<0.001

Hemorrhoids Disease

Hemorrhoids disease (HD) is a common disorder, characterized by itching, inflammation, pain, tenderness, bleeding and difficulty defecating. According to National Institutes of Health reports, HD affects approximately 5% of the U.S. adult population, or approximately 12.5 million adults in the U.S. Almost half of individuals 50 years and older have experienced symptomatic hemorrhoids. Despite the high prevalence of hemorrhoids, we are not aware of any prescription drugs with an approved New Drug Application for the treatment of hemorrhoids. While there are commonly used prescription and over-the-counter products for HD, none has been approved by the FDA through the NDA process because they entered the market prior to 1962. The mechanism of action of these treatments is either general, such as steroids, or unknown, in the case of herbal remedies, and we are not aware of any reports published in medical journals on the efficacy of safety of any product currently marketed in the U.S. As a result of these factors, we believe that HD remains a significant unmet medical need and market opportunity.

Confusion often arises because the term hemorrhoid has been used to refer to both normal anatomic structures and pathologic structures. Hemorrhoids are cushions of fibromuscular tissue that line the anal canal. With HD, the muscle fibers that anchor the cushions become attenuated, the hemorrhoids slide, become congested, bleed, and eventually prolapse or protrude into the anal canal. The two types of hemorrhoids, external and internal, refer to their location. Internal hemorrhoids are typically classified as first degree (grade I) – hemorrhoids bleed but do not protrude; second degree (grade II) – hemorrhoids protrude but reduce on their own; third degree (grade III) – hemorrhoids protrude and require manual re-insertion; and fourth degree (grade IV) – hemorrhoids are permanently prolapsed and cannot be re-inserted.

The treatment of HD typically begins with conservative therapy consisting of diet and lifestyle modification, fiber supplements, sitz baths and stool softeners. In addition to this conservative therapy, physicians may prescribe topical steroids and analgesics. Because of the lack of effective prescription products, most hemorrhoid patients will use over-the-counter preparations or the prescription drugs available, which are similar to the over-the-counter treatment, but formulated with a higher dose. Based on public filings and reports, we estimate that as many as 4.0 million prescriptions are written and more than 20 million over-the-counter units are sold each year in the U.S. for the treatment of HD. Alternatives are invasive procedures, including rubber band ligation, the injection of a sclerosing agent, electrocoagulation, light therapy and hemorrhoidectomy.

EB02

Overview and Status

EB02 represents a potential extension of our $sPLA_2$ anti-inflammatory technology. Based on our analysis of clinical data in dermatitis, we believe that EB02, which is currently formulated as a cream, may be effective in treating the erythema, swelling and exudation associated with HD. Specifically, $sPLA_2$ has been demonstrated to be a mediator of processes that characterize hemorrhoidal pathophysiology, including inflammation and micro-vascularization.

In September 2019, we received approval from Health Canada to begin a clinical study of EB02 as a potential treatment for patients with grade I-III internal hemorrhoids. Health Canada reviewed our clinical trial application (CTA) and approved it by issuing a "no objection letter," a standard guidance document that allows us to proceed with our study. We believe this approval represents a significant milestone in our goal of demonstrating the broad potential of our novel non-steroidal anti-inflammatory technology.

Our exploratory Phase 2a study is designed to assess the safety and efficacy of EB02 among hemorrhoid patients at investigational centers in Canada. The study plan includes up to 48 subjects in a randomized, double-blind, vehicle-controlled design. Should the initial results be encouraging, we plan to transition from a proof of concept study to a Phase 2 study of up to 80 to 400 subjects. We are currently evaluating the timing of the initiation of the study based in part on other company priorities and available funding.

Other Product Candidates

We have exclusive worldwide licensed rights to an additional product candidate for the topical treatment of anal fissures. This potential development program is part of our long-term growth opportunities. In addition, we plan to continue to identify, evaluate and potentially obtain rights to and develop additional clinical assets across various stages of development, focusing primarily on dermatological and gastrointestinal diseases.

Intellectual Property

We have an exclusive license from Yissum Research Development Company, the technology transfer company of Hebrew University of Jerusalem Ltd. (Yissum), for patents and patent applications that cover our product candidates EB01 and EB02 in the United States, Canada, Australia and various countries in Europe. Method of use patents, for which we hold an inbound license from Yissum, have been issued for use in dermatologic and gastrointestinal conditions and infections that will expire in 2024. We expect to seek patent life extension in the United States related to time under our IND, which could add another three to five years of protection. Additional patents subject to the license agreement have been filed by Yissum which we believe, if issued, could potentially prevent generic substitution until after 2033.

We also rely on trade secrets, know-how, continuing technological innovation and other in-licensing opportunities to develop and maintain our proprietary position. In the event we are successful in commercializing a new drug candidate, we believe we would be eligible for regulatory exclusivity, in addition to exclusivity rights granted through patent protection. We would be eligible for five years of regulatory exclusivity after approval in the United States, eight years of regulatory exclusivity in Canada and ten years of regulatory exclusivity in the European Union.

We expect patents and other proprietary intellectual property rights to be an essential element of our business. Our intention is to seek to protect our proprietary positions by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements. Our success will depend, in part, on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights.

Material Licenses

License Agreement with Yissum

On June 29, 2016, our wholly owned subsidiary, Edesa Biotech Research, Inc., entered into an exclusive license agreement with Yissum, which agreement was subsequently amended on each of April 3, 2017 and May 7, 2017. Pursuant to the license agreement as amended, we obtained exclusive rights throughout the world to certain know-how, patents and data relating to a pharmaceutical product. We will use the exclusive rights to develop the product for therapeutic, prophylactic and diagnostic uses in topical dermal applications and anorectal applications. Unless earlier terminated, the term of the license agreement will expire on a country by country basis on the later of (i) the date of expiry of the last valid licensed patent in such country; (ii) the date of expiry of any period of exclusivity granted to a product by a regulatory authority in such country or (iii) the date that is 15 years after the first commercial sale of a product in such country.

Under the license agreement, we are exclusively responsible, at our expense, for the development of the product, including conducting clinical trials and seeking regulatory approval for the product, and once regulatory approval has been obtained, for the commercialization of the product. We are required to use our commercially reasonable efforts to develop and commercialize the product in accordance with the terms of a development plan established by the parties. Subject to certain conditions, we are permitted to engage third parties to perform our activities or obligations under the agreement.

In exchange for the exclusive rights to develop and commercialize the product topical dermal applications and anorectal applications, we are committed to payments of various amounts to Yissum upon meeting certain milestones outlined in the license agreement up to an aggregate amount of $18.6 million. In addition, upon divestiture of substantially all of our assets, we are obligated to pay Yissum a percentage of the valuation of the licensed technology sold as determined by an external objective expert.

We also have a commitment to pay Yissum a royalty based on net sales of the product in countries where we, or an affiliate of ours, directly commercializes the product and a percentage of sublicensing revenue received by us and our affiliates in the countries where we do not directly commercialize the product.

The license agreement provides that Yissum shall remain the exclusive owner of the licensed technology and that we are responsible for preparing, filing, prosecuting and maintaining the patents on the licensed technology in Yissum’s name. Notwithstanding the foregoing, we will be the exclusive owner of all patents and other intellectual property that is made by or on our behalf after the date of the agreement, including all improvements to the licensed technology.

If we default or fail to perform any of the terms, covenants, provisions or our obligations under the license agreement, Yissum has the option to terminate the license agreement, subject to providing us with an opportunity to cure such default. We have the right to terminate the agreement if we determine that the development and commercialization of the product is no longer commercially viable.

Subject to certain exceptions, we have undertaken to indemnify Yissum against any liability, including product liability, damage, loss or expense derived from the use, development, manufacture, marketing, sale or sublicensing of the licensed product and technology.

License Agreement with Cipher

On June 15, 2016, our wholly owned subsidiary, Edesa Biotech Research, Inc., entered into an exclusive license agreement with Cipher Pharmaceuticals Inc., an Ontario corporation. Pursuant to the license agreement, we obtained exclusive rights throughout the world to certain know-how, patents and data relating to a pharmaceutical product. We will use the exclusive rights to develop the product for therapeutic, prophylactic and diagnostic uses in human and veterinary anorectal applications. Unless earlier terminated, the term of the license agreement will expire on the date that is 20 years after the first commercial sale of the product, subject to automatic renewal for successive one-year periods.

Under the license agreement, we are exclusively responsible, at our expense, for the development of the product, including conducting clinical trials and seeking regulatory approval for the product, and once regulatory approval has been obtained, for the commercialization of the product. We are required to use our diligent efforts to develop and commercialize the product in accordance with the terms of the agreement and with a goal to maximize profits from net sales of the product. Subject to certain conditions, we are permitted to engage third parties to perform our activities or obligations under the agreement.

In exchange for the exclusive rights to develop and commercialize the product for therapeutic, prophylactic and diagnostic uses in human and veterinary anorectal applications, we are committed to payments of various amounts to Cipher upon meeting certain milestones outlined in the license agreement up to an aggregate amount of $18.5 million.

We also have a commitment to pay Cipher a royalty based on net sales of the product in countries where we, or an affiliate of ours, directly commercializes the product and a percentage of sublicensing revenue received by us and our affiliates in the countries where we do not directly commercialize the product.

The license agreement provides that Cipher shall remain the exclusive owner of the licensed technology. Notwithstanding the foregoing, we will be the exclusive owner of all patents and other intellectual property that is made by or on our behalf after the date of the agreement, including all improvements to the licensed technology.

If we default or fail to perform any of the terms, covenants, provisions or our obligations under the license agreement, Cipher has the option to terminate the license agreement, subject to providing us with an opportunity to cure such default. We have the right to terminate the agreement without cause upon 60 days prior written notice to Cipher.

Subject to certain exceptions, we have undertaken to indemnify Cipher against any liability, including product liability, damage, loss or expense derived from the use, development, manufacture, marketing, sale or sublicensing of the licensed product and technology.

License and Development Agreement with Pendopharm

On August 27, 2017, our wholly owned subsidiary, Edesa Biotech Research, Inc. entered into an exclusive license and development agreement with Pendopharm, a division of Pharmascience Inc. Pursuant to the license and development agreement, we granted to Pendopharm an exclusive license throughout Canada to certain know-how, patents and data for the sole purpose of obtaining regulatory approval for certain pharmaceutical products to allow Pendopharm to distribute, market and sell the licensed products for human therapeutic use in the conditions of HD and anal fissures.

On a licensed product by licensed product basis, we are required to use reasonable commercial efforts to develop the licensed products in the indications of HD and anal fissures for the purposes of obtaining regulatory approval with the FDA and provide to Pendopharm, on a licensed product by licensed product basis, the data package submitted to the FDA. Upon receipt of the data package, Pendopharm will elect whether it desires to seek regulatory approval in Canada of the applicable product. If Pendopharm elects not to seek regulatory approval of the applicable product, the applicable product will be removed from the license rights granted to Pendopharm and will revert to us. If Pendopharm elects to seek regulatory approval in Canada for the sale and marketing of the applicable product, Pendopharm will be responsible for obtaining regulatory approval for the applicable licensed product in Canada.

In exchange for the exclusive rights to market, import, distribute, and sell the pharmaceutical products, Pendopharm is required to pay us a royalty in respect of aggregate annual net sales for each pharmaceutical product sold in Canada.

Unless earlier terminated, the term of the license and development agreement will expire, on a licensed product by licensed product basis, on the later to occur of (i) the date that is 13 years after the first commercial sale of the licensed product in Canada; (ii) the date of expiry of the last valid licensed patent in Canada relating to the licensed product; or (iii) the date of expiry of any period of exclusivity granted to the licensed product by a regulatory authority in Canada. The license and development agreement shall also terminate upon the termination of the license agreement with Yissum or the license agreement with Cipher, each described above. Pendopharm also has the right to terminate the license and development agreement for any reason upon 120 days notice to us.

The license and development agreement provides that we will remain the exclusive owner of the licensed technology and any improvements to the licensed technology made by us alone or jointly with Pendopharm.

Manufacturing and Marketing

We rely on third parties for the synthesis, formulation and manufacturing, including optimization, technology transfers and scaling up of clinical scale quantities of our product candidates. We believe that this strategy will enable us to direct operational and financial resources to the development of our product candidates rather than diverting resources to establishing manufacturing infrastructure. Our arrangements with our manufacturers are subject to industry-standard terms and conditions and manufacturing is performed on an as-requested basis. We believe there is sufficient manufacturing capacity with our current manufacturers, as well as others, to service our current and future product needs. We do not have current plans to establish laboratories or manufacturing facilities for significant clinical production.

Synthetic drugs, such as those being developed by Edesa, are based on a chemical manufacturing process that requires raw materials, such as various solvents, sugars, fats and polymers. There are many suppliers of raw materials for these products and, in recent years, no material changes have occurred with respect to the prices of these raw materials that are required for the research, development and manufacturing of the drugs we are developing.

Because we are focused on the discovery and development of drugs, we do not have any marketing or distribution capabilities, nor are we at a stage where we would have any customers for our investigational medicines.

If we receive marketing approval in the United States, Canada or Europe for EB01 to treat ACD or approval of any other product candidate, we plan to build the capabilities to commercialize the product candidate in the applicable region with our own focused, specialized sales force. Outside of the United States and Canada, we plan to selectively utilize collaboration, distribution or other marketing arrangements with third parties to commercialize our product candidates. Also, we intend to selectively seek licensing, collaboration or similar arrangements to assist us in furthering the development or commercialization of product candidates, such as EB01, targeting large primary care markets that must be served by large sales and marketing organizations.

Competition

The pharmaceutical and biotechnology industry is highly competitive, and the development and commercialization of new drugs is influenced by rapid technological developments and innovation. We face competition from companies developing and commercializing products that will be competitive with our drug candidates, including large pharmaceutical and smaller biotechnology companies, many of which have greater financial and commercial resources than we do. For our EB01 and EB02 product candidates, our potential competitors include Aclaris Therapeutics, Inc., Brickell Biotech, Inc., Citius Pharmaceuticals Inc., Dermavant Sciences, Inc. and Leo Pharma A/S. Some of the competing product development programs may be based on scientific approaches that are similar to our approach, and others may be based on entirely different approaches. Potential competitors also include new entrants to the market, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of products similar to ours or that otherwise target indications that we are pursuing. Key factors affecting the success of any approved product will be its efficacy, safety profile, drug interactions, method of administration, pricing, reimbursement and level of promotional activity relative to those of competing drugs. We believe that our product candidates will compete favorably with respect to such factors. However, we may not be able to maintain our competitive position against current and potential competitors.

Government Regulation

We plan to seek approvals for our product candidates in the United States from the FDA and in Canada from Health Canada. Therefore, we currently are, and may in the future be, subject to a variety of national and regional regulations governing clinical trials as well as commercial sales and distribution of our products, if approved.

To conduct clinical trials for our product candidates, we rely on third parties, such as contract research organizations, medical institutions, and clinical investigators. Although we have entered into agreements with these third parties, we continue to be responsible for confirming that each of our clinical trials are conducted in accordance with our general investigational plan and protocol, as well as regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials.

United States

The FDA and comparable regulatory agencies in foreign, state and local jurisdictions impose substantial requirements upon the clinical development, manufacturing, marketing and distribution of drugs. These agencies and other applicable federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our product candidates and commercialized drugs.

In the United States, the FDA regulates drugs under the federal Food, Drug and Cosmetic Act. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical laboratory tests, animal studies and formulation studies, performed in accordance with the FDA's good laboratory practice regulations and other applicable requirements;
- submission to the FDA of an IND which must become effective before clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission of a New Drug Application, NDA, to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, regulations;
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug; and
- regulation of commercial marketing and sale of drugs.

The testing and review processes require substantial time, effort and financial resources. Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of pre-clinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30-days after receipt by the FDA, unless the FDA, within the 30-day time frame, raises concerns and/or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent Institutional Review Board (IRB) for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the clinical trial until completed. The FDA, the IRB or the clinical trial sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations for informed consent.

Clinical Trials

For purposes of an NDA submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap:

- *Phase 1:* The clinical trials are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. Phase 1 clinical trials can be designed to evaluate the impact of the product candidate in combination with currently approved drugs.

- *Phase 2:* These clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning a larger and more expensive Phase 3 clinical trial.

- *Phase 3:* These clinical trials are commonly referred to as pivotal clinical trials. If the Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile, Phase 3 clinical trials are then undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In some cases, the FDA may conditionally approve an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval.

New Drug Application

The results of product candidate development, pre-clinical testing and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180-days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators do. Once issued, the FDA may withdraw a drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require further testing, including Phase 4 clinical trials, and surveillance programs to monitor the effect of approved drugs which have been commercialized. The FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to a drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

Satisfaction of FDA regulations and requirements or similar requirements of state, local and foreign regulatory agencies typically take several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a product candidate is intended to treat a chronic disease, as is the case with some of our product candidates, safety and efficacy data must be gathered over an extended period of time.

Other regulatory requirements

Any products manufactured or distributed by us or our collaborators (pursuant to FDA approval) are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

The federal anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and pharmacy benefit managers, among others. Several other countries, including the United Kingdom, have enacted similar anti-kickback laws and regulations.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The federal Physician Payments Sunshine Act requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, referred to together as the Affordable Care Act, require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report to the Department of Health and Human Services information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Among other payments, the law requires payments made to physicians and teaching hospitals for clinical trials be disclosed.

Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to future potential sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Employees

As of December 12, 2019, we had 10 full-time employees: five employees are engaged in research and development, and five employees are engaged in management, administration, business development and finance. All employees are located in the U.S. or Canada. None of our employees are members of any labor unions.

Business Combination

On June 7, 2019, we completed a business combination with Edesa Biotech Research, Inc., formerly known as Edesa Biotech Inc. ("Edesa Research"), a company organized under the laws of the province of Ontario, in accordance with the terms of a Share Exchange Agreement, dated March 7, 2019, by and among the Company, Edesa Research and the shareholders of Edesa Research. At the closing of the transaction, we acquired the entire issued share capital of Edesa Research, with Edesa Research becoming a wholly owned subsidiary of ours. Also on June 7, 2019, in connection with and following the completion of the reverse acquisition, we effected a 1-for-6 reverse split of our Common Shares and changed our name to "Edesa Biotech, Inc." At the closing of the transaction, the Edesa Research shareholders exchanged their shares for 88% of our outstanding shares on a fully diluted basis.

At the closing of the transaction, the Edesa Research shareholders received 6,249,780 of our Common Shares in exchange for the capital shares of Edesa Research and the holders of unexercised Edesa Research share options immediately prior to the closing of the transaction were issued replacement share options ("Replacement Options") to purchase an aggregate of 297,422 of our Common Shares. On July 26, 2019, pursuant to the post-closing adjustment contemplated by the Share Exchange Agreement, we issued an additional 366,234 of our Common Shares to the Edesa Research shareholders and the holders of unexercised Edesa Research stock options immediately prior to the closing of the transaction were issued 17,701 additional Replacement Options to purchase our Common Shares. Following the completion of the transactions contemplated by the Share Exchange Agreement and the reverse split, there were approximately 7,504,468, of our Common Shares issued and outstanding and approximately 7,876,292 of our Common Shares outstanding on a fully-diluted basis, and the former Edesa Research shareholders and option holders owned approximately 6,931,137 of our Common Shares on a fully-diluted basis, or 88% of our Common Shares on a fully-diluted basis, and our shareholders and option holders prior to the transactions contemplated by the Share Exchange Agreement owned approximately 945,155 of our Common Shares on a fully-diluted basis, or 12% of our Common Shares on a fully-diluted basis.

