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

FORM 10-K

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

For the fiscal year ended September 30, 2021

OR

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

For the transition period from _____ to _____

Commission file number: 001-37619

EDESA BIOTECH, INC.

(Exact name of registrant as specified in its charter)

British Columbia, Canada	**N/A**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
100 Spy Court, Markham, ON, Canada L3R 5H6	**(289) 800-9600**
(Address of principal executive offices and zip code)	(Registrant's telephone number, including area code)

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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 31, 2021, 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 $42,402,749, which was calculated based on 13,246,559 common shares outstanding as of that date, of which 7,852,361 common shares were held by non-affiliates at the closing price of the registrant's common shares on The Nasdaq Capital Market on such date.

As of December 27, 2021, the registrant had 13,518,799 common shares issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

EDESA BIOTECH, INC.
ANNUAL REPORT ON FORM 10-K
Year Ended September 30, 2021

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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, including those caused by COVID-19 and its variants.

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.

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PART I

Item 1. BUSINESS.

Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing clinical-stage drugs for inflammatory and immune-related diseases with clear unmet medical needs. Our two lead product candidates, EB05 and EB01, are in later stage clinical studies.

EB05 is a monoclonal antibody therapy that we are developing as a treatment for Acute Respiratory Distress Syndrome (ARDS) in COVID-19 patients. ARDS is a life-threatening form of respiratory failure, and the leading cause of death among COVID-19 patients. ARDS can be also caused by bacterial pneumonia, sepsis, chest injury and other causes. Specifically, EB05 inhibits toll-like receptor 4 (TLR4), a key immune signaling protein and an important mediator of inflammation that has been shown to be activated by SARS-COV2 as well as other respiratory infections such as influenza. In multiple third-party studies, high serum levels of alarmins (damage signaling molecules) that bind to and activate TLR4 are associated with poor outcomes and disease progression in COVID-19 patients. Since EB05 has demonstrated the ability to block signaling irrespective of the presence or concentration of the various molecules that frequently bind with TLR4, we believe that EB05 could ameliorate TLR4-mediated inflammation cascades in ARDS patients, thereby reducing lung injury, ventilation rates and mortality. In September 2021, an independent data and safety monitoring board pre-emptively unblinded the Phase 2 part of a Phase 2/3 study of EB05 in hospitalized COVID-19 patients and identified "a clinically important" mortality benefit. The monitoring board further recommended continuation of the study into a Phase 3 confirmatory trial. The Phase 2 part of the study was funded primarily by a $11 million (C$14 million) reimbursement grant that was awarded by the Canadian government's Strategic Innovation Fund (SIF) following a multi-disciplinary technical review of our drug technology and plans.

In addition to EB05, we are developing an sPLA2 inhibitor, designated as EB01, as a topical treatment for 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. EB01 is currently being evaluated in a Phase 2b clinical study.

In addition to our current clinical programs, we intend to expand the utility of our technologies and clinical-stage assets across other indications.

Competitive Strengths

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

- *Validated technology and drug development capabilities*. We believe that the strength of our technologies has been validated by our $11 million competitive grant award; favorable clinical data; and our multiple arrangements with third parties to develop and commercialize their clinical- stage drug candidates.

- *Novel pipeline addressing large underserved markets.* Our product candidates include novel clinical-stage compounds and antibodies 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 sPLA2 technology will be an appealing alternative for managing the symptoms of ACD and hemorrhoids disease (HD). These diseases impact millions of people, 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 leadership*. Our leadership team possesses core capabilities in dermatology, infectious diseases, gastrointestinal medicine, drug development and commercialization, chemistry, manufacturing and controls, 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 treatments for inflammatory and immune-related diseases.

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Our Business Strategy

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

- *Rapidly develop EB05 as a novel therapy for ARDS*. We are applying our expertise in immune modulation and inflammation therapies, and clinical trial management, to rapidly develop EB05 as a potential treatment for ARDS. In September 2021, an independent data and safety monitoring board pre-emptively unblinded the Phase 2 part of the Phase 2/3 study of EB05 and identified "a clinically important" mortality benefit for EB05 treated patients. Based on these positive preliminary results, we are evaluating opportunities to apply, as applicable, for expedited regulatory review programs, which could potentially lead to accelerated clinical development and commercialization timelines.

- *Establish EB01 as the leading treatment for chronic ACD*. Our goal is to obtain regulatory approval for EB01 and commercialize EB01 for use in the treatment of ACD. Based on previous early-stage clinical trial results in which patients treated with EB01 experienced statistically significant improvements of their symptoms with minimal side effects, we initiated a confirmatory Phase 2b clinical study evaluating EB01 in chronic ACD patients. In June 2021, an independent data and safety monitoring board (DSMB) completed an interim review of blinded data from the first cohort of our study and determined that EB01 met key interim study parameters. Enrollment in the final part of the study is ongoing.

- *Maximize our current portfolio opportunity by expanding use across multiple indications.* We aim to identify clinical-stage assets that have the potential to treat multiple diseases. Our assets are designed to modulate pathways that are implicated across a number of immune and inflammatory/allergic conditions. For example, we are planning a proof-of-concept clinical study of our sPLA2 technology as a potential treatment for patients with HD. We also believe that our monoclonal antibody candidates have potential utility in additional indications, including chronic conditions.

- *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 biopharmaceutical companies, and, from time to time, we plan 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, 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.

- *Maximize the commercial potential of our product candidates via direct marketing or strategic arrangements*. If our product candidates are successfully developed and approved, we plan to either build commercial infrastructure capable of directly marketing the products, or alternatively, outsource the sales and marketing of our products. We also plan to evaluate strategic licensing or partnering arrangements with pharmaceutical companies for the further development or commercialization of our drugs, where applicable, such as in areas where a partner may contribute additional resources, infrastructure and expertise.

Acute Respiratory Distress Syndrome (ARDS)

Acute respiratory distress syndrome (ARDS) is a life-threatening form of respiratory failure, and the leading cause of death among COVID-19 patients. In addition to virus-induced pneumonia, ARDS can be caused by bacterial pneumonia, sepsis, chest injury and other causes.

Specifically, ARDS involves an exaggerated immune response leading to inflammation and injury to the lungs that deprives the body of oxygen. ARDS is classified as mild, moderate and severe by using an arterial partial pressure of oxygen (PaO2) to fraction of inspired oxygen (FIO2) threshold of 300, 200, and 100 mm Hg, respectively. For moderate to severe cases, there are currently few meaningful treatments, other than supplemental oxygen and mechanical ventilation, and patients suffer