Corporate Information

We are incorporated under the laws of British Columbia, Canada, and operate through our wholly owned subsidiaries, Edesa Biotech Research, Inc., an Ontario, Canada corporation founded in 2015; and Stellar Biotechnologies, Inc., a California, USA corporation founded in 1999. As further described above under the heading "Business Combination", in June 2019, we acquired the Ontario corporation through a reverse acquisition and changed our name from Stellar Biotechnologies, Inc. to Edesa Biotech, Inc. We subsequently changed the name of the Ontario subsidiary to Edesa Biotech Research, Inc. (formerly Edesa Biotech Inc.). The California subsidiary was acquired through a reverse merger in April 2010, when the company was organized as a Canadian capital pool company.

Our executive offices are located at 100 Spy Court, Markham, Ontario, L3R 5H6, Canada. Our phone number is 289-800-9600. Our registered and records office is 2900 - 550 Burrard Street, Vancouver, British Columbia, V6C 0A3, Canada. Our website address is www.edesabiotech.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. Any references to website addresses contained in this report are intended to be inactive textual references only.

Available Information

We file or furnish periodic reports and amendments thereto, 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 U.S. Securities and Exchange Commission (SEC). Such reports and other information filed or furnished by us with the SEC are available free of charge on our website at www.edesabiotech.com/investors/sec-filings as soon as reasonably practicable after such reports are available on the SEC's website at www.sec.gov. Our filings are also available at the Canadian Securities Administrators' SEDAR website at www.sedar.com.

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, prospects, financial condition 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 incurred significant losses since our inception and expect to continue to incur losses and may never generate profits from operations or maintain profitability.

Since inception, we have incurred significant operating losses. As of September 30, 2019, we have an accumulated deficit of $6.73 million. We have historically financed operations primarily through issuances of preferred shares that were converted into common shares, loans that were converted into common shares and government grants. We have devoted substantially all of our efforts to research and development, including clinical trials, and have not completed the development of any of our drug candidates.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue the development of, and seek marketing approvals for our product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States and Canada. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

Our ability to generate profits from operations and thereafter to remain profitable depends heavily on, among other things:

- the scope, number, progress, duration, cost, results and timing of clinical trials and nonclinical studies of our current or future product candidates;
- our ability to raise sufficient funds to support the development and potential commercialization of our product candidates;
- the outcomes and timing of regulatory reviews, approvals or other actions;
- our ability to obtain marketing approval for our product candidates;
- our ability to establish and maintain licensing, collaboration or similar arrangements on favorable terms and whether and to what extent we retain development or commercialization responsibilities under any new licensing, collaboration or similar arrangement;
- the success of any other business, product or technology that we acquire or in which we invest;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio;
- our ability to manufacture any approved products on commercially reasonable terms;
- our ability to establish a sales and marketing organization or suitable third-party alternatives for any approved product; and
- the number and characteristics of product candidates and programs that we pursue.

Based on our current plans, we do not expect to generate significant revenue unless and until we or a current or potential future licensee obtains marketing approval for, and commercializes, one or more of our product candidates, which may require several years. Neither we nor a licensee may ever succeed in obtaining marketing approval for, or commercializing our product candidates and, even if marketing approval is obtained, we may never generate revenues that are significant enough to generate profits from operations. Even if we do generate profits from operations, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to generate profits from operations and remain profitable would decrease the value of the company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations. A decline in the value of the company could also cause you to lose all or part of your investment.

We will need substantial additional funding to finance our operations through regulatory approval of one or more of our product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our research and development expenses to increase substantially in the future, particularly if we advance any drug candidates beyond Phase 2 clinical development or expand the number of drug candidates in clinical studies. In addition, if we obtain marketing approval for any of our product candidates that are not then subject to licensing, collaboration or similar arrangements with third parties, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. If we are unable to raise capital when needed, or on attractive terms, we could be forced to delay, reduce or eliminate research and development programs or future commercialization efforts.

We depend heavily on the success of our lead product candidate, EB01, which we are developing for the treatment of chronic ACD. If we are unable to obtain regulatory approval or commercialize EB01, or experience significant delays in doing so, our business will be materially harmed.

EB01 is in Phase 2B clinical development. Our ability to generate product revenues, which may not occur for multiple years, if at all, will depend heavily on the successful development and commercialization of EB01 as a treatment for chronic ACD. The success of our product candidates, including EB01, will depend on a number of factors, including the following:

- our ability to obtain additional capital from potential future licensing, collaboration or similar arrangements or from any future offering of our debt or equity securities;
- our ability to identify and enter into potential future licenses or other collaboration arrangements with third parties and the terms of the arrangements;
- successful completion of clinical development;
- the ability to provide acceptable evidence demonstrating a product candidates' safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities and similar foreign regulatory authorities;
- the availability of raw materials to produce our product candidates;
- obtaining and maintaining commercial manufacturing arrangements with third-party manufacturers or establishing commercial-scale manufacturing capabilities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- establishing sales, marketing and distribution capabilities;
- generating commercial sales of the product candidate, if and when approved, whether alone or in collaboration with others;
- acceptance of the product candidate, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of the product candidate following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize EB01 or any of our other product candidates, which would materially harm our business. Many of these factors are beyond our control. Accordingly, we may never be able to generate revenues through the license or sale of any of our product candidates.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our primarily operating entity, Edesa Biotech Research, Inc. was formed in July 2015. To date, our operations have been limited to organization and staffing, developing and securing our technology, entering into licensing arrangements, raising capital and undertaking preclinical studies and clinical trials of our product candidates. We have not yet demonstrated our ability to successfully complete development of any product candidate, obtain marketing approval, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Assuming we obtain marketing approval for any of our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We may not be successful in our efforts to identify and acquire or in-license additional product candidates.

Part of our strategy involves diversifying our product development risk by identifying and acquiring or in-licensing novel product candidates. We may fail to identify and acquire or in-license promising product candidates. The competition to acquire or in-license promising product candidates is fierce, especially from large multinational companies that have greater resources and experience than we have. If we are unable to identify and acquire or in-license suitable product candidates, we will be unable to diversify our product risk. We believe that any such failure could have a significant negative impact on our prospects because the risk of failure of any particular development program in the pharmaceutical field is high.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates that later could prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, our business may be negatively impacted.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Dr. Pardeep Nijhawan, our Chief Executive Officer and Secretary; and Michael Brooks, our President; as well as other principal members of our management and scientific teams. Although we have employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with the company at any time. The unplanned loss of the services of any of these persons could materially impact the achievement of our research, development, financial and commercialization objectives. Recruiting and retaining qualified personnel, including in the United States and Canada, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments with other entities that may limit their availability to us.

We expect to expand our capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, finance and administration and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are exposed to risks related to currency exchange rates.

We conduct a significant portion of our operations outside of the United States. Because our financial statements are presented in U.S. dollars, changes in currency exchange rates have had and could have in the future a significant effect on our operating results when our operating results are translated into U.S. dollars.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, it could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or the FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. We are also subject to other laws and regulations governing our international operations, including regulations administered by the government of the United States and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA and other anti-corruption laws or Trade Control laws, it may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or Trade Control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and collaborators, including intentional failures to comply with FDA or Office of Inspector General regulations or similar regulations of comparable non-U.S. regulatory authorities, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of ours clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

The wind down or spinoff of our Stellar subsidiary's legacy business may not deliver the expected results.

Following the business combination with Edesa Biotech Research, Inc., formerly known as Edesa Biotech Inc., we refocused our primary business on the development of innovative therapeutics for dermatological and gastrointestinal indications with clear unmet medical needs. Over the course of the next 12 months, we intend to sell or wind down the principal assets and operations of our Stellar subsidiary's legacy business, which includes leased aquaculture facilities, equipment and office space located in Port Hueneme, California. The sale or wind down of the legacy business operations may require additional time, may interfere with our ability to achieve our business objectives and may be difficult to manage. In addition, we cannot be sure that the sale and wind down will be as successful in providing meaningful cash proceeds, if at all; reducing or eliminating costs related to the legacy business; or result in any unplanned expenditures or unknown, contingent or other liabilities, including litigation arising in connection with the wind down or sale of the legacy business assets and operations. If our plans do not achieve the expected results, our business and results of operations will be adversely impacted.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, Health Canada (HC) or the European Medicines Agency (EMA), or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization our product candidates.

In connection with obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials. In particular, the small number of subjects and patients in early clinical trials of our product candidates may make the results of these clinical trials less predictive of the outcome of later clinical trials. The design of a clinical trial can determine whether our results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. There is no assurance that we will be able to design and execute a clinical trial to support marketing approval. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Positive results in pre-clinical studies of a product candidate may not be predictive of similar results in humans during clinical trials, and promising results from early clinical trials of a product candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from completed pre-clinical studies and clinical trials for our product candidates may not be predictive of the results we may obtain in later stage trials or studies. Pre-clinical studies or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional pre-clinical studies or clinical trials, or to discontinue clinical trials altogether. Ultimately, we may be unable to complete the development and commercialization of any of our product candidates.

Interim results, top-line, initial data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose interim, top-line or initial data from time to time that is based on a preliminary analysis of then-available efficacy and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimates, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Interim, top-line and initial data should be viewed with caution until the final data are available. In addition, the information we may publicly disclose regarding a particular preclinical or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the interim, top-line or initial data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed or delayed, which could harm our business, financial condition, operating results or prospects.

If clinical trials for our product candidates are prolonged or delayed, we may be unable to commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials. A number of events, including any of the following, could delay the completion of our ongoing and planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of product candidates supply or materials to produce our product candidates or other materials necessary to conduct our clinical trials;
- delays in obtaining regulatory agreement for the conduct of the clinical trials;
- lower than anticipated enrollment and retention rate of subjects in clinical trials for a variety of reasons, including size of patient population, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- serious and unexpected drug-related side effects experienced by patients in clinical trials;
- failure of third-party contractors to meet their contractual obligations in a timely manner;
- pre-clinical or clinical trials may produce negative or inconclusive results, which may require us or any potential future collaborators to conduct additional pre-clinical or clinical testing or to abandon projects that we expect to be promising;
- even if pre-clinical or clinical trial results are positive, the FDA or foreign regulatory authorities could nonetheless require unanticipated additional clinical trials;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- product candidates may not have the desired effects; and
- the lack of adequate funding to continue clinical trials.

Additionally, changes in standard of care or regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Such amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the cost, timing or successful completion of a clinical trial. Such changes may also require us to reassess the viability of the program in question.

We do not know whether our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Delays in clinical trials will result in increased development costs for our product candidates. In addition, if we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our product candidates may be affected and our ability to generate product revenues will be delayed. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

The clinical trial designs, endpoints and outcomes that will be required to obtain marketing approval of a drug to treat chronic ACD or any other indication are uncertain. We may never receive marketing approval for EB01 as a treatment for chronic ACD.

To our knowledge, there are currently no FDA-approved treatment options specifically indicated for chronic ACD. Accordingly, there is not a well-established development path that, with positive outcomes in clinical trials, would be reasonably assured of receiving marketing approval for chronic ACD. In particular, if our Phase 2B clinical trial of EB01 in individuals with chronic ACD is successful, we plan to use the trial to support pivotal clinical trials designed to establish the efficacy of EB01 to support, together with additional long-term safety data, an application for regulatory approval as a treatment for chronic ACD. The FDA or any regulatory authority outside of the United States may determine that the designs or endpoints of any potentially pivotal trial that we conduct, or that the outcome shown on any particular endpoint in any potentially pivotal trial that we conduct, are not sufficient to establish a clinically meaningful benefit for EB01 in the treatment of chronic ACD or otherwise to support approval, even if the primary endpoint or endpoints of the trial is or are met with statistical significance. If this occurs, our business could be materially harmed. Moreover, if the FDA requires us to conduct additional clinical trials beyond the ones that we currently contemplate in order to support regulatory approval in the United States of EB01 for the treatment of chronic ACD, our finances and results from operations will be adversely impacted.

Likewise, if we conduct any future clinical trials designed to support marketing approval of EB02 as a treatment for HD or clinical trials designed to support marketing approval of any other of our product candidates, the FDA or any regulatory authority outside of the United States may determine that the designs or endpoints of the trial, or that the outcomes shown on any particular endpoint in the trial, are not sufficient to establish a clinically meaningful benefit or otherwise to support approval, even if the primary endpoint of the trial is met with statistical significance.

Our Phase 2B clinical trial of EB01 in individuals with chronic ACD will not be sufficient to be considered a pivotal trial to support an application for marketing approval of EB01. Even if our Phase 2B study meets our primary endpoints, it is not certain that additional pivotal Phase 3 studies, together with additional long-term safety data will have positive outcomes and or will be sufficient to enable EB01 to gain regulatory approval as a treatment for chronic ACD.

If our Phase 2B clinical trial of EB01 in individuals with chronic ACD meets our primary endpoints, we plan to request an end of Phase 2 meeting with the FDA and regulatory authorities outside the United States to seek guidance on the requirements for a new drug application. We cannot predict the requirements for each of these regulatory agencies and the requirements set forth by the agencies could delay and/or negatively impact our ability to obtain regulatory approval for, and to market and sell a particular product candidate. We expect to be required by the FDA to conduct two Phase 3 pivotal clinical trials in patients with chronic ACD to establish the efficacy of EB01 to support, together with additional long-term safety data, an application for regulatory approval of EB01 as a treatment for chronic ACD. The likelihood that the FDA or any regulatory authority outside the United States will concur with our plan is uncertain. The FDA or any other regulatory authority may instead determine that additional clinical and/or non-clinical trials are required to establish the efficacy of EB01 as a treatment for chronic ACD, even if the outcome of our Phase 2B study in individuals is favorable. The risk that the FDA or any other regulatory authority will determine that additional clinical and/or non-clinical trials are required to establish the efficacy of EB01 as a treatment for chronic ACD may be even higher if we select a primary endpoint for our planned pivotal Phase 3 trials in chronic ACD for which there is only limited data generated in our Phase 2 studies. In addition, we intend to enroll in our study individuals with chronic ACD caused by any of a number of different conditions (allergens). This may also increase the risk of the FDA or another regulatory authority determining that additional clinical and/or non-clinical trials are required to establish the efficacy of EB01 as a treatment for chronic ACD. If the FDA or a regulatory authority outside of the United States makes the determination that additional clinical and/or non-clinical trials are required, it would result in a more expensive and potentially longer development program for EB01 than we currently contemplate, which could delay our ability to generate product revenues with EB01, interfere with our ability to enter into any potential licensing or collaboration arrangements with respect to this program, cause the value of the company to decline, and limit our ability to obtain additional financing.

If we experience new or additional delays or difficulties in the enrollment of patients in our clinical trial of EB01 or any other product candidate, our application and or receipt of marketing approvals could be delayed or prevented.

Recruiting patients with moderate to severe chronic ACD may be challenging as there have not been recent clinical studies conducted with this patient population. If we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials of our product candidates including, in particular, our ongoing trial of EB01 and our planned pivotal trials of EB01 as a treatment for ACD, we may not be able to initiate or complete the clinical trials.

Enrollment delays in our ongoing or planned clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients in our ongoing or planned clinical trials of EB01, or any other Edesa product candidate, would result in significant delays or may require us to abandon one or more clinical trials altogether.

If the commercial opportunity in chronic ACD is smaller than we anticipate, or if we elect to develop EB01 to treat only a specific subpopulation of patients with chronic ACD, our future revenue from EB01 will be adversely affected and our business will suffer.

It is critical to our ability to grow and become profitable that we successfully identify patients with chronic ACD. Our projections of the number of people who have chronic ACD as well as the subset who have the potential to benefit from treatment with EB01, are based on a variety of sources, including third-party estimates and analyses in the scientific literature, and may prove to be incorrect. Further, new information may emerge that changes our estimate of the prevalence of these diseases or the number of patient candidates for EB01. The effort to identify patients with chronic ACD or our other potential target indications is at an early stage, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for EB01 may be limited or may not be amenable to treatment with EB01, and new patients may become increasingly difficult to identify or access. If the commercial opportunity in chronic ACD is smaller than we anticipate, or if we elect to develop EB01 to treat only a specific subpopulation of patients with chronic ACD, our future financial performance may be adversely impacted.

While we have chosen to test our product candidates in specific clinical indications based in part on our understanding of their mechanisms of action, our understanding may be incorrect or incomplete and, therefore, our product candidates may not be effective against the diseases tested in our clinical trials.

Our rationale for selecting the particular therapeutic indications for each of our product candidates is based in part on our understanding of the mechanism of action of these product candidates. However, our understanding of the product candidates' mechanism of action may be incomplete or incorrect, or the mechanism may not be clinically relevant to the diseases treated. In such cases, our product candidates may prove to be ineffective in the clinical trials for treating those diseases, and adverse clinical trial results would likely negatively impact our business and results from operations.

A successful $sPLA_2$ drug has not been developed to date and we can provide no assurances that we will be successful or that there will be no adverse side effects.

Our unique lead product candidates are first-in-class, novel, non-steroidal, synthetic anti-inflammatory products that address the need to target $sPLA_2$ in a broad-ranged manner while avoiding any interference with the homeostatic $sPLA_2$ family. To date no drug companies have successfully commercialized an $sPLA_2$ inhibitor and as a result the efficacy and long-term side effects are not known. There is no guarantee that we will successfully develop and/or commercialize an $sPLA_2$ inhibitor and/or that our product candidates will have no adverse side effects.

Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any product candidate receives marketing approval, the approved product may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If an approved product does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. Our ability to negotiate, secure and maintain third-party coverage and reimbursement for our product candidates may be affected by political, economic and regulatory developments in the United States, Canada, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any of our future product candidates that receive marketing approval.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and any of our other current or future product candidates, we may not be successful in commercializing the applicable product candidate if it receives marketing approval.

We do not have a sales or marketing infrastructure and have no experience as a company in the sale or marketing of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. There are risks involved with establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products to treat our target indications or markets before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and any products we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

Competitors may also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining approvals from regulatory authorities and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies that may be complementary to or necessary for our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are approved for broader indications or patient populations, or are more convenient or less expensive than any products that we develop and commercializes. Our competitors may also obtain marketing approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. If approved, our product candidates will compete for a share of the existing market with numerous other products being used to treat ACD.

Even if we are able to commercialize one of our product candidates, the product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted and, in some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize EB01 or any other product candidate successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities.

We have separate liability insurance policies that cover each of our ongoing clinical trials, which provide coverage in varying amounts. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when and if we begin conducting more expansive clinical development of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We will be dependent on third parties for the synthesis, formulation, and manufacturing, including optimization, technology transfers and scaling up of clinical scale quantities of all of our product candidates.

We have no direct experience in synthesizing, formulating and manufacturing any of our product candidates, and currently lack the resources or capability to synthesize, formulate and manufacture any of our product candidates on a clinical or commercial scale. As a result, we will be dependent on third parties for the synthesis, formulation, and manufacturing, including optimization, technology transfers and scaling up of clinical scale quantities of all our product candidates. We believe that this strategy will enable us to direct operational and financial resources to the development of our product candidates rather than diverting resources to establishing manufacturing infrastructure; however our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have any agreements with third-party manufacturers for the long-term clinical or commercial supply of any of our product candidates and may in the future be unable to scale-up and/or conclude agreements for commercial supply with commercial third-party manufacturers on acceptable terms, or at all. Even if we are able to establish and maintain arrangements with third-party manufacturers, they may encounter difficulties in achieving volume production, laboratory testing, quality control or quality assurance or suffer shortages of qualified personnel, any of which could result in our inability to manufacture sufficient quantities to meet clinical timelines for a particular product candidate, to obtain marketing approval for the product candidate or to commercialize the product candidate. In addition, third-party manufacturers may not be able to comply with current good manufacturing practice, or GMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. If the third parties that we contract to manufacture product for our preclinical tests and clinical trials cease to continue to do so for any reason or if we elect to change suppliers, we likely would experience delays in advancing these clinical trials while we identify and qualify replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality, and delivery schedules. We cannot be certain that our current suppliers will continue to provide us with the quantities of these raw materials that we require to satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, can be identified and qualified. Although we believe there are several other suppliers of these raw materials, we may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, or interrupt production of the existing products that are already marketed, which would have a material adverse effect on our business.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials.

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions, drug distributers, clinical investigators and government agencies, to perform this function. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Our product development costs will increase if we experience delays in testing or obtaining marketing approvals.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA and foreign regulatory authorities require us to comply with standards, commonly referred to as Good Clinical Practice, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity of data and confidentiality of clinical trial participants are protected.

We may depend on additional collaborations, licenses or similar arrangements with third parties for the development and commercialization of some of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may in the future enter into other licensing, collaboration or similar arrangements for the development and commercialization of our product candidates for any or all indications and for any or all territories. Our likely counterparties for any licensing, collaboration or similar arrangement include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. However, if we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of the applicable product candidate. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans.

We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of EB01 or other product candidates. Collaborations are complex and time-consuming to negotiate and document and we face significant competition in seeking appropriate collaborators. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we would likely need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Even if we complete the necessary clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market EB01 or any other Edesa product candidate from regulatory authorities in any jurisdiction.

We have only limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates and expect to rely on third-party contract research organizations to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and effectiveness. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that EB01, or any of our other product candidates is not effective, is only moderately effective or has undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval or that prevent or limit commercial use.

The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies, clinical trials or other trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Even if we obtain marketing approval for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of a product candidate is granted, an approved product and our manufacturer and marketer are subject to ongoing review and extensive regulation, including the possible requirement to implement a risk evaluation and mitigation strategy or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Our relationships with customers, healthcare providers and professionals and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidate for which we may obtain marketing approval. Our future arrangements with customers, healthcare providers and professionals, and third-party payors may expose us to broadly applicable federal anti-kickback, federal and state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidate for which we obtain marketing approval.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Violation of certain of these laws could also result in exclusion, suspension and debarment from government funded healthcare programs. Exclusion, suspension or debarment would significantly impact our ability to commercialize, sell or distribute any product candidate for which we obtain regulatory approval. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Use of social media platforms presents new risks.

We believe that our potential patient population is active on social media. Social media practices in the pharmaceutical and biotechnology industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, a product candidate, which could result in reporting obligations. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our product candidates on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

Risks Related to Our Intellectual Property

We are dependent on a license relationship with Yissum for our EB01 and EB02 programs

In 2016, we entered into an exclusive license agreement with Yissum Research Development Company of the Hebrew University of Jerusalem to obtain exclusive rights to certain know-how, patents and data relating to a pharmaceutical product. We are using the exclusive rights to develop the product for therapeutic, prophylactic and diagnostic uses in topical dermal applications and anorectal applications, including for the development of EB01 to treat ACD and EB02 to treat HD. Concurrently, we also entered into a consulting agreement with an individual associated with Yissum for the development of the product. If we default or fail to perform any of the terms, covenants, provisions or our obligations under the License Agreement, Yissum has the option to terminate the License Agreement, subject to advance notice to cure such default. Any termination of this license agreement would have a materially adverse impact on our business and results from operations.

If we are unable to obtain and maintain patent protection for our licensed technology and products, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our licensed technology and products may be adversely affected.

Our success will partially depend on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We intend to protect our proprietary position by filing patent applications in the United States, in Europe and in certain additional jurisdictions related to our novel technologies and product candidates that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, if we license technology or product candidates from third parties in the future, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering the licensed technology or product candidates. These agreements could also give our licensors the right to enforce the licensed patents without our involvement, or to decide not to enforce the patents at all. Therefore, in these circumstances, these patents and applications may not be prosecuted or enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents issued to us will likely be highly uncertain. Patent applications that we file may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may also diminish the value of patents issued to us, narrow the scope of our patent protection or make enforcement more difficult or uncertain.

We may become involved in lawsuits or other enforcement proceedings to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and potentially unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file claims, which can be expensive and time consuming to prosecute. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property or that our patent and other intellectual property rights are invalid or unenforceable, including for antitrust reasons. As a result, in a patent infringement proceeding, a court or administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, or may construe the patent's claims narrowly and so refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the competitor technology in question. Even if we are successful in a patent infringement action, the unsuccessful party may subsequently raise antitrust issues and bring a follow-on action thereon. Antitrust issues may also provide a bar to settlement or constrain the permissible settlement terms.

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 commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, *inter partes* review, reexamination, reissue or post-grant review proceedings before the USPTO. The risks of being involved in such litigation and office proceedings may also increase as our product candidates approach commercialization, and as our business gains greater visibility operating as a publicly traded company in the United States. Third parties may assert infringement claims against us based on existing or future intellectual property rights and to restrict our freedom to operate. Third parties may also seek injunctive relief against us, whereby they would attempt to prevent us from practicing our technologies altogether pending outcome of any litigation against us. We may not be aware of all such intellectual property rights potentially relating to our product candidates prior to their assertion against us. For example, we have not conducted an in-depth freedom-to-operate search or analysis of any of our product candidates. Any freedom-to-operate search or analysis previously conducted may not have uncovered all relevant patents and pending patent applications, and there may be pending or future patent applications that, if issued, would block us from commercializing any of our product candidates. Thus, we do not know with certainty whether our product candidates or our commercialization thereof, does not and will not infringe any third party's intellectual property.

If we are found to infringe a third party's intellectual property rights, to avoid or settle litigation, we could be required to obtain a license to enable us to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors access to the same technologies as are licensed to us, and could require us to make substantial payments. Absent a license, we could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

We may be subject to claims by third parties asserting that the company or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary or otherwise confidential information or know-how of others in their work for us, we may be subject to claims that the company or these employees have without authorization used or disclosed intellectual property, including trade secrets or other proprietary or confidential information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us and agree to cooperate and assist us with securing and defending our intellectual property, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. These assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and could distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and likely would distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments that could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, costs and lost management time, as well as uncertainties resulting from the initiation and continuation of patent litigation or other proceedings, could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We partially rely on trade secrets and know-how, including unpatented know-how, technology and other proprietary and confidential information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary or confidential information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, particularly unpatented know-how, were to be obtained or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Owning Our Securities

The price of our common shares may continue to be volatile.

Market prices for securities of early stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile, and the market price of our common shares has been subject to significant fluctuations. This volatility can be exacerbated by low trading volume. Some of the factors that may cause the market price of our shares to fluctuate include:

- sales or potential sales of substantial amounts of our common shares;
- announcements about us or our competitors, including funding announcements, corporate or business updates, updates on manufacturing of our products, clinical trial results, regulatory approvals or new product introductions;
- developments concerning our product manufacturers;
- litigation and other developments relating to our licensed patents or other proprietary rights or those of our competitors;
- governmental regulation and legislation;
- change in securities analysts' estimates of our performance, or failure to meet analysts' expectations;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- Our ability to raise additional capital to carry through with our development plans and current and future operations;
- the timing of achievement of, or failure to achieve, our manufacturing, pre-clinical, clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- actions taken by regulatory agencies with respect to our product candidates;
- uncontemplated problems in the supply of the raw materials used to produce our product candidates;
- introductions or announcements of technological innovations or new products candidates by us, our potential future collaborators, or our competitors, and the timing of these introductions or announcements;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- we may have limited or very low trading volume that may increase the volatility of the market price of our common shares;
- actual or anticipated fluctuations in our results of operations;
- hedging or arbitrage trading activity that may develop regarding our common shares;
- regional or worldwide recession;
- sales of large blocks of our common shares;
- sales of our common shares by our executive officers, directors and significant shareholders;
- managerial costs and expenses;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common shares. In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted class action securities litigation. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

If we fail to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common shares, the delisting could adversely affect the market liquidity of our common shares and the market price of our common shares could decrease.

Our common shares are listed on The Nasdaq Capital Market. To maintain our listing, we must meet minimum financial, operating and other requirements, including requirements for a minimum amount of capital, a minimum price per share, and active operations. If we are unable to comply with Nasdaq's listing standards, Nasdaq may determine to delist our common shares. If our common shares are delisted for any reason, it could reduce the value of our common shares and their liquidity. Delisting could also adversely affect our ability to obtain financing for the continuation of our operations, or to use our common shares in acquisitions. Delisting may also result in the loss of confidence by suppliers, investors and employees.

Raising additional capital may cause dilution to our investors, restrict our operations or require us to relinquish rights to our technologies or product candidates

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, licensing, collaboration or similar arrangements, grants and debt financings. We do not have any committed external source of funds. To the extent that the we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends or other distributions.

If we raise additional funds through licensing, collaboration or similar arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research and development programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our share price.

Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC require an annual management assessment of the effectiveness of our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. If we cannot in the future favorably assess the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our share price.

The ownership of our common shares is highly concentrated, which may prevent you and other shareholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our common shares price to decline.

The ownership of our common shares is highly concentrated among insiders and affiliates. Accordingly, these shareholders will have substantial influence over the outcome of corporate actions requiring shareholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the company's assets or any other significant corporate transaction. These shareholders may also delay or prevent a change of control of the company, even if such a change of control would benefit the other shareholders of the company. The significant concentration of share ownership may adversely affect the trading price of our common shares due to investors' perception that conflicts of interest may exist or arise.

We qualify as a foreign private issuer, and as a result, shareholders may receive less information and be afforded less protection under the U.S. federal securities laws.

We believe we qualify as a foreign private issuer within the meaning of rules promulgated under the Securities and Exchange Act of 1934, as amended. If we qualify as a foreign private issuer, we may be exempt from certain Exchange Act rules and requirements that apply to U.S. public companies, including: (i) the requirement to file with the SEC quarterly reports on Form 10-Q and current reports on Form 8-K; (ii) rules regulating the solicitation of proxies in connection with shareholder meetings; (iii) Regulation FD prohibiting selective disclosures of material information; and (iv) rules requiring insiders to disclose stock ownership and trading activities and establishing liability for profits realized from "short-swing" trading transactions (i.e., a purchase and sale, or sale and purchase, of the issuer's equity securities within less than six months). If in the future we elect to be treated as a foreign private issuer, shareholders will receive less information about the company and trading in our shares by our affiliates, and will be afforded less protection under the U.S. federal securities laws than would be afforded to shareholders of a domestic U.S. company.

We may be deemed a passive foreign investment company, and as a result, shareholders may be subject to special taxation rules that restrict capital gains treatment, unless the shareholders make a timely tax election to treat the company as a qualified electing fund.

A special set of U.S. federal income tax rules applies to a foreign corporation that is deemed a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. 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, 2019 taxable year. There can be no assurance, however, that we 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 our control, generally cannot be determined until the close of the taxable year in question, and is determined annually.

If we are deemed to be a PFIC during the current or any future taxable year, U.S. shareholders would be subject to special taxation rules related to gain on sale or disposition of our shares and excess distributions unless they make a timely election to treat our shares as a qualified electing fund ("QEF election"). A QEF election cannot be made unless we provide U.S. shareholders the information and computations needed to report income and gains pursuant to a QEF election. Without a QEF election, U.S. shareholders may not be able to use capital gains tax treatment and may be subject to potentially adverse tax consequences. Given the complexities of the PFIC and QEF election rules, U.S. shareholders may need to incur the time and expense of consulting a tax adviser about these rules.

Item 1B. UNRESOLVED STAFF COMMENTS.

None.

Item 2. PROPERTIES.

We currently lease approximately 2,800 square feet of office space in Markham, Ontario, from a related company under a lease that expires in December 2022, with an option to renew for another two-year term.

We also hold three leases that we intend to allow to expire at the end of their current respective terms: 4,300 square feet of office space in Port Hueneme, California under a lease that expires in June 2020, and two subleases for 37,000 square feet of oceanfront land in the Port Hueneme Aquaculture Business Park that expire in September 2020 and October 2020, respectively.

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 "EDSA".

Holders

As of December 12, 2019, we had 7,504,468 common shares outstanding, with 31 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 "Forward-Looking Statements and Other Matters" 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, Edesa Biotech Research, Inc. and Stellar Biotechnologies, Inc.

In the past, operations of the Company have primarily been funded through issuances of preferred shares that were converted into common shares, loans that were converted into common shares and government grants. We have devoted substantially all of our efforts to research and development, including clinical trials, and have not completed the development of any of our drug candidates. Management believes the Company's working capital is sufficient to support the Company's operations for at least the next 12 months.

As a clinical-stage biopharmaceutical company, we expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue the development of, and seek marketing approvals for our product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States and Canada. Management expects to seek additional financing through debt and/or equity financings, including transactions with strategic companies that may include debt and/or equity arrangements.

Results of Operations

Nine-month Period Ended September 30, 2019 Compared to Year Ended December 31, 2018

Financial results for any periods ended prior to June 7, 2019 reflect the financials of our subsidiary Edesa Biotech Research, Inc. on a standalone basis. Upon the completion of the reverse acquisition, Edesa Biotech Research, Inc. changed its year end to September 30 from December 31 to align with our fiscal year end. As a result, our financial results for the nine-month period ended September 30, 2019 may not be directly comparable to the prior reported year.

Our total revenues for the nine-month period ended September 30, 2019 were $0.41 million as we initiated sales of product inventory obtained in the reverse acquisition completed in June 2019. There were no revenues for the year ended December 31, 2018.

Our total operating expenses increased by $1.62 million to $3.24 million for the nine-month period ended September 30, 2019 compared to $1.62 million for the prior year ended December 31, 2018:

- Our cost of sales was $0.10 million for the nine-month period ended September 30, 2019, reflecting the initiation of sales of product inventory obtained in the reverse acquisition. There were no revenues in the prior year ended December 31, 2018.
- Our research and development expenses were $1.10 million for the nine-month period ended September 30, 2019, reflecting greater clinical research activities related to the initiation of the Phase 2B clinical study of our EB01 product candidate as well as higher personnel expenses. Research and development expenses were $1.08 million for the prior year ended December 31, 2018.
- General and administrative expenses were $2.05 million for the nine-month period ended September 30, 2019, reflecting increased legal and professional fees related to our reverse acquisition, increased personnel expenses and the initiation of public company expenses, which we did not incur as a privately held company. General and administrative expenses were $0.54 million for the prior year ended December 31, 2018.

Our total other income was $0.06 million for the nine-month period ended September 30, 2019, reflecting relatively lower interest income and the negative impact of fluctuations in Canadian exchange rates. Total other income was $0.08 million for the prior year ended December 31, 2018.

For the nine-month period ended September 30, 2019, our net loss was $2.78 million, or $0.55 per basic share, compared to a net loss of $1.54 million, or $0.47 per basic share, for the prior year ended December 31, 2018.

Capital Expenditures

Our capital expenditures, which primarily consist of computer equipment, were $8,095 and $6,869 for the nine-month period ended September 30, 2019 and year ended December 31, 2018, respectively.

Liquidity and Capital Resources

Our operations have historically been funded through issuances of preferred shares that were converted into common shares, loans that were converted into common shares and government grants. For the nine-month period ended September 30, 2019 and the year ended December 31, 2018, the Company reported net losses of approximately $2.78 million and $1.54 million, respectively. At September 30, 2019, we had cash and cash equivalents of $5.03 million, working capital of $5.18 million, shareholders' equity of $5.26 million and an accumulated deficit of $6.73 million.

We plan to finance company operations for at least the next twelve months with cash and cash equivalents on hand. Management expects to continue incurring losses for the foreseeable future and will need to raise additional capital to pursue our business plan beyond December 2020. Management has flexibility to adjust this timeline by a making changes to planned expenditures related to, among other factors, the size and timing of clinical trial expenditures, staffing levels, and the acquisition or in-licensing of new product candidates. Management also expects to seek additional financing through debt and/or equity financings, including transactions with strategic companies that may include debt and/or equity arrangements.

Research and Development

Our core business is focused on acquiring, developing and commercializing clinical-stage drugs for dermatological and gastrointestinal indications with clear unmet medical needs.

Research and development costs, including (i) the costs of contract research organizations for clinical trial management services, (ii) the costs of contract manufacturing organizations for manufacturing our drug compound(s) for use in clinical trials and (iii) salaries of employees directly involved in research and development efforts, are expensed as incurred.

The following table includes our research and development costs for the nine-month period ended September 30, 2019 and the year ended December 31, 2018:

2019	$ 1,096,426
2018	1,075,491

The research and development expenses for the nine-month period ended September 30, 2019 were primarily for greater clinical research activities related to the initiation of the Phase 2B clinical study of our EB01 product candidate as well as higher personnel expenses.

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. We have balances in Canadian dollars which are subject to foreign currency fluctuations relating to the impact of translating to U.S. dollars for financial statements presentation. We also periodically exchange U.S. dollars for Canadian dollars since most operating expenses are incurred in Canadian dollars. 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, 2019, we had assets of approximately C$2.4 million and the U.S. dollar was equal to 1.324 Canadian dollars. Based on the exposure at September 30, 2019, a 10% annual change in the Canadian/U.S. exchange rate would impact our net loss and other comprehensive loss by $0.18 million.

Concentration of Credit Risk

We are potentially subject to financial instrument concentration of credit risk through our cash and cash equivalents, US Treasury bills and accounts and other receivable. 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. There were no Treasury bills outstanding at September 30, 2019 and December 31, 2018. 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. Accounts and other receivable also include Harmonized Sales Tax (HST) refunds receivable from the Canada Revenue Agency. As of September 30, 2019 and December 31, 2018, all outstanding accounts and other 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.

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.

Accounts and other 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. Accounts and other receivable include Harmonized Sales Tax (HST) refunds receivable. As of September 30, 2019, all outstanding accounts and HST refunds receivable were deemed to be fully collectible, and therefore, no allowance for doubtful accounts was recorded.

Revenue Recognition

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed under ASC Topic 606: (1) identify contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenues when (or as) the Company satisfies the performance obligation(s). Revenues consist of sales of product inventory obtained in the reverse acquisition completed in June 2019, which are recognized upon shipment when the customer obtains control of the product and the Company has no further performance obligations.

Share-based compensation

The Company measures the cost of equity-settled transactions by reference to the fair value of the equity instruments at the date at which they are granted if the fair value of the goods or services received by the Company cannot be reliably estimated.

The Company grants options to buy common shares of the Company to its directors, officers, employees and consultants, and grants other equity-based instruments such as warrants 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 provisions of the Company's share-based compensation plans do not require the Company to settle any options by transferring cash or other assets, and therefore the Company classifies the awards as equity. 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.

Translation of foreign currency transactions

The Company's reporting currency is the U.S. dollar. The financial statements of the parent Company and its wholly-owned Canadian subsidiary are measured using the Canadian dollar as the functional currency. Assets and liabilities of the Canadian operations have been translated at year-end exchange rates and related revenue and expenses have been translated at average exchange rates for the year. Accumulated gains and losses resulting from the translation of the financial statements of the Canadian operations are included as part of accumulated other comprehensive loss, a separate component of shareholders' equity.

In respect of other transactions denominated in currencies other than the Company’s functional currency, the monetary assets and liabilities are translated at the year-end rates. Revenue and expenses are translated at rates of exchange prevailing on the transaction dates. Non-monetary balance sheet and related income statement accounts are remeasured into U.S. dollar using historical exchange rates. All of the exchange gains or losses resulting from these other transactions are recognized in the statements of operations and comprehensive loss.

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.

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

We are a smaller reporting company and are not required to provide disclosure 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.

Upon the completion of our business combination with Edesa Research on June 7, 2019, the audit committee of our Board of Directors approved the engagement of MNP LLP as our independent registered public accounting firm and Moss Adams LLP ("Moss Adams") resigned as our independent registered public accounting firm.

During the years ended September 30, 2018 and 2017, and through the subsequent interim period through June 7, 2019, (i) there were no disagreements between us and Moss Adams on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Moss Adams, would have caused Moss Adams to make reference to the subject matter of the disagreements in connection with its reports and (ii) there were no “reportable events,” as described in Item 304(a)(1)(iv) of Regulation S-K of the SEC promulgated under the Exchange Act.

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 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, 2019. Our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures as of September 30, 2019, 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, 2019.

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 nine-month period ended September 30, 2019 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 December 12, 2019 are set forth below.

Name	Age	Position(s) Held	Director Since
Lorin Johnson, PhD (2)	67	Director	June 7, 2019
Sean MacDonald (1)(2)(3)	43	Chairman of Board of Directors	June 7, 2019
Pardeep Nijhawan, MD	49	Director, Chief Executive Officer and Corporate Secretary	June 7, 2019
Frank Oakes	69	Director	April 9, 2010
Paul Pay (1)(2)	65	Director	June 7, 2019
Carlo Sistilli, CPA, CMA (1)(3)	63	Director	June 7, 2019
Peter van der Velden (3)	58	Director	June 7, 2019

(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:

Lorin Johnson, PhD is a seasoned pharmaceutical entrepreneur and innovator with more than 30 years of experience in building companies. He has been a member of our board of directors since June 2019, having previously served as a director of the company's principal operating subsidiary, Edesa Biotech Research, Inc., from its founding in January 2015 to January 2016. Dr. Johnson is currently the Chief Scientist of Glycyx Pharma Ventures Ltd., a biopharma investment and development company he founded in March 2016. Prior to Glycyx, Dr. Johnson co-founded Salix Pharmaceuticals, Inc., a specialty pharmaceutical company, and held senior leadership positions prior to its acquisition by Valeant Pharmaceuticals International, Inc. in April 2015. Earlier in his career, Dr. Johnson served as Director of Scientific Operations and Chief Scientist at Scios, Inc. (formerly California Biotechnology, Inc). In addition to Edesa, he currently serves on the boards of Innovate Biopharmaceuticals, Inc. (trading symbol INNT), Glycyx MOR, LTD, Kinisi Therapeutics, Ltd., Intact Therapeutics, Inc. and ATXA Therapeutics, Ltd. Dr. Johnson has also held academic positions at Stanford University School of Medicine where he served as an Assistant Professor of Pathology and at the University of California, San Francisco. He is the co-author of 76 journal articles and book chapters and is the co-inventor on 23 issued patents. Dr. Johnson holds a PhD from the University of Southern California and was a Postdoctoral Fellow at the University of California, San Francisco. Dr. Johnson's qualifications to serve on the board of directors include his knowledge of our business and his significant experience in the pharmaceutical industry.

Sean MacDonald has been our Chairman of the Board since June 2019, having previously served as a director of the company's principal operating subsidiary, Edesa Biotech Research, Inc., since September 2017. Mr. MacDonald is currently the Head of Business Development for Cosmo Pharmaceuticals NV, a European gastroenterology focused pharmaceutical company, a position he has held since April 2019, as well as the chief executive of Corbin Therapeutics, a Montreal-based biotech company focused on treating neuroinflammation, a role he has held since October 2018. From October 2012 to October 2018, Mr. MacDonald held various operational and executive leadership roles at Pharmascience Inc., one of Canada's largest pharmaceutical companies, including Vice President of Business Development and Corporate Development. He received his BSc in Molecular Biology and MBA from the University of Ottawa. Mr. MacDonald's qualifications to serve on the board of directors include his extensive operational experience and background in the pharmaceutical/biotechnology industry.

Pardeep Nijhawan, MD, FRCPC, AGAF has served as our Chief Executive Officer, Corporate Secretary and a member of our board of directors since June 2019, having previously founded and led the company's principal operating subsidiary, Edesa Biotech Research, Inc., since January 2015. Dr. Nijhawan is a seasoned pharmaceutical entrepreneur with 20 years of experience in cross-functional leadership roles in finance, marketing, corporate strategy and business development. Prior to Edesa, in 2002 Dr. Nijhawan founded Medical Futures Inc., and served as its CEO. He sold Medical Futures to Tribute Pharmaceuticals in 2015. Dr. Nijhawan also founded Digestive Health Clinic in 2000 and led it to become Canada's largest provider of private endoscopy services. In 2014, he founded Exzell Pharma, a specialty Canadian-based pharmaceutical organization that markets and commercializes approved products. He continues to serve on the Boards of Exzell Pharma and Digestive Health Clinic. Dr. Nijhawan received his MD from the University of Ottawa and completed his internship at Yale University, and his internal medicine residency and fellowship at the Mayo Clinic. Dr. Nijhawan's qualifications to serve on the board of directors include his extensive executive leadership and experience in the life sciences industry and his knowledge of our business as its chief executive.

Frank Oakes has more than 40 years of executive leadership experience. He has been a director of the company since April 2010 and served as the Chairman of the Board until June 2019. From 1999 to 2019, he also served as the President and Chief Executive Officer of the company's legacy operating subsidiary, which he founded. Prior to founding Stellar Biotechnologies, Inc., he was the Chief Executive Officer of The Abalone Farm, Inc., where he led the company through the research and development, capitalization, and commercialization phases of development to become the largest abalone producer in the United States at the time. Mr. Oakes has consulted and lectured around the world. He received his BS degree from California State Polytechnic University, San Luis Obispo and is a graduate of the Los Angeles Regional Technology Alliance University's management program. Mr. Oakes qualifications to serve on the board of directors include his extensive operational experience building companies and management teams and leading a U.S. and Canadian publicly listed life science company.

Paul Pay is an executive with 40 years of experience in the pharmaceutical/biotechnology industry. He has been a member of our board of directors since June 2019, having previously served as a director of the company's principal operating subsidiary, Edesa Biotech Research, Inc., since its founding in January 2015. From November 2002 to present, he has led all business development activity at Norgine and is currently the Chief Business Development Officer and serves as a member of the company's executive committee. Prior to joining Norgine, Mr. Pay held senior management positions at large, specialty and early-stage pharmaceutical companies, and cofounded a university spin-out company. His commercial roles have included sales, marketing, market research, licensing, business development, public relations, intellectual property and product development. In addition to Edesa, Mr. Pay is currently a director of Exzell Pharma, a specialty pharmaceutical company; Arc Medical Design, a medical device development company and a portfolio company of Norgine; and Norgine Ltd., an affiliate of Norgine. Mr. Pay is also the President and CEO of Merus Labs Inc., a Norgine wholly owned affiliate company. Mr. Pay received a BSC (hons) from the University of Leeds. Mr. Pay's qualifications to serve on the board of directors include his extensive experience in the pharmaceutical/biotechnology industry and his knowledge of Edesa's business.

Carlo Sistilli, CPA, CMA has more than 35 years of financial experience and has held a variety of executive positions in accounting and finance during his career. He has been a member of our board of directors since June 2019, having previously served as a board observer of the company's principal operating subsidiary, Edesa Biotech Research, Inc., since September 2017. Mr. Sistilli has served as the Chief Financial Officer of Arista Homes since March 2003 to present. Prior to Arista, Mr. Sistilli was a founder and served as CFO and a board member of an Internet start-up company in the automotive sector, and played a key role in taking the company public on the Alberta Ventures Exchange. Earlier in his career, Mr. Sistilli was the Controller and a member of the senior management team of a major regional trust company, which Mr. Sistilli helped sell to Manulife Financial. In addition to his professional career, Mr. Sistilli is an officer and a member of the board of directors of Mother of Mercy Centre. Mr. Sistilli holds a Bachelor of Arts from York University, with a major in economics, Certified Management Accountant Designation and a Chartered Professional Accountant Designation. Mr. Sistilli's qualifications to serve on the board of directors include his knowledge of Edesa's business and his background in accounting and finance.

Peter van der Velden is an investor and business executive with more than 28 years of experience in building growth companies. He has been a member of our board of directors since June 2019, having previously served as a director of the company's principal operating subsidiary, Edesa Biotech Research, Inc., since September 2017. From 2007 to present, Mr. van der Velden has been the Managing General Partner of Lumira Ventures, one of Canada's largest dedicated life sciences venture capital investors. Mr. van der Velden currently serves on the boards of Exact Imaging, Medexus Pharmaceuticals (trading symbol PDDPF) and AmacaThera. His past corporate board roles include: Milcom Ventures, Spinal Kinetics, Alveolus Inc., CML Healthcare, First Aid Shot Therapy, Life Sciences Ontario, Skinstore.com, and Vendorlink.ca. Mr. van der Velden is a past President and Chairman of the Canadian Venture and Private Equity Association and currently serves on the board or as an advisor to a number of industry groups and non-profit organizations. Mr. van der Velden holds an MBA in Finance and Policy from the Schulich School of Business, and a MSc in Pathology and BSc (honors) in Life Sciences from Queen's University. Mr. van der Velden's qualifications to serve on the board of directors include his extensive operational experience building growth companies and his knowledge acquired from serving on the boards of other companies.

Executive Officers

Set forth below is certain information with respect to the names, ages, and positions of our executive officers as of December 12, 2019. Biographical information pertaining to Dr. Nijhawan, 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
Pardeep Nijhawan, MD	49	Director, Chief Executive Officer and Corporate Secretary	June 7, 2019
Kathi Niffenegger, CPA	62	Chief Financial Officer	November 1, 2013
Michael Brooks, PhD	41	President	June 7, 2019

Kathi Niffenegger, CPA has served as our Chief Financial Officer since 2013. She also previously served as the company’s Corporate Secretary from 2013 to June 2019. Ms. Niffenegger has more than 30 years of experience in accounting and finance in a range of industries, and has led audits of manufacturing, pharmaceutical and governmental grant clients. She has also developed specialized expertise in cost accounting systems and internal controls. Prior to joining the company, she held positions of increasing responsibility in the audit division of Glenn Burdette CPAs and served most recently as technical partner. Earlier in her career, she was the Chief Financial Officer of Martin Aviation. Ms. Niffenegger holds a B.S. degree in Business Administration, Accounting from California State University, Long Beach. She is a member of the American Institute of Certified Public Accountants (AICPA) and holds the Chartered Global Management Accountant (CGMA) designation.

Michael Brooks, PhD was appointed President of Edesa in June 2019, having served as Vice President of Corporate Development and Strategy for the company’s principal operating subsidiary, Edesa Biotech Research, Inc., since January 2015. Prior to joining Edesa, Dr. Brooks held positions of increasing responsibility at Cipher Pharmaceuticals Inc from 2010 to 2015 and served most recently as the company's as Director of Business Development. Prior to joining Cipher, Dr. Brooks was a Post-Doctoral fellow at the University of Toronto. Dr. Brooks holds a Hons B.Sc. degree in Microbiology and a PhD in Molecular Genetics from the University of Toronto. Dr. Brooks received his MBA degree from the Rotman School of Management where he was a Canadian Institute for Health Research (CIHR) Science-to-Business Scholar.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires that our directors, executive officers, and beneficial owners of more than ten percent of our common shares 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 filed electronically with the Securities and Exchange Commission during the Company’s nine-month period ended September 30, 2019, during such period, each of our directors, executive officers, and beneficial owners of more than ten percent of our common shares filed on a timely basis all reports required by Section 16(a) of the Exchange Act, except for one report on Form 4 reporting one transaction that was filed late by Frank Oakes.

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 office, principal financial office, 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 edesabiotech.com/investors/governance, in the Corporate Governance section, under the Governance Documents section. 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, Edesa Biotech, Inc., 100 Spy Court, Markham, ON Canada L3R 5H6.

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 edesabiotech.com/investors/governance.

Audit Committee

Our Audit Committee is composed of Sean MacDonald, Paul Pay and Carlo Sistilli (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.

Carlo Sistilli is the Chair of our Audit Committee and has extensive financial experience. He holds a Bachelor of Arts from York University, with a major in economics, Certified Management Accountant Designation and a Chartered Professional Accountant Designation. He has held a variety of executive positions in accounting and finance during the past 35 years. The Board has determined that Mr. Sistilli 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 Lorin Johnson, Sean MacDonald and Paul Pay (chair). The purpose of the Compensation Committee is to assist the Board's oversight relating to compensation, including (i) the approval of compensation for our Chief Executive Officer and (ii) the review of compensation for our other named executive officers. It has overall responsibility for evaluating, and approving or recommending to the independent members of the Board for approval, 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 Sean MacDonald, Carlo Sistilli and Peter van der Velden (chair). 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 the nine-month period ended September 30, 2019 were Pardeep Nijhawan, MD, Director, Chief Executive Officer and Corporate Secretary; Kathi Niffenegger, CPA, Chief Financial Officer; and Michael Brooks, PhD, President.

Summary Compensation Table

The following table sets forth information regarding the compensation awarded to, earned by or paid to the named executive officers for the nine-month period ended September 30, 2019 and the year ended December 31, 2018.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards($) (1)	All Other Compensation ($)	Total ($)
Pardeep Nijhawan, MD	2019	$ 105,461	$ -	$ -	$ 24,571(2)	$ 130,032
Director, Chief Executive	2018	27,116	-	1,594	32,415(2)	61,125
Officer and Corporate Secretary						
Kathi Niffenegger, CPA	2019(3)	63,604	53,750	-	5,000(4)	122,354
Chief Financial Officer	2018(3)	-	-	-	-	-
Michael Brooks, PhD	2019	158,114	37,243	-	11,897(5)	207,254
President	2018	170,445	51,706	1,594	7,280(5)	231,025

(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 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 6 to our audited consolidated financial statements for the nine-month period ended September 30, 2019 included in this Annual Report.

(2) Represents (i) $23,884 in car allowance and (ii) $687 in health insurance in 2019 and (i) $32,415 in car allowance in 2018. The compensation was paid in Canadian dollars and was converted to US dollars using the average foreign exchange rate for the year from oanada.com.

(3) Ms. Niffenegger was our Chief Financial Officer prior to our business combination with Edesa Research and her compensation during that time is not reflected in our audited consolidated financial statements included in this Annual Report. In the nine-month period September 30, 2019 prior to our business combination on June 7, 2019, she received salary of $97,599, bonus of $53,725 and other compensation of (i) $6,775 in health insurance and (ii) $4,540 in 401(k) company contributions. During fiscal 2018 she received salary of $208,637, bonus of $60,512 and other compensation of (i) $12,962 in health insurance and (ii) $6,077 in 401(k) company contributions.

(4) Represents (i) $3,719 in health insurance and (ii) $1,281 in 401(k) company contributions.

(5) Represents (i) $9,698 in car allowance and (ii) $2,199 in health insurance in 2019 and (i) $5,094 in car allowance and (ii) $2,186 in health insurance in 2018. The compensation was paid in Canadian dollars and was converted to US dollars using the average foreign exchange rate for the year from oanda.com.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

Prior to the completion of our business combination with Edesa Research, Edesa Research had employment agreements in effect with Dr. Pardeep Nijhawan and Dr. Michael Brooks which are described below. Upon completion of our business combination transaction with Edesa Research, Dr. Nijhawan and Dr. Brooks each entered into new employment agreements with us which are also described below, and the old employment agreements were terminated.

Terminated Employment Agreement with Dr. Pardeep Nijhawan

On August 1, 2017, Edesa Research entered into an employment agreement with Dr. Pardeep Nijhawan which was to continue indefinitely until terminated in accordance with its terms. The employment agreement provided that during the term of the agreement, Dr. Nijhawan was to serve as Edesa Research's Chief Executive Officer. In consideration for his services to Edesa Research, Dr. Nijhawan received a base salary of C$35,000 per annum and was eligible for coverage under Edesa Research's standard benefit programs. The agreement was terminable by Edesa Research (i) for cause without notice or severance pay or (ii) without cause, in which case Edesa Research was to provide 18 months notice of termination or pay in lieu of notice (based on Dr. Nijhawan's base salary) and benefits for up to 18 months following the provision of notice of termination. In addition, upon a termination by Edesa Research without cause, all options on a pro-rated basis were to be deemed vested on the business day immediately preceding the termination date and would remain exercisable for a period of 180 days. Dr. Nijhawan could resign from his employment at any time by providing two weeks advance notice to Edesa Research.

New Employment Agreement with Pardeep Nijhawan

On June 14, 2019 but effective as of June 7, 2019, we entered into an employment agreement with Pardeep Nijhawan. Pursuant to the employment agreement, Dr. Nijhawan will serve as our Chief Executive Officer for an indefinite term until Dr. Nijhawan's employment is terminated in accordance with the agreement. As compensation for his services to us, Dr. Nijhawan will receive a base salary of $300,000 per year and be eligible to receive a target annual bonus of 40% of his base salary, subject to achieving corporate and personal targets to be determined by us. Dr. Nijhawan will also receive an automobile allowance of $2,700 per month and be eligible to participate in our group insured benefits program, as may be in effect from time-to-time for our employees generally, and executive employees specifically. Dr. Nijhawan is also eligible for future share and/or option grants, as determined by our Compensation Committee, commensurate with Dr. Nijhawan's position and any business milestones which may be established by the Compensation Committee and subject to availability of shares and/or options for grant under our Equity Incentive Compensation Plan.

If Dr. Nijhawan's employment with us is terminated for "Cause" (as such term is defined in the employment agreement), subject to applicable law, our only obligation shall be to provide Dr. Nijhawan with his base salary and vacation pay earned through the date of termination and all of Dr. Nijhawan's vested or non-vested stock options which have not been exercised by Dr. Nijhawan as of the date of termination will be automatically extinguished. If Dr. Nijhawan is terminated by us without "Cause", our only obligation shall be to provide Dr. Nijhawan with (i) a lump sum payment equal to Dr. Nijhawan's then current base salary for twenty-four months (the "Severance Period"), (ii) a lump sum payment of the annual bonus to which Dr. Nijhawan is entitled for the fiscal year immediately preceding the date of termination, if such bonus has not already been paid, (iii) a lump sum payment equal to Dr. Nijhawan's annual bonus entitlement, prorated over Dr. Nijhawan's length of service in the fiscal year in which his employment is terminated, calculated in accordance with the terms of the employment agreement, (iv) payment of Dr. Nijhawan's annual bonus entitlement during the full Severance Period, calculated in accordance with the terms of the employment agreement, (v) continuation of Dr. Nijhawan's benefits and car allowance and any other benefit required to be maintained by law in accordance with the terms of the employment agreement and (vi) subject to applicable law, all stock options granted to Dr. Nijhawan shall be exercisable in accordance with the terms of the applicable stock option plan. Dr. Nijhawan may resign from his employment at any time by providing us with a minimum of sixty days advance notice, in writing. Dr. Nijhawan's notice may be waived by us, subject only to providing Dr. Nijhawan with payment of his base salary and continuation of benefits until the end of the notice period. If Dr. Nijhawan resigns from his employment, subject to applicable law, (i) all non-vested stock options and all vested stock options held by Dr. Nijhawan which have not been exercised by Dr. Nijhawan as of the date of termination shall be automatically extinguished and (ii) Dr. Nijhawan shall not be entitled to any bonus or pro rata bonus payment not already paid on or before the date of termination.

During the term of Dr. Nijhawan's employment with us and for twelve months following the cessation of Dr. Nijhawan's employment with us, Dr. Nijhawan is prohibited from competing with our business in North America. In addition, for twenty-four months following the cessation of Dr. Nijhawan's employment with us, Dr. Nijhawan is prohibited from soliciting customers or prospective customers for any purpose competitive with our business, encouraging any customer to cease doing business with us and soliciting the employment or engagement of certain of our employees.

Terminated Employment Agreement with Michael Brooks

On August 28, 2017, Edesa Research entered into an employment agreement with Michael Brooks which was to continue indefinitely until terminated in accordance with its terms. The employment agreement provided that during the term of the agreement, Dr. Brooks was to serve as Edesa Research's Vice President Corporate Development and Strategy. In consideration for his services to Edesa Research, Dr. Brooks received a base salary of C$220,000 per annum and was eligible for coverage under Edesa Research's standard benefit programs. In addition, subject to achievement of bonus criteria established by Edesa Research, Dr. Brooks was eligible to receive an annual bonus award of up to 30% of his base salary.

The agreement was terminable by Edesa Research (i) for cause without notice or severance pay or (ii) without cause, in which case Edesa Research was to provide 12 months notice of termination or pay in lieu of notice (based on Dr. Brooks' base salary) and benefits for up to 12 months following the provision of notice of termination. In addition, upon a termination by Edesa Research without cause, Dr. Brooks was entitled to a pro-rated bonus covering any year or partial actively worked from the time of the past applicable bonus period through to the termination date of Dr. Brooks employment and all options on a pro-rated basis would be deemed to be vested on the business day immediately preceding the termination date and would remain exercisable for a period of 180 days. In the event Dr. Brook's employment was terminated in connection with a change of control event, any unvested options or other equity awards then held by Dr. Brooks would be deemed to be vested on the business day immediately preceding the termination date and were to remain exercisable for a period of 180 days. Dr. Brooks could also resign from his employment at any time by providing two weeks advance notice to Edesa Research. During the term of his employment and for a period of 12 months thereafter, Dr. Brooks was subject to certain non-solicitation provisions relating to Edesa Research's employees, customers, prospective customers and suppliers. In addition, the agreement provided that, subject to certain exceptions, Dr. Brooks could not compete with the business of Edesa Research during the employment period and any notice period (or period paid in lieu of notice).

New Employment Agreement with Michael Brooks

On June 14, 2019 but effective as of June 7, 2019, we entered into an employment agreement with Michael Brooks, PhD. Pursuant to the employment agreement, Dr. Brooks will serve as our President for an indefinite term until Dr. Brooks' employment is terminated in accordance with the agreement. As compensation for his services to us, Dr. Brooks will receive a base salary of $275,000 per year and be eligible to receive a target annual bonus of 40% of his base salary, subject to achieving corporate and personal targets to be determined by us. Dr. Brooks will also receive an automobile allowance of $2,000 per month and be eligible to participate in our group insured benefits program, as may be in effect from time-to-time for our employees generally, and executive employees specifically. Dr. Brooks is also eligible for future share and/or option grants, as determined by our Compensation Committee, commensurate with Dr. Brooks' position and any business milestones which may be established by the Compensation Committee and subject to availability of shares and/or options for grant under our Equity Incentive Compensation Plan.

If Dr. Brooks' employment with us is terminated for "Cause" (as such term is defined in the employment agreement), subject to applicable law, our only obligation shall be to provide Dr. Brooks with his base salary and vacation pay earned through the date of termination and all of Dr. Brooks' vested or non-vested stock options which have not been exercised by Dr. Brooks as of the date of termination will be automatically extinguished. If Dr. Brooks is terminated by us without "Cause", our only obligation shall be to provide Dr. Brooks with (i) a lump sum payment equal to Dr. Brooks' then current base salary for twelve months plus one additional month for every completed year of service since September 2015, not to exceed an aggregate of twenty-four months (the "Severance Period"), (ii) a lump sum payment of the annual bonus to which Dr. Brooks is entitled for the fiscal year immediately preceding the date of termination, if such bonus has not already been paid, (iii) a lump sum payment equal to Dr. Brooks' annual bonus entitlement, prorated over Dr. Brooks' length of service in the fiscal year in which his employment is terminated, calculated in accordance with the terms of the employment agreement, (iv) payment of Dr. Brooks' annual bonus entitlement during the full Severance Period, calculated in accordance with the terms of the employment agreement, (v) continuation of Dr. Brooks' benefits and car allowance and any other benefit required to be maintained by law in accordance with the terms of the employment agreement and (vi) subject to applicable law, all stock options granted to Dr. Brooks shall be exercisable in accordance with the terms of the applicable stock option plan. If Dr. Brooks' employment is terminated or "constructively terminated" (as such term is defined in the employment agreement) by us without "Cause" upon or within a twelve month period following a Change of Control (as such term is defined in the employment agreement), Dr. Brooks shall be entitled to the payments and benefits provided as described in clauses (ii) to (vi) above, plus a change of control payment equal to twenty-four months of the his then current base salary. Dr. Brooks may resign from his employment at any time by providing us with a minimum of sixty days advance notice, in writing. Dr. Brooks' notice may be waived by us, subject only to providing Dr. Brooks with payment of his base salary and continuation of benefits until the end of the notice period. If Dr. Brooks resigns from his employment, subject to applicable law, (i) all non-vested stock options and all vested stock options held by Dr. Brooks which have not been exercised by Dr. Brooks as of the date of termination shall be automatically extinguished and (ii) Dr. Brooks shall not be entitled to any bonus or pro rata bonus payment not already paid on or before the date of termination.

During the term of Dr. Brooks' employment with us and for twelve months following the cessation of Dr. Brooks' employment with us, Dr. Brooks is prohibited from competing with our business in North America. In addition, for twenty-four months following the cessation of Dr. Brooks' employment with us, Dr. Brooks is prohibited from soliciting customers or prospective customers for any purpose competitive with our business, encouraging any customer to cease doing business with us and soliciting the employment or engagement of certain of our employees.

New Employment Agreement with Kathi Niffenegger

On June 7, 2019, we entered into an employment agreement with Ms. Niffenegger. Pursuant to the employment agreement, Ms. Niffenegger will serve as our Chief Financial Officer. Both Ms. Niffenegger and us have the right to terminate the employment relationship at any time, with or without cause. As compensation for her services to us, Ms. Niffenegger will receive a base salary of $215,000 per year, a discretionary bonus in an amount up to 25% of her base salary based on her performance and the company's performance, a one-time hiring and retention bonus of $53,750 which is subject to partial claw back if Ms. Niffenegger voluntary terminates her employment prior to March 1, 2020 and such other employee benefits as are generally provided to similarly situated employees of the company. Ms. Niffenegger may be eligible for future share and/or option grants in accordance with our executive compensation policy as in effect from time to time as determined by our Compensation Committee subject to availability of shares and/or options for grant under our Equity Incentive Compensation Plan.

If Ms. Niffenegger's employment with us is terminated for "Cause" (as such term is defined in the employment agreement) or if Ms. Niffenegger resigns from her employment at any time, our only obligation shall be to provide Ms. Niffenegger with: (i) her accrued salary through and including her last day of employment (the "Separation Date"); (ii) reimbursement of any reimbursable expenses properly incurred through and including the Separation Date; and (iii) any benefit required under applicable law. If we terminate Ms. Niffenegger's employment without "Cause" or if Ms. Niffenegger's employment with us is "constructively terminated" (as such term is defined in the employment agreement) our only obligations shall be: (a) to provide Ms. Niffenegger with the same payments and benefits as would be provided if we had terminated her employment for Cause; and (b) subject to Ms. Niffenegger's execution of a release in our favor, Ms. Niffenegger will also be paid, as severance, an amount equal to twelve months of her base salary at her then-current rate. In the event that Ms. Niffenegger's employment is terminated or constructively terminated by us without Cause upon or within a twelve month period following a Change of Control (as defined in the employment agreement), Ms. Niffenegger shall be entitled to the payments and benefits as though she was terminated without "Cause", plus an additional change of control payment equal to twelve months of her base salary.

During the term of Ms. Niffenegger's employment with us, Ms. Niffenegger is prohibited from competing with our business. In addition, while Ms. Niffenegger is employed by us and for a period of one year thereafter, Ms. Niffenegger is prohibited from soliciting for employment certain of our employees.

Outstanding Equity Awards at September 30, 2019

The following table summarizes the equity awards made to our named executive officers that were outstanding at September 30, 2019.

		Option Awards			
Name	**Award grant date**	**Number of securities underlying unexercised options (#)exercisable**	**Number of securities underlying unexercised options (#)unexercisable (1)**	**Option exercise prices ($)**	**Option expiration date**
Pardeep Nijhawan, MD	9/26/17	32,977	14,513(2)	C$ 2.16	9/26/27
	12/28/18	-	1,620(2)	C$ 2.16	12/28/28
Kathi Niffenegger, CPA	12/19/12	119	-	C$ 105.00	12/19/19
	5/14/13	214	-	C$ 243.60	5/14/20
	11/1/13	238	-	$ 768.60	11/1/20
	11/12/14	214	-	C$ 638.40	11/12/21
	12/22/15	238	-	$ 304.08	12/22/22
	12/20/16	238	-	$ 85.26	12/20/23
	3/12/18	833	-	$ 35.28	3/12/25
Michael Brooks, PhD	8/28/17	136,416	-	C$ 2.16	8/28/27
	9/26/17	16,875	7,424(2)	C$ 2.16	9/26/27
	12/28/18	-	1,620(2)	C$ 2.16	12/28/28

(1) Our options vesting policy is described in the Outstanding Equity Awards Narrative Disclosure section.
(2) The option will vest over a period of three years, with one-third vesting on the first anniversary of the date of grant and the remainder vesting on a pro-rata basis monthly thereafter.

Outstanding Equity Awards Narrative Disclosure

Equity Incentive Compensation Plan

We adopted an Equity Incentive Compensation Plan in 2019 (the "2019 Plan") which amended and restated our 2017 Incentive Compensation Plan (the "2017 Plan"). Under the 2019 Plan, we are authorized to grant options, restricted shares and restricted share units (RSUs) to any of our officers, directors, employees, and consultants and those of our subsidiaries and other designated affiliates. The number of shares available for issuance under the 2019 Plan is 1,153,147, including shares available for the exercise of outstanding options under the 2017 Plan. The purpose of the 2019 Plan is to advance the interests of the Company by encouraging equity participation through the acquisition of common shares of the Company. The 2019 Plan is to be administered by the Compensation Committee of our Board of Directors, except to the extent (and subject to the limitations set forth in the 2019 Plan) the Board elects to administer the 2019 Plan, in which case the 2019 Plan shall be administered by only those members of the Board who are "independent" members of the Board. . The administrator of the 2019 Plan 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 to purchase 319,645 common shares at prices ranging from C$2.16 to C$638.40 and $35.28 to $768.60 are outstanding at September 30, 2019. No restricted shares or restricted share units have been granted as of September 30, 2019.

There were no options granted during the nine-month period ended September 30, 2019 to directors, officers, employees or consultants under the 2019 Plan.

Options Vesting Policy

Vesting requirements for option awards are determined by the Compensation Committee or independent directors on the board. Outstanding options granted by Stellar Biotechnologies before the completion of our business combination became fully vested on June 7, 2019, the date of our business combination with Edesa Research. Options granted by Edesa Research generally vested one-third upon the first anniversary of the date of grant and monthly thereafter until the third anniversary of the date of grant. The options granted by Edesa Research on August 28, 2017 were fully vested upon the grant date.

Retirement Benefits

Executive officers and employees of our California subsidiary are eligible to receive the company's non-elective contribution of 3% of eligible compensation under a 401(k) plan to provide retirement benefits. 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 the nine-month period ended September 30, 2019 or in the year ended December 31, 2018 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 nine-month period ended September 30, 2019.

Name	Fees Earned or Paid in Cash($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Lorin Johnson, PhD	$ 10,608	$ -	$ -	$ 10,608
Sean MacDonald	15,833(1)	-	-	15,833
Frank Oakes (2)	9,500	-	-	9,500
Paul Pay	23,238(3)	-	-	23,238
Carlo Sistilli, CPA, CMA	13,775(1)	-		13,775
	(1)			
Peter van der Velden	11,875(4)	-	-	11,875

(1) The compensation was paid in Canadian dollars and was converted to US dollars using the average foreign exchange rate for the year from oanda.com.

(2) Mr. Oakes was our Chief Executive Officer prior to our business combination with Edesa Research and his compensation during that time is not reflected in our audited consolidated financial statements included in this Annual Report. In the nine-month period ended September 30, 2019 prior to our business combination on June 7, 2019, he received salary of $120,269 and other compensation of (i) $9,752 in health insurance and (ii) $3,608 in 401(k) company contributions. During fiscal 2018 he received salary of $264,813, bonus of $50,000 and other compensation of (i) $20,197 in health insurance and (ii) $8,100 in 401(k) company contributions.

(3) Includes $9,780 for board services rendered to Edesa Research prior to our business combination on June 7, 2019. The compensation was paid in British pounds and was converted to US dollars using the average foreign exchange rate for the year from oanda.com.

(4) Fees of $10,870 and $1,005 were paid to Lumira Capital II, L.P. and Lumira Capital II (International), L.P., respectively, as compensation for Mr. van der Velden's services on our board of directors.

Outstanding Equity Awards at September 30, 2019

The following table summarizes the equity awards made to our directors that were outstanding at September 30, 2019.

Name	Outstanding Options (#)
Lorin Johnson, PhD	-
Sean MacDonald	-
Frank Oakes	952
Paul Pay	32,399
Carlo Sistilli, CPA, CMA	-
Peter van der Velden	-

Narrative to Director Compensation Table

Non-Employee Director Compensation Policy

The board adopted a compensation policy effective upon completion of our business combination on June 7, 2019. As compensation for their services on the board of directors, each non-executive board member will receive annual base remuneration of $30,000 and the Chairman of the Board will receive annual remuneration of $50,000, inclusive of compensation for his services on committees of the board of directors. Each member of the Company's Audit Committee will receive annual remuneration of $5,000, and the Chair of the Audit Committee will receive $10,000 annually for his services. Each member of the Company's Compensation Committee and Nominating and Corporate Governance Committee will receive annual remuneration of $3,500 for each committee on which they serve, and the Chairs of each of the Compensation Committee and Nominating and Corporate Governance Committee shall receive $7,500 annually for their services. The Chief Executive Officer will not receive any additional compensation for his services on the board of directors.

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, 2019 about our common shares that may be issued under our equity compensation plans, which consists of our 2017 Incentive Compensation Plan in effect at September 30, 2019:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)(1)
Equity compensation plans approved by security holders	319,645	$ 3.38	33,502
Equity compensation plans not approved by security holders	N/A	N/A	N/A
Total	319,645	$ 3.38	33,502

(1) On October 22, 2019, a majority of the shareholders of Edesa adopted the 2019 Equity Incentive Compensation Plan which increased the number of securities available for future issuance under our equity compensation plan by 800,000 common shares.

Security Ownership of Certain Beneficial Owners and Management

The following tables sets forth certain information as of December 12, 2019, 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 December 12, 2019 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 7,504,468 common shares outstanding as of December 12, 2019.

Directors and Officers

Name and Address of Beneficial Owner (1)	Amount and Nature of Beneficial Ownership	Percent of Shares Beneficially Owned
Lorin Johnson, PhD	-	*
Sean MacDonald	14,369(2)	*
Pardeep Nijhawan, MD	2,907,058(3)	38.5%
Frank Oakes	7,117(4)	*
Paul Pay	26,100(5)	*
Carlo Sistilli, CPA, CMA	-	*
Peter van der Velden	1,861,943(6)	24.8
Michael Brooks, PhD	156,621(7)	2.0
Kathi Niffenegger, CPA	2,094(8)	*
All directors and executive officers as a group (9 persons)	**4,975,302(9)**	**66.0%**

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

(1) Unless otherwise indicated, the address of each beneficial owner is c/o Edesa Biotech, Inc., 100 Spy Court, Markham, ON Canada L3R 5H6.

(2) Consists of 14,369 common shares.

(3) This amount includes (i) 38,883 common shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of December 12, 2019 and (ii) 537,312 common shares held directly by Dr. Nijhawan; 2,106,769 common shares held by Pardeep Nijhawan Medicine Professional Corporation, a corporation wholly owned by Dr. Nijhawan; and 224,094 shares held by The Digestive Health Clinic Inc., a corporation wholly owned by Dr. Nijhawan.

(4) This amount includes 952 common shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of December 12, 2019 and 6,165 common shares.

(5) Represents 26,100 common shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of December 12, 2019.

(6) Consists of 1,704,344 common shares held by Lumira Capital II, L.P. and 157,599 common shares held by Lumira Capital II (International), L.P., an affiliate of Lumira Capital II, L.P. Lumira Capital GP, L.P., the general partners of which are Lumira GP Inc. and Lumira GP Holdings Co., is the general partner of each of Lumira Capital II, L.P. and Lumira Capital II (International), L.P. Each of Lumira Capital II, L.P. and Lumira Capital II (International), L.P. is managed by Lumira Capital Investment Management Inc. Each of Lumira Capital GP, L.P., Lumira GP Inc., Lumira GP Holdings Co. and Lumira Capital Investment Management Inc. may be deemed to beneficially own the shares held by Lumira Capital II, L.P. and Lumira Capital II (International), L.P. Mr. van der Velden is an executive officer of Lumira GP Inc., Lumira GP Holdings Co. and Lumira Capital Investment Management Inc.

(7) Represents 156,621 common shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of December 12, 2019.

(8) Represents 2,094 common shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of December 12, 2019.

(9) This amount includes 224,650 shares issuable upon the exercise of options currently exercisable or exercisable within 60 days of December 12, 2019 and 4,750,652 common shares.

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
10379085 Canada Inc. (1)	675,218	9.0%
Inveready (2)	531,986	7.1%
Lumira Capital II, L.P. (3)	1,861,943	24.8%

(1) The address of the shareholder is 6111 vie. Royalmount Ave., Montreal, Quebec, Canada, H4P 2T4. Voting and investment power over the shares held by 10379085 Canada Inc. is exercised by an investment committee of PCRI Inc., the parent of 10379085 Canada Inc.

(2) The address of the shareholder is c/o Inveready Technology Investment Group, C/dels Cavaliers, 50, Barcelona, 08034, Spain. Voting and investment power over the shares held by Inveready Innvierte Biotech II, S.C.R. S.A is exercised by its board of directors.

(3) Consists of 1,704,344 common shares held by Lumira Capital II, L.P. and 157,599 common shares held by Lumira Capital II (International), L.P., an affiliate of Lumira Capital II, L.P. Lumira Capital GP, L.P., the general partners of which are Lumira GP Inc. and Lumira GP Holdings Co., is the general partner of each of Lumira Capital II, L.P. and Lumira Capital II (International), L.P. Each of Lumira Capital II, L.P. and Lumira Capital II (International), L.P. is managed by Lumira Capital Investment Management Inc. Each of Lumira Capital GP, L.P., Lumira GP Inc., Lumira GP Holdings Co. and Lumira Capital Investment Management Inc. may be deemed to beneficially own the shares held by Lumira Capital II, L.P. and Lumira Capital II (International), L.P and such entities control voting and investment power over such shares through an investment committee of the Lumira group. The address of each entity listed in this note is 141 Adelaide Street West, Suite 770, Toronto, Ontario, Canada M5H 3L5.

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

Related Party Transactions

Lease Agreement

In January 2017, Edesa Research entered into a lease agreement with a company related to Pardeep Nijhawan, our Chief Executive Officer, for executive office space which serves as our head office through December 2022, with the option to extend the lease for an additional two years. Monthly rents range from C$8,320 to C$9,020 plus HST. Rents of approximately $58,000 and $79,000 were incurred in the nine-month period ended September 30, 2019 and the year ended December 31, 2018, respectively, of which approximately $14,000 was payable at December 31, 2018. No rent was payable at September 30, 2019.

Patent Royalty Agreement

In August 2002, our California subsidiary entered into an agreement with Frank Oakes, a director, where he would receive royalty payments in exchange for the assignment of his rights to U.S. Patent No. 6,852,338 to Stellar Biotechnologies, Inc. The royalty is 5% of gross receipts from products using this invention in excess of $500,000 annually. Patent royalties of approximately $20,000 were incurred in the nine-month period ended September 30, 2019 and royalties payable of approximately $23,000 were outstanding at September 30, 2019. No patent royalties were incurred or payable for the year ended December 31, 2018.

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 Lorin Johnson, Sean MacDonald, Paul Pay, Carlo Sistilli and Peter van der Velden 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 nine-month period ended September 30, 2019 and year ended December 31, 2018 rendered by MNP LLP.

Principal Accountant Fees and Services

Type of Service	Nine-month Period 2019	Year Ended 2018
Audit Fees	$ 143,095	$ 88,260
Tax Fees	14,254	14,175
Total	$ 157,349	$ 102,435

Audit Fees consisted of fees incurred for professional services rendered for audits of the nine-month period ended September 30, 2019 and year ended December 31, 2018 and include procedures related to registrations and offerings.

Tax Fees consisted of fees incurred for professional services rendered for tax compliance related to tax returns during the nine-month period ended September 30, 2019 and year ended December 31, 2018.

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 and non-audit services performed by our independent registered public accounting firm for the nine-month period ended September 30, 2019.

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
2.1*	Share Exchange Agreement, dated as of March 7, 2019, by and between Stellar Biotechnologies Inc., Edesa Biotech Inc. and the Edesa Shareholders (included as Exhibit 2.1 to the Company's Current Report on Form 8-K filed on March 8, 2019, and incorporated herein by reference).
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	Certificate of Change of Name of the Company, dated June 7, 2019 (filed herewith).
3.7	Notice of Articles of the Company, dated June 7, 2019 (included as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 10, 2019, and incorporated herein by reference).
4.1	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).
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	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).
10.3	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).
10.4@	Employment Agreement by and between the Company and Kathi Niffenegger, dated June 7, 2019 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 10, 2019, and incorporated herein by reference).
10.5@	Employment Agreement by and between the Company and Pardeep Nijhawan, dated June 14, 2019 (included as Exhibit 10.2 to the Company's Current Report on Form 8-K/A filed on June 20, 2019, and incorporated herein by reference).
10.6@	Employment Agreement by and between the Company and Michael Brooks, dated June 14, 2019 (included as Exhibit 10.3 to the Company's Current Report on Form 8-K/A filed on June 20, 2019, and incorporated herein by reference).
10.7@	Form of Indemnification Agreement, by and between the Company and each of its directors and executive officers (included as Exhibit 10.4 to the Company's Current Report on Form 8-K/A filed on June 20, 2019, 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@	2019 Equity Incentive Compensation Plan (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 25, 2019, and incorporated herein by reference).
10.11	Lease, dated as of January 1, 2017, by and between the Registrant and 1968160 Ontario Inc. (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 30, 2019, and incorporated herein by reference).
10.12+	Exclusive License Agreement, dated as of June 29, 2016, by and between the Registrant and Yissum Research Development Company (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 30, 2019, and incorporated herein by reference).
10.13	First Amendment to Exclusive License Agreement, dated April 3, 2017, by and between the Registrant and Yissum Research Development Company (included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on August 30, 2019, and incorporated herein by reference).
10.14	Second Amendment to Exclusive License Agreement, dated May 7, 2017, by and between the Registrant and Yissum Research

	Development Company (included as Exhibit 10.4 to the Company's Current Report on Form 8-K filed on August 30, 2019, and incorporated herein by reference).
10.15+	Exclusive License Agreement, dated as of June 15, 2016, by and between the Registrant and Cipher Pharmaceuticals Inc. (included as Exhibit 10.5 to the Company's Current Report on Form 8-K filed on August 30, 2019, and incorporated herein by reference).
10.16+	License and Development Agreement, dated as of August 27, 2017, by and between the Registrant and Pendopharm, a division of Pharmascience Inc. (included as Exhibit 10.6 to the Company's Current Report on Form 8-K filed on August 30, 2019, and incorporated herein by reference).
14.1	Code of Ethics and Business Conduct (filed herewith).
21	Subsidiaries of Edesa Biotech, Inc. (filed herewith).
23.1	Consent of MNP LLP (filed herewith).
24.1	Power of Attorney (included on signature page).
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

* All schedules and exhibits to the Share Exchange Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

@ Management contract or compensatory plan or arrangement.

+ Portions of this exhibit have been omitted pursuant to Rule 601(b)(10)(iv) of Regulation S-K.

Item 16. FORM 10-K Summary

None.

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: December 12, 2019

EDESA BIOTECH, INC.

/s/ Pardeep Nijhawan

Pardeep Nijhawan, MD
Director, Chief Executive Officer and Corporate Secretary
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Pardeep Nijhawan and Kathi Niffenegger, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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.

Signature	Title	Date
/s/ Pardeep Nijhawan **Pardeep Nijhawan**	Director, Chief Executive Officer, and Corporate Secretary (Principal Executive Officer)	December 12, 2019
/s/ Kathi Niffenegger **Kathi Niffenegger**	Chief Financial Officer (Principal Financial and Accounting Officer)	December 12, 2019
/s/ Lorin Johnson **Lorin Johnson**	Director	December 12, 2019
/s/ Sean MacDonald **Sean MacDonald**	Chairman of the Board of Directors	December 12, 2019
/s/ Frank Oakes **Frank Oakes**	Director	December 12, 2019
/s/ Paul Pay **Paul Pay**	Director	December 12, 2019
/s/ Carlo Sistilli **Carlo Sistilli**	Director	December 12, 2019
/s/ Peter van der Velden **Peter van der Velden**	Director	December 12, 2019

EDESA BIOTECH, INC.
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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
Edesa Biotech, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Edesa Biotech, Inc. (the "Company") as of September 30, 2019 and December 31, 2018, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for the nine-month period ended September 30, 2019 and year ended December 31, 2018, 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, 2019 and December 31, 2018, and the consolidated results of its operations and cash flows for the nine-month period ended September 30, 2019 and year ended December 31, 2018, 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 audits 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/ MNP LLP
Chartered Professional Accountants
Licensed Public Accountants
Toronto, Canada
December 12, 2019

We have served as the Company's auditor since 2019.

Edesa Biotech, Inc.
Consolidated Balance Sheets

	September 30, 2019	December 31, 2018
Assets:		
Current assets:		
Cash and cash equivalents	**$ 5,030,583**	$ 3,367,098
Accounts and other receivable	**217,101**	7,339
Prepaid expenses and deposits	**397,022**	16,487
Total current assets	**5,644,706**	3,390,924
Property and equipment, net	**73,058**	7,386
Total assets	**$ 5,717,764**	$ 3,398,310
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable and accrued liabilities	**$ 461,634**	$ 183,820
Total current liabilities	**461,634**	183,820
Commitments *(Note 5)*		
Shareholders' equity:		
Capital shares		
Authorized unlimited common and preferred shares without par value		
Issued and outstanding:		
7,504,468 common shares (2018 - 3,239,902)	**12,005,051**	1,111,253
No Class A preferred shares (2018 - 1,007,143)	**-**	6,064,013
Additional paid-in capital	**327,768**	230,792
Accumulated other comprehensive loss	**(342,074)**	(429,973)
Accumulated deficit	**(6,734,615)**	(3,761,595)
Total shareholders' equity	**5,256,130**	3,214,490
Total liabilities and shareholders' equity	**$ 5,717,764**	$ 3,398,310

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

Edesa Biotech, Inc.
Consolidated Statements of Operations and Comprehensive Loss

	Nine-month Period Ended September 30, 2019	Year Ended December 31, 2018
Revenues:		
Product sales	**$ 410,870**	$ -
Expenses:		
Cost of sales	**101,286**	-
Research and development	**1,096,426**	1,075,491
General and administrative	**2,045,296**	543,155
	3,243,008	1,618,646
Loss from Operations	**(2,832,138)**	(1,618,646)
Other Income (Loss):		
Interest income	**56,840**	64,307
Foreign exchange gain (loss)	**(1,436)**	17,783
	55,404	82,090
Net Loss	**(2,776,734)**	(1,536,556)
Exchange differences on translation	**87,899**	(328,838)
Net Loss and Comprehensive Loss	**$ (2,688,835)**	$ (1,865,394)
Weighted average number of common shares	**5,036,331**	3,239,902
Loss per share - basic and diluted	**$ (0.55)**	$ (0.47)

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

Edesa Biotech, Inc.
Consolidated Statements of Cash Flows

	Nine-month Period Ended September 30, 2019	Year Ended December 31, 2018
Cash Flows From Operating Activities:		
Net loss	**$ (2,776,734)**	$ (1,536,556)
Adjustments for:		
Depreciation	**4,779**	1,655
Gain on disposition of property and equipment	**(2,172)**	-
Share-based compensation	**35,074**	81,344
Change in working capital items:		
Accounts and other receivable	**9,737**	4,029
Prepaid expenses and deposits	**(311,466)**	81,658
Inventory	**77,913**	-
Accounts payable and accrued liabilities	**(1,882,918)**	79,040
Net cash used in operating activities	**(4,845,787)**	(1,288,830)
Cash Flows From Investing Activities:		
Cash acquired from reverse acquisition	**6,389,322**	-
Purchases of property and equipment	**(8,095)**	(6,869)
Proceeds on sales of property and equipment	**36,741**	-
Net cash provided by (used in) investing activities	**6,417,968**	(6,869)
Effect of exchange rate changes on cash and cash equivalents	**91,304**	(337,325)
Net change in cash and cash equivalents	**1,663,485**	(1,633,024)
Cash and cash equivalents, beginning of period or year	**3,367,098**	5,000,122
Cash and cash equivalents, end of period or year	**$ 5,030,583**	$ 3,367,098
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Non-cash assets acquired and liabilities assumed in reverse acquisition-See Note 11	**(1,693,921)**	-
Preferred shares exchanged for common shares in reverse acquisition	**6,260,299**	-

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

Edesa Biotech, Inc.
Consolidated Statements of Changes in Shareholders' Equity

	Shares #	Common Shares	Class A Preferred Shares	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
Balance - December 31, 2017	**3,239,902**	**$ 1,111,253**	**$ 5,616,801**	**$ 149,448**	**$ (101,135)**	**$ (1,777,827)**	**$ 4,998,540**
Preferred return for Class A preferred shares	-	-	447,212	-	-	(447,212)	-
Share-based compensation	-	-	-	81,344	-	-	81,344
Net loss and comprehensive loss	-	-	-	-	(328,838)	(1,536,556)	(1,865,394)
Balance - December 31, 2018	**3,239,902**	**$ 1,111,253**	**$ 6,064,013**	**$ 230,792**	**$ (429,973)**	**$ (3,761,595)**	**$ 3,214,490**
Preferred return for Class A preferred shares	-	-	196,286	-	-	(196,286)	-
Effect of reverse acquisition	4,264,566	10,893,798	(6,260,299)	61,902	-	-	4,695,401
Share-based compensation	-	-	-	35,074	-	-	35,074
Net loss and comprehensive loss	-	-	-	-	87,899	(2,776,734)	(2,688,835)
Balance - September 30, 2019	**7,504,468**	**$ 12,005,051**	**$ -**	**$ 327,768**	**$ (342,074)**	**$ (6,734,615)**	**$ 5,256,130**

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

1. Nature of operations

Edesa Biotech, Inc. (the "Company" or "Edesa") is a biopharmaceutical company focused on acquiring, developing and commercializing clinical stage drugs for dermatological and gastrointestinal indications with clear unmet medical needs. The Company is organized under the laws of British Columbia, Canada and is headquartered in Markham, Ontario.

In June 2019, the Company changed its name from Stellar Biotechnologies, Inc. to Edesa Biotech, Inc. following a reverse acquisition with Edesa Biotech Research, Inc., formerly known as Edesa Biotech Inc., a company organized under the laws of the province of Ontario. At the closing of the transaction, which occurred on June 7, 2019, the Company acquired the entire issued share capital of Edesa Biotech Research, Inc., with Edesa Biotech Research, Inc., becoming a wholly-owned subsidiary of the Company. Also, on June 7, 2019, in connection with and following the completion of the reverse acquisition, the Company effected a 1- for-6 reverse split of its common shares.

The Company's common shares trade on The Nasdaq Capital Market in the United States under the symbol "EDSA".

Liquidity

The Company's operations have historically been funded through issuances of preferred shares that were converted into common shares, loans that were converted into common shares and government grants. For the nine-month period ended September 30, 2019 and year ended December 31, 2018, the Company reported net losses of $2.78 million and $1.54 million, respectively. At September 30, 2019, the Company had cash and cash equivalents of $5.03 million, working capital of $5.18 million, shareholders' equity of $5.26 million and an accumulated deficit of $6.73 million.

The Company plans to finance its operations for at least the next twelve months with cash and cash equivalents on hand. Management expects to continue incurring losses for the foreseeable future and will need to raise additional capital to pursue the Company's business plan beyond December 2020. Management has flexibility to adjust this timeline by making changes to planned expenditures related to, among other factors, the size and timing of clinical trial expenditures, staffing levels, and the acquisition or in-licensing of new product candidates. Management also expects to seek additional financing through debt and/or equity financings, including transactions with strategic companies that may include debt and/or equity arrangements.

2. Basis of preparation

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 and its wholly-owned subsidiaries, Edesa Biotech Research, Inc., an Ontario corporation, and Stellar Biotechnologies, Inc., a California corporation in the U.S. All intercompany balances and transactions have been eliminated upon consolidation.

Upon the completion of the reverse acquisition, Edesa Biotech Research, Inc. changed its fiscal year end from December 31 to September 30 to align with the Company's fiscal year end. The accompanying consolidated financial statements include the nine-month period ended September 30, 2019 and the year ended December 31, 2018.

3. Significant accounting policies

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period or year. Actual results could differ from those estimates. Areas where significant judgment is involved in making estimates are valuation of accounts and other receivable; valuation and useful lives of property and equipment; deferred income taxes; classification of Class A convertible preferred shares as liability or equity; the determination of fair value of share-based compensation; the determination of fair value of shares and replacement warrants for reverse acquisition; and forecasting future cash flows for assessing the going concern assumption.

Functional and reporting currencies

The consolidated financial statements of the Company are presented in U.S. dollars, unless otherwise stated. The functional currency of the Company and its wholly-owned subsidiary, Edesa Biotech Research, Inc., as determined by management, is Canadian dollars. The functional currency of the Company's wholly-owned subsidiary, Stellar Biotechnologies, Inc. is U.S. dollars.

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. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

Investments

Investments during the year 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. There were no investments outstanding at September 30, 2019 or December 31, 2018.

Accounts and other 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. Accounts and other receivable include Harmonized Sales Tax (HST) refunds receivable. As of September 30, 2019, all outstanding accounts and HST refunds receivable were deemed to be fully collectible, and therefore, no allowance for doubtful accounts was recorded.

Property and equipment

Property and equipment are recorded at historical cost less accumulated depreciation and any accumulated impairment losses. Depreciation is recorded to write off the cost of assets less their residual values over their useful lives, using the declining balance and straight-line methods. Assets not in use and on consignment for sale are carried at the expected net proceeds value. Maintenance and repair expenditures that do not improve or extend the life are expensed in the period incurred. Any gain or loss arising on the disposal or retirement of an item of property and equipment is recognized as the difference between the sales proceeds and the carrying amount of the asset. The estimated useful lives, residual values and depreciation methods are reviewed at the end of each year, with the effect of any changes in estimate accounted for on a prospective basis.

Impairment of long-lived assets

Long-lived assets are tested for impairment when indicators of impairment exist. When a significant change in the expected timing or amount of the future cash flows of the financial asset is identified, the carrying amount of the financial asset is reduced and the amount of the write-down is recognized as a loss. A previously recognized impairment loss may be reversed to the extent of the improvement, provided it is not greater than the amount that would have been reported at the date of the reversal had the impairment not been recognized previously, and the amount of the reversal is recognized in net income (loss).

Fair value measurement

The Company uses the fair value measurement framework for valuing financial assets and liabilities. See Note 8.

Revenue Recognition

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed under ASC Topic 606: (1) identify contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenues when (or as) the Company satisfies the performance obligation(s). Revenues consist of sales of product inventory obtained in the reverse acquisition completed in June 2019, which are recognized upon shipment when the customer obtains control of the product and the Company has no further performance obligations.

Research and development

Research and development expenses principally consist of (i) contract research organizations for clinical trial management services, (ii) contract manufacturing organizations for manufacturing the drug compound(s) for use in clinical trials and (iii) salaries of employees directly involved in research and development efforts. Research and development costs are expensed as incurred.

Share-based compensation

The Company measures the cost of equity-settled transactions by reference to the fair value of the equity instruments at the date at which they are granted since the fair value of the goods or services received by the Company cannot be reliably estimated.

The Company grants options to buy common shares of the Company to its directors, officers, employees and consultants, and grants other equity-based instruments such as warrants 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 provisions of the Company's share-based compensation plans do not require the Company to settle any options by transferring cash or other assets, and therefore the Company classifies the awards as equity. 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.

Translation of foreign currency transactions

The Company's reporting currency is the U.S. dollar. The financial statements of the parent Company and its wholly-owned Canadian subsidiary are measured using the Canadian dollar as the functional currency. Assets and liabilities of the Canadian operations have been translated at year-end exchange rates and related revenue and expenses have been translated at average exchange rates for the year. Accumulated gains and losses resulting from the translation of the financial statements of the Canadian operations are included as part of accumulated other comprehensive loss, a separate component of shareholders' equity.

For other transactions denominated in currencies other than the Company’s functional currency, the monetary assets and liabilities are translated at the year-end rates. Revenue and expenses are translated at rates of exchange prevailing on the transaction dates. Non-monetary balance sheet and related income statement accounts are remeasured into U.S. dollar using historical exchange rates. All of the exchange gains or losses resulting from these other transactions are recognized in the statements of operations and comprehensive loss.

Income taxes

Deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the tax bases of assets and liabilities and their financial statement reported amounts using enacted tax rates and laws in effect in the year in which the differences are expected to reverse. A valuation allowance is provided against deferred tax assets when it is determined to be more likely than not that the deferred tax asset will not be realized.

The Company assesses the likelihood of the financial statement effect of a tax position that should be recognized when it is more likely than not that the position will be sustained upon examination by a taxing authority based on the technical merits of the tax position, circumstances, and information available as of the reporting date. The Company is subject to examination by taxing authorities in Canada and the U.S. Management does not believe that there are any uncertain tax positions that would result in an asset or liability for taxes being recognized in the accompanying financial statements. The Company recognizes tax-related interest and penalties, if any, as a component of income tax expense.

The Company accounts for income taxes on a tax jurisdictional basis. The Company files income tax returns in Canada, the provinces of British Columbia and Ontario, the U.S. and the state of California.

Earnings (loss) per share

Basic earnings (loss) per share is calculated by dividing income (loss) 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 options and warrants would have an antidilutive effect on loss per share for the nine-month period ended September 30, 2019 and year ended December 31, 2018 and are therefore excluded from the computation of diluted loss per share.

Segmented Information

The Company's operations comprise a single reportable segment engaged in the research and development, manufacturing and commercialization of innovative pharmaceutical products. As the operations comprise a single reportable segment, amounts disclosed in the consolidated financial statements for loss, comprehensive loss, depreciation and total assets also represent segmented amounts.

Adoption of Recent Accounting Pronouncements

On October 1, 2018, the Company adopted Accounting Standards Codification (ASC) 606 *Revenue Recognition – Revenue from Contracts with Customers* using the modified retrospective method applied to those contracts which were not completed as of this date. Results for reporting periods beginning after October 1, 2018 are presented under ASC Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the historical accounting under ASC Topic 605. There was no impact to the historical consolidated financial statements resulting from the Company’s adoption of ASC Topic 606. There are no revenues in the accompanying consolidated financial statements prior to the completion of the reverse acquisition on June 7, 2019.

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed under ASC Topic 606: (1) identify contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenues when (or as) the Company satisfies the performance obligation(s). Revenues consist of sales of product inventory obtained in the reverse acquisition, which are recognized upon shipment when the customer obtains control of the product and the Company has no further performance obligations.

Future accounting pronouncements

In February 2016, the FASB issued new guidance, ASU No. 2016-02, Leases (Topic 842). The new standard establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. Additional qualitative and quantitative disclosures are also required by the new guidance. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. Topic 842 is effective for annual reporting periods beginning after December 15, 2018. Early adoption is permitted. The Company will adopt the new standard on October 1, 2019 and use the effective date as its date of initial application.

The new standard provides a number of optional practical expedients in transition. The Company expects to elect the 'package of practical expedients', which permits the Company not to reassess under the new standard prior conclusions about lease identification, lease classification and initial direct costs.

The Company expects that this standard will have a material effect on the consolidated financial statements. The Company has assessed that the most significant effects relate to (1) the recognition of new ROU assets and lease liabilities on the balance sheet for the Company's operating leases; and (2) providing significant new disclosures about the Company's leasing activities. The Company does not expect a significant change in leasing activities between now and adoption. Currently, the Company estimates that the discounted value of operating lease commitments at September 30, 2019 totaling approximately $305,000 will be recognized as a right-of-use asset and corresponding lease liability at the transition date, with no impact to opening retained earnings at that date.

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.

4. Property and equipment

Property and equipment, net consisted of the following:

	September 30, 2019	December 31, 2018
Computer equipment	**$ 42,910**	$ 4,828
Furniture and equipment	**7,932**	5,578
	50,842	10,406
Less: accumulated depreciation	**(29,194)**	(3,020)
Depreciable assets, net	**21,648**	7,386
Assets not in service	**51,410**	-
Total property and equipment, net	**$ 73,058**	$ 7,386

Assets not in service represent equipment acquired in the reverse acquisition and held for sale on consignment by a third party.

Depreciation expense amounted to approximately $4,800 and $1,700 for the nine-month period ended September 30, 2019 and year ended December 31, 2018, respectively.

5. Commitments

Operating leases

The Company leases facilities used for executive offices from a related company for a six-year term through December 2022, with options to renew for another two-year term.

The Company leases buildings and facilities used by its California subsidiary under three lease agreements. The Company intends to allow the leases to expire at the end of their current respective terms in June 2020, September 2020 and October 2020.

Aggregate future minimum lease payments at September 30, 2019 are as follows:

Year Ending	
September 30, 2020	$ 245,000
September 30, 2021	85,000
September 30, 2022	80,000
September 30, 2023	20,000
	$ 430,000

Total rent was approximately $126,000 and $79,000 for the nine-month period ended September 30, 2019 and year ended December 31, 2018, respectively.

Related party commitments

On August 14, 2002, through its California subsidiary, the Company entered into a patent royalty agreement with a director of the Company, whereby 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.

Other license and royalty commitments

In 2016, through its Ontario subsidiary, the Company entered into a license agreement with a third party to obtain exclusive rights to certain know-how, patents and data relating to a pharmaceutical product. The Company will use the exclusive rights to develop the product for therapeutic, prophylactic and diagnostic uses in topical dermal applications and anorectal applications. No intangible assets have been recognized under the license agreement with the third party as of September 30, 2019 and December 31, 2018. Under the license agreement, the Company is committed to payments of various amounts to the third party upon meeting certain milestones outlined in the license agreement, up to an aggregate amount of $18.6 million. Upon divestiture of substantially all of the assets of the Company, the Company shall pay the third party a percentage of the valuation of the licensed technology sold as determined by an external objective expert. The Company also has a commitment to pay the third party a royalty based on net sales of the product in countries where the Company, or an affiliate, directly commercializes the product and a percentage of sublicensing revenue received by the Company and its affiliates in the countries where it does not directly commercialize the product. No license or royalty payments were made to the third party during the nine-month period ended September 30, 2019 and year ended December 31, 2018.

In 2016, also through its Ontario subsidiary, the Company entered into an exclusive license agreement with another third party to obtain exclusive rights to certain know-how, patents and data relating to a pharmaceutical product. No intangible assets have been recognized under the license agreement as of September 30, 2019 and December 31, 2018. Under the license agreement, the Company is committed to payments of up to a total of $18.5 million upon meeting certain milestones outlined in the license agreement. The Company also has a commitment to pay a royalty based on net sales of the product in the countries where the Company directly commercializes the product and a percentage of sublicensing revenue received by the Company and its affiliates in the countries where it does not directly commercialize the product. No license or royalty payments were made to the third party during the nine-month period ended September 30, 2019 and year ended December 31, 2018.

Other commitments

The Company contracted research organizations who perform clinical trials for the Company's on-going clinical studies and other service providers. Aggregate future contractual payments to those service organizations at September 30, 2019 are as follows:

Year Ending	
September 30, 2020	$ 2,253,000
September 30, 2021	18,000
September 30, 2022	5,000
	$ 2,276,000

Retirement savings plan 401(k) contributions

Executive officers and employees of our California subsidiary are eligible to receive the Company's non-elective safe harbor employer contribution of 3% of eligible compensation under a 401(k) plan to provide retirement benefits. Employees are 100% vested in employer contributions and in any voluntary employee contributions. Contributions to the 401(k) plan were approximately $5,000 during the nine-month period ended September 30, 2019. There are no 401(k) contributions in the accompanying consolidated financial statements prior to the completion of the reverse acquisition on June 7, 2019.

6. Capital shares

Reverse Share Split

On June 7, 2019, the Company effected a reverse split of the Company's common shares at a ratio of 1-for-6. As a result of the reverse split, every six shares of the issued and outstanding common shares, without par value, consolidated into one newly issued outstanding common share, without par value, after fractional rounding. All shares and exercise prices are presented on a post-split basis in these consolidated financial statements.

Black-Scholes option valuation model

The Company uses the Black-Scholes option valuation model to determine the fair value of share-based compensation for share options and compensation warrants granted. 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 and share options.

Warrants

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

	Number of Warrants (#)	**Weighted Average Exercise Price**
Balance – December 31, 2018 and 2017	-	$ -
Effect of reverse acquisition	362,430	31.60
Black-Scholes value payout	(313,516)	33.01
Balance – September 30, 2019	48,914	$ 11.19

The fair value of warrants acquired in the reverse acquisition that subsequently had a Black-Scholes value payout totaled $1,187,124. The weighted average contractual life remaining on the outstanding warrants at September 30, 2019 is 49 months.

The following table summarizes information about the warrants outstanding at September 30, 2019:

Number of Warrants (#)	Exercise Prices	Expiry Dates
28,124	$ 15.90	May 2023
20,790	4.81	June 2024
48,914		

Share Options

The Company adopted an Equity Incentive Compensation Plan in 2019 (the 2019 Plan) administered by the Board of Directors, which amended and restated the 2017 Incentive Compensation Plan (the 2017 Plan). Options, restricted shares and restricted share units are eligible for grant under the 2019 Plan. The number of shares available for issuance under the 2019 Plan is 1,153,147, including shares available for the exercise of outstanding options under the 2017 Plan. Option holders under the Edesa Share Option Plan received substitute options upon completion of the reverse acquisition.

The Company's 2019 Plan allows options to be granted to directors, officers, employees and certain external consultants and advisers. Under the 2019 Plan, the option term is not to exceed 10 years. The term, vesting and exercise price of each option is determined by the independent members of the Board of Directors upon grant.

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

	Number of Options (#)	Weighted Average Exercise Price
Balance – December 31, 2017	289,203	$ 1.65
Granted	25,920	1.65
Balance – December 31, 2018	315,123	$ 1.65
Effect of reverse acquisition	7,787	124.80
Expired	(3,265)	125.75
Balance – September 30, 2019	319,645	$ 3.39

The weighted average contractual life remaining on the outstanding options at September 30, 2019 is 96 months.

The following table summarizes information about the options under the 2019 Plan outstanding and exercisable at September 30, 2019:

Number of Options (#)	Exercisable at September 30, 2019 (#)		Range of Exercise Prices	Expiry Dates
315,123	242,428	C$	2.16	Aug 2027-Dec 2028
333	333	C$	105.00-243.60	Dec 2019-May 2020
214	214	C$	638.40	Nov 2021
3,499	3,499	$	35.28-93.24	Sep 2023-Mar 2025
238	238	$	304.08	Dec 2022
238	238	$	768.60	Nov 2020
319,645	246,950			

The fair value of options granted during the year ended December 31, 2018 was estimated using the Black-Scholes Option Pricing Model using the following assumptions:

Risk free interest rate	1.98%
Expected life (years)	4
Expected share price volatility	79.46%
Expected dividend yield	0%

No share options were granted during the nine-month period ended September 30, 2019, however share options were assumed in the reverse acquisition.

The Company recorded approximately $35,000 and $81,000 of share-based compensation expenses for the nine-month period ended September 30, 2019 and year ended December 31, 2018 respectively.

As of September 30, 2019, the Company had approximately $30,000 of unrecognized share-based compensation expense, which is expected to be recognized over a period of 27 months.

Issued and outstanding common shares:

	Number of Common Shares (#)	Common Shares
Balance – December 31, 2018 and 2017	3,239,902	$ 1,111,253
Conversion of preferred shares upon reverse acquisition	3,376,112	6,260,299
Share consideration transferred upon reverse acquisition	888,454	4,633,499
Balance – September 30, 2019	7,504,468	$ 12,005,051

Issued and outstanding preferred shares:

	Class A Preferred Shares (#)	Class A Preferred Shares
Balance – December 31, 2017	1,007,143	$ 5,616,801
Preferred return on Class A preferred shares	-	447,212
Balance – December 31, 2018	1,007,143	$ 6,064,013
Preferred return on Class A preferred shares	-	196,286
Conversion upon reverse acquisition	(1,007,143)	(6,260,299)
Balance – September 30, 2019	-	$ -

The Class A preferred shares are voting and convertible into common shares at the option of the holder at any time. Upon the occurrence of a liquidation event, as defined in the resolutions of the shareholders dated August 28, 2017, the Class A preferred shares have a liquidation amount preference over the rights of holders of common shares or any class of shares ranking junior to Class A preferred shares. The Class A preferred shares also contain an 8% preferred return that accrues daily and compounds annually and is payable in shares upon conversion.

The Company has evaluated the convertible preferred shares and the embedded conversion option. The embedded conversion option does not meet the criteria for bifurcation and has therefore been classified to equity.

Following the completion of the reverse acquisition on June 7, 2019, all the outstanding Class A preferred shares and accumulated accrued preferred return were fully converted to 3,376,112 common shares based on the fair market value upon conversion.

7. Income Tax

The reconciliation of the combined Canadian federal and provincial statutory income tax rate to the approximate effective tax rate is as follows:

	Nine-month Period Ended September 30, 2019	Year Ended December 31, 2018
Net loss before recovery of income taxes	**$ (2,776,734)**	$ (1,536,556)
Canadian federal and provincial statutory income tax rate	**26.5%**	26.5%
Expected income tax recovery	**$ (736,000)**	$ (407,000)
Permanent differences	**11,000**	41,000
Effect of foreign currency and foreign tax rate differences	**(60,000)**	-
Change in valuation allowance	**785,000**	366,000
Income tax (recovery) expense	**$ -**	$ -

Unrecognized deferred tax assets

Deferred taxes are provided as a result of temporary differences that arise due to the difference between the income tax values and the carrying amount of assets and liabilities. Approximate deferred tax assets are as follows:

	September 30, 2019	December 31, 2018
Non-capital losses carried forward - Canada	**$ 3,592,000**	$ 575,000
Non-capital losses carried forward - U.S.	**1,587,000**	-
Share issuance and financing costs	**517,000**	26,000
Research and development tax credits	**626,000**	121,000
Other temporary differences	**28,000**	15,000
Total deferred tax assets	**$ 6,350,000**	$ 737,000
Valuation allowance	**(6,350,000)**	(737,000)
Net deferred taxes	**$ -**	$ -

Realization of the deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. It is more likely than not that a tax benefit will not be realized. Accordingly, net deferred tax assets have been fully offset by a valuation allowance.

Non-capital losses, capital losses, and research and development credits generated by Stellar Biotechnologies, Inc. prior to changes in share ownership that occurred as a result of the reverse acquisition are substantially limited. It is unlikely that tax losses totaling $25.5 million and credits totaling $0.6 million will be utilized to offset potential future taxable income before expiration and they are excluded from deferred tax assets above.

The approximate Canadian non-capital losses carried forward at September 30, 2019 expire as follows:

2028	C$ 21,000
2029	56,000
2030	346,000
2031	688,000
2032	860,000
2033	685,000
2034	780,000
2035	1,369,000
2036	1,705,000
2037	1,909,000
2038	3,243,000
2039	6,058,000
Total	C$ 17,720,000

Share issuance and financing costs will be fully amortized in 2024.

The U.S. non-capital losses carried forward at September 30, 2019 totalled approximately $7,536,000, which do not expire for federal taxes and include $70,000 that expires in 2039 for state taxes.

8. Financial instruments

(a) Fair values

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 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. Observable inputs are inputs that reflect assumptions market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

There are three levels of inputs that may be used to measure fair value:

- Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets and liabilities in markets that are not active.
- Level 3 - Unobservable inputs for the asset or liability that are supported by little or no market activity.

The carrying value of certain financial instruments such as cash and cash equivalents, accounts and other receivable, accounts payable and accrued liabilities 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 using level 1 inputs.

(b) Interest rate and credit risk

Interest rate risk is the risk that the value of a financial instrument might be adversely affected by a change in interest rates. The Company does not believe that the results of operations or cash flows would be affected to any significant degree by a significant change in market interest rates, relative to interest rates on cash and cash equivalents due to the short-term nature of these balances.

The Company is also exposed to credit risk at period end from the carrying value of its cash and cash equivalents and accounts and other receivable. The Company manages this risk by maintaining bank accounts with Canadian Chartered Banks, U.S. banks believed to be credit worthy and U.S. Treasury Bills. The Company’s cash is not subject to any external restrictions. The Company assesses the collectability of accounts receivable through a review of the current aging, as well as an analysis of historical collection rates, general economic conditions and credit status of customers. Credit risk for HST refunds receivable is not considered significant since amounts are due from the Canada Revenue Agency.

(c) Foreign exchange risk

The Company and its subsidiary have balances in Canadian dollars that give rise to exposure to foreign exchange (“FX”) risk relating to the impact of translating certain non-U.S. dollar balance sheet accounts as these statements are presented in U.S. dollars. A strengthening U.S. dollar will lead to a FX loss while a weakening U.S. dollar will lead to a FX gain. The Company has not entered into any agreements or purchased any instruments to hedge possible currency risks. At September 30, 2019, the Company and its Canadian subsidiary had assets of C$2.4 million and the U.S. dollar was equal to 1.324 Canadian dollars. Based on the exposure at September 30, 2019, a 10% annual change in the Canadian/U.S. exchange rate would impact the Company’s loss and other comprehensive loss by approximately $182,000.

(d) Liquidity risk

Liquidity risk is the risk that the Company will encounter difficulty raising liquid funds to meet commitments as they fall due. In meeting its liquidity requirements, the Company closely monitors its forecasted cash requirements with expected cash drawdown.

9. Related party transactions

During the periods presented, the Company incurred the following related party transactions:

- During the nine-month period ended September 30, 2019 and year ended December 31, 2018, the Company incurred rent expense of approximately $58,000 and $79,000 from a related company, respectively. These transactions are in the normal course of operations and are measured at the exchange amount, which is the amount of consideration established and agreed to by both parties. Included in accounts payable and accrued liabilities at December 31, 2018 was rent payable of approximately $14,000. No rent was payable at September 30, 2019.

- During the nine-month period ended September 30, 2019, the Company incurred royalty expenses of approximately $20,000 to a director related to products sales by the California subsidiary. Included in accounts payable and accrued liabilities at September 30, 2019 was royalty payable of approximately $23,000 to that director, including for products sales by the California subsidiary prior to the completion of the reverse acquisition.

10. Comparative figures

Certain reclassifications have been made to the prior year's financial statements to enhance comparability with the current year's financial statements. In the accompanying year ended December 31, 2018 Statement of Operations and Comprehensive Loss, depreciation of $1,655 was reclassified to general and administrative expenses and share based compensation expense of $27,139 and $54,205 was reclassified to research and development expenses and general and administrative expenses, respectively.

Unaudited summary comparative financial information for the transition period is as follows:

	(Unaudited) Nine Months Ended September 30, 2018
Total Expenses	$ (1,212,905)
Other Income	41,198
Net Loss	(1,171,707)
Exchange differences on translation	(346,598)
Net Loss and Comprehensive Loss	$ (1,518,305)
Weighted average number of common shares	3,239,902
Loss per share - basic and diluted	$ (0.36)

11. Business Combination

On June 7, 2019, the Edesa Biotech Research, Inc., formerly known as Edesa Biotech Inc., a company organized under the laws of the province of Ontario, Canada ("Edesa Research"), completed its business combination with Stellar Biotechnologies, Inc. a company organized under the laws of British Columbia, Canada ("Stellar"), in accordance with the terms of the Share Exchange Agreement, dated March 7, 2019 (the "Exchange Agreement"), by and among Stellar, Edesa Research and the shareholders of Edesa Research (the "Edesa Research Shareholders"). At the closing of the transaction (the "Closing"), Stellar acquired the entire issued share capital of Edesa Research, with Edesa Research becoming a wholly-owned subsidiary of Stellar (the "Exchange"). The Edesa Research Shareholders exchanged their shares for 88% of the outstanding shares of Stellar on a fully diluted basis. Edesa Research is considered the accounting acquirer of Stellar. Upon closing, Stellar changed its name to Edesa Biotech, Inc. Edesa Research entered into the Exchange primarily to provide greater liquidity to its shareholders, broaden its investment base, increase its profile, and facilitate the process of raising capital as the Company contemplates pursuing new growth opportunities including acquisition of new clinical assets. For the period of June 7, 2019 to September 30, 2019, Stellar, the acquiree for accounting purposes, recorded revenues of $410,870 and a net loss of $452,416. These operating results are included within the accompanying consolidated statements of operations and comprehensive loss.

The fair value of consideration transferred in the reverse acquisition is calculated as follows:

Fair value of 888,454 share consideration transferred, net of liquidity discount	$ 4,633,499
Excess fair value of replacement warrants	61,902
Total acquisition date fair value of consideration transferred	$ 4,695,401

The fair value of the replacement warrants was determined using Black-Scholes valuation model based on exercise price of C$6.45, expected life of 5 years, risk free rate of 1.34% and volatility of 130%.

The major classes of assets acquired and liabilities assumed in the reverse acquisition are as follows:

Cash and cash equivalents	$ 6,389,322
Other current assets	418,837
Noncurrent assets	42,045
Fair value of warrants payable	(1,187,124)
Other current liabilities	(967,679)
Net assets of Stellar	$ 4,695,401

The following are the unaudited supplemental pro forma results of operations for the nine-month period ended September 30, 2019 and year ended December 31, 2018. These pro forma results are reported as if the reverse acquisition had been completed on January 1, 2018 and include estimates and assumptions that management believes are reasonable. Since these pro forma results include all one-time reverse acquisition costs and do not include any anticipated cost savings or other effects of the planned integration of the entities, they are not necessarily indicative of the actual results that would have occurred if the combined business had been in effect beginning January 1, 2018.

	(Unaudited) Supplemental Pro Forma Combined Financial Information	
	Nine-month Period Ended September 30, 2019	**Year Ended December 31, 2018**
Total Revenues	**$ 930,565**	$ 244,395
Net Loss	**$ (8,126,749)**	$ (6,580,463)
Weighted average number of common shares	**7,504,468**	7,504,468
Loss per share - basic and diluted	**$ (1.08)**	$ (0.88)

BRITISH COLUMBIA

Number: C0867178

CERTIFICATE
OF
CHANGE OF NAME

BUSINESS CORPORATIONS ACT

I Hereby Certify that STELLAR BIOTECHNOLOGIES, INC. changed its name to EDESA BIOTECH, INC. on June 7, 2019 at 08:08 AM Pacific Time.

ELECTRONIC CERTIFICATE

Issued under my hand at Victoria, British Columbia
On June 7, 2019

CAROL PREST
Registrar of Companies
Province of British Columbia
Canada

EDESA BIOTECH, INC.

CODE OF ETHICS AND BUSINESS CONDUCT
As Amended and Restated by the Board on June 7, 2019

1. Introduction.

The Board of Directors (the "Board") of Edesa Biotech, Inc. (together with its subsidiaries, the "Company") has adopted this Code of Ethics and Business Conduct (the "Code"), which is applicable to all directors, officers and employees of the Company. The purpose of this Code is to:

(a) promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;

(b) promote the full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the U.S. Securities and Exchange Commission (the "SEC") and in all other public communications made by the Company;

(c) promote compliance with applicable governmental laws, rules and regulations of both the United States and Canada;

(d) promote fair dealing practices;

(e) deter wrongdoing;

(f) require prompt internal reporting of violations of the Code to an appropriate person or persons identified in this Code; and

(g) require accountability for adherence to this Code.

All directors, officers and employees are required to be familiar with the Code, comply with its provisions and report any suspected violations as described below in Section 13, "Reporting and Enforcement."

This Code may be amended only by unanimous resolution of the Board.

2. Honest, Ethical and Fair Conduct.

The Company's policy is to promote high standards of integrity by conducting its affairs honestly and ethically.

Each director, officer and employee of the Company must act with integrity and observe the highest ethical standards of business conduct in his or her dealings with the Company's customers, suppliers, partners, service providers, competitors, employees and anyone else with whom he or she has contact in the course of performing his or her job.

Each director, officer and employee must:

(a) Act with integrity, including being honest and candid while still maintaining the confidentiality of information relating to the affairs of the Company.

(b) Safeguard the confidentiality of information relating to the affairs of the Company acquired in the course of their service as directors, officers and employees, by keeping it secure, limiting access to those who have a need to know in order to do their job, and avoiding discussion of confidential information in public areas. The obligation to preserve the Company's confidential information is ongoing, even after service to the Company ends.

(c) Observe all applicable governmental laws, rules and regulations.

(d) Comply with the requirements of applicable accounting and auditing standards, as well as Company policies, in the maintenance of a high standard of accuracy and completeness in the Company's financial records and other business-related information and data.

(e) Adhere to a high standard of business ethics and not seek competitive advantage through unlawful or unethical business practices.

(f) Deal fairly with the Company's customers, suppliers, competitors and employees.

(g) Refrain from taking advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair-dealing practice.

(h) Protect the assets of the Company and ensure their proper use.

(i) Refrain from taking for themselves personally opportunities that are discovered through the use of corporate assets or using corporate assets, confidential information or position for general personal gain outside the scope of employment with the Company.

3. Conflicts of Interest.

3.1 A conflict of interest occurs when an individual's private interest (or the interest of a member of his or her family) interferes, or even appears to interfere, with the interests of the Company as a whole. A conflict of interest can arise when an employee, officer or director (or a member of his or her family) takes actions or has interests that may make it difficult to perform his or her work for the Company objectively and effectively. Conflicts of interest also arise when an employee, officer or director (or a member of his or her family) receives improper personal benefits as a result of his or her position in the Company.

Examples of conflict of interest situations include, but are not limited to, the following:

- any significant ownership interest in any supplier or customer;
- any consulting or employment relationship with any customer, supplier or competitor;
- any outside business activity that detracts from an individual's ability to devote appropriate time and attention to his or her responsibilities with the Company;
- the receipt of any money, non-nominal gifts or excessive entertainment from any company with which the Company has current or prospective business dealings;

- being in the position of supervising, reviewing or having any influence on the job evaluation, pay or benefit of any close relative;
- selling anything to the Company or buying anything from the Company, except on the same terms and conditions as comparable officers or directors are permitted to so purchase or sell; and
- any other circumstance, event, relationship or situation in which the personal interest of a person subject to this Code interferes – or even appears to interfere – with the interests of the Company as a whole.

3.2 Loans by the Company to, or guarantees by the Company of obligations of, employees or their family members are of special concern and could constitute improper personal benefits to the recipients of such loans or guarantees, depending on the facts and circumstances. Loans by the Company to, or guarantees by the Company of obligations of, any director or executive officer are expressly prohibited.

3.3 Whether or not a conflict of interest exists or will exist can be unclear. Conflicts of interest should be avoided unless specifically authorized as described in this Section. Persons other than directors and executive officers who have questions about a potential conflict of interest or who become aware of an actual or potential conflict should discuss the matter with, and seek a determination and prior authorization or approval from, their supervisor or the Company's Chief Financial Officer. A supervisor may not authorize or approve conflict of interest matters or make determinations as to whether a problematic conflict of interest exists without first providing the Chief Financial Officer with a written description of the activity and seeking the Chief Financial Officer's written approval. If the supervisor is himself involved in the potential or actual conflict, the matter should instead be discussed directly with the Chief Financial Officer. Directors and executive officers must seek determinations and prior authorizations or approvals of potential conflicts of interest exclusively from the Audit Committee of the Board (the "Audit Committee").

4. Compliance.

4.1 Employees, officers and directors should comply, both in letter and spirit, with all applicable laws, rules and regulations in the cities, states and countries in which the Company operates.

4.2 Although not all employees, officers and directors are expected to know the details of all applicable laws, rules and regulations, it is important to know enough to determine when to seek advice from appropriate personnel. Questions about compliance should be addressed to the Chief Financial Officer.

5. Disclosure.

5.1 The Company strives to ensure that the contents of and the disclosures in the reports and documents that the Company files with the SEC and all other public communications shall be full, fair, accurate, timely and understandable in accordance with applicable disclosure standards, including standards of materiality, where appropriate. Each person must:

(a) not knowingly misrepresent, or cause others to misrepresent, facts about the Company to others, whether within or outside the Company, including to the Company's independent auditors, governmental regulators, self-regulating organizations and other governmental officials, as appropriate; and

(b) in relation to his or her area of responsibility, properly review and critically analyze proposed disclosure for accuracy and completeness.

5.2 Each director, officer and employee who contributes in any way to the preparation or verification of the Company's financial statements and other financial information must ensure that the Company's books, records and accounts are accurately maintained. Each director, officer and employee must cooperate fully with the Company's accounting and internal audit departments, as well as the Company's independent public accountants and counsel.

5.3 Each director, officer and employee who is involved in the Company's disclosure process must:

(a) be familiar with and comply with the Company's disclosure controls and procedures and its internal control over financial reporting; and

(b) take all necessary steps to ensure that all filings with the SEC and all other public communications about the financial and business condition of the Company provide full, fair, accurate, timely and understandable disclosure.

5.4 Each person must promptly bring to the attention of the Chairman of the Audit Committee any information he or she may have concerning (a) significant deficiencies in the design or operation of internal and/or disclosure controls which could adversely affect the Company's ability to record, process, summarize and report financial data, or (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's financial reporting, disclosures or internal controls.

6. Confidentiality.

Directors, officers and employees should maintain the confidentiality of information entrusted to them by the Company or by its customers, suppliers or partners, except when disclosure is expressly authorized or legally required. Confidential information includes all non-public information (regardless of its source) (i) that might be of use to the Company's competitors or harmful to the Company or its customers, suppliers or partners if disclosed, or (ii) that might be material to an investor in making an investment decision with respect to the Company's securities, or securities of any of the Company's customers, suppliers, or partners, as applicable.

7. Fair Dealing.

Each director, officer and employee must deal fairly with the Company's customers, suppliers, partners, service providers, competitors, employees and anyone else with whom he or she has contact in the course of performing his or her job. No director, officer or employee may take unfair advantage of anyone through manipulation, concealment, abuse or privileged information, misrepresentation of facts or any other unfair dealing practice.

8. Competitors.

Directors, officers and employees are not permitted to discuss prices or make formal or informal arrangements with any competitor regarding prices, discounts, business terms, or market segments and channels in which the Company competes where the purpose or result of such discussion or agreement would be inconsistent with applicable antitrust laws.

9. Insider Trading.

Directors, officers, and employees who have access to confidential information relating to the Company are not permitted to use or share that information for stock trading purposes or for any other purpose except the conduct of the Company's business. All non-public information about the Company should be considered confidential information. To use non-public information for personal financial benefit or to "tip" others who might make an investment decision on the basis of this information is not only unethical and against Company policy, it is also illegal.

Insider trading rules are strictly enforced, even in instances when the financial transactions seem small. The Company's Insider Trading Policy governs trading in securities of the Company, and all directors, officers and employees are expected to review and follow the Policy. Under this Policy, directors, officers, and employees are subject to certain trading blackout periods which will normally be instituted by the Chief Executive Officer or Chief Financial Officer. If a question arises regarding the Company's Insider Trading Policy, the director, officer, or employee should consult with the Company's Chief Financial Officer who serves as the Compliance Officer for purposes of the policy

10. Payments to Government Personnel.

Many federal, state and foreign jurisdictions have certain rules governing payments to government personnel.

For example, the U.S. Foreign Corrupt Practices Act (the "Act") prohibits giving anything of value, directly or indirectly, to officials of foreign governments or foreign political candidates in order to obtain or retain business. Under the Act, it is strictly prohibited to make illegal payments to government officials of any country.

Further, the U.S. government has a number of laws and regulations regarding business gratuities that may be accepted by U.S. government personnel. The promise, offer, or delivery to an official or employee of the U.S. government of a gift, favor, or other gratuity in violation of these rules would not only violate Company policy but could also be a criminal offense.

11. Discrimination and Harassment.

The Company provides equal opportunities in all aspects of employment and does not tolerate any illegal discrimination or harassment of any kind.

12. Health and Safety.

The Company desires to provide a clean, safe and healthy work environment to all employees. Each person to whom this Code applies is responsible for maintaining a safe and healthy workplace by following safety and health rules and practices and reporting accidents, injuries and unsafe conditions, procedures, or behaviors.

13. Reporting and Enforcement.

13.1 The Board and the Audit Committee are responsible for applying this Code to specific situations in which questions are presented to either the Board or Audit Committee, and have the authority to interpret this Code in any particular situation. Any person who becomes aware of any existing or potential breach of this Code is required to notify the Chairman of the Board and the Chairman of the Audit Committee promptly. Failure to do so is itself a breach of this Code.

Specifically, each person must:

(a) notify the Chairman of the Board and the Chairman of the Audit Committee promptly of any existing or potential violation of this Code; and

(b) not retaliate against any other person for reports of potential violations that are made in good faith.

All directors, officers and employees are expected to cooperate in any internal investigation of misconduct.

13.2 The Company will follow the following procedures in investigating and enforcing this Code and in reporting on the Code:

(a) The Audit Committee will promptly take all appropriate action to investigate any violations reported to it.

(b) If, after investigating a report of an alleged prohibited action by a director, executive officer, or employee, the Audit Committee determines that a violation of this Code has occurred, it will report such determination to the Board.

(c) Upon being notified that a violation of this Code has occurred, the Board (by majority decision of members disinterested in the matter) will take or authorize such disciplinary or preventive action as it deems appropriate, after consultation with the Audit Committee and/or legal counsel, including, but not limited to, reassignment, demotion, dismissal and, in the event of criminal conduct or other serious violations of the law, notification of appropriate governmental authorities.

13.3 No person following the above procedure shall, as a result of following such procedure, be subject by the Company or any officer or employee thereof to discharge, demotion suspension, threat, harassment or, in any manner, discrimination against such person in terms and conditions of employment.

14. Waivers and Amendments.

Any waiver or an implicit waiver from a provision of this Code for a director, the Company's principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions, or any amendment to this Code shall be disclosed as required by the SEC and Nasdaq rules.

A "waiver" means the approval by the entire Board of a material departure from a provision of the Code. An "implicit waiver" means the Company's failure to take action within a reasonable period of time regarding a material departure from a provision of the Code that has been made known to a director or an executive officer of the Company. An "amendment" means any amendment to this Code other than minor technical, administrative or other non-substantive amendments hereto.

All persons should note that it is not the Company's intention to grant or to permit waivers from the requirements of this Code. The Company expects full compliance with this Code.

15. Other Policies and Procedures.

Any other policy or procedure set out by the Company in writing or made generally known to employees, officers or directors of the Company prior to the date hereof or hereafter are separate requirements and remain in full force and effect.

16. Inquiries.

All inquiries and questions in relation to this Code or its applicability to particular people or situations should be addressed to the Company's Chief Financial officer.

17. Annual Certification.

Directors, officers and employees are required to annually sign a confirmation that they have read and will comply with this Code.

EDESA BIOTECH, INC.

CODE OF ETHICS AND BUSINESS CONDUCT

ACKNOWLEDGEMENT OF RECEIPT AND REVIEW

I acknowledge that I have received and read a copy of the Code of Ethics and Business Conduct (the "Code") of **Edesa Biotech, Inc.** I understand the contents of the Code and I agree to comply with the policies and procedures set out in the Code.

I understand that I should approach the Chief Financial Officer if I have any questions about the Code generally or any questions about reporting a suspected conflict of interest or other violation of the Code.

By signing this acknowledgement I am indicating that I have read and will abide by the Code of **Edesa Biotech, Inc.**

DATED this _____day of _____,20 _____.

_____
Signature

_____
Name (Please Print)

Exhibit 21

EDESA BIOTECH, INC. AND SUBSIDIARIES

Entity	State of Incorporation/ Organization
Edesa Biotech Research, Inc.	Ontario, Canada
Stellar Biotechnologies, Inc.	California, USA

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-217480) and S-3 (No. 333-233567) of Edesa Biotech, Inc. of our report dated December 12, 2019, relating to the consolidated financial statements of Edesa Biotech, Inc. for the nine-month period ended September 30, 2019 and the year ended December 31, 2018, which report appears in this Annual Report on Form 10-K for the nine-month period ended September 30, 2019 listed in the accompanying index.

/s/ MNP LLP
Chartered Professional Accountants
Licensed Public Accountants
Toronto, Canada
December 12, 2019

Exhibit 31.1

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

I, Pardeep Nijhawan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Edesa Biotech, 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: December 12, 2019

By: /s/ Pardeep Nijhawan

Pardeep Nijhawan
Director, Chief Executive Officer and Corporate Secretary
(Principal Executive Officer)

Exhibit 31.2

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 Edesa Biotech, 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: December 12, 2019

By: /s/ Kathi Niffenegger

Kathi Niffenegger
Chief Financial Officer
(Principal Financial Officer)

Exhibit 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

In connection with the Annual Report of Edesa Biotech, Inc. (the Company) on Form 10-K for the nine-month period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Pardeep Nijhawan, 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: December 12, 2019

By: /s/ Pardeep Nijhawan
Pardeep Nijhawan
Director, Chief Executive Officer and Corporate Secretary
(Principal Executive Officer)

Exhibit 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

In connection with the Annual Report of Edesa Biotech, Inc. (the Company) on Form 10-K for the nine-month period ended September 30, 2019 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: December 12, 2019

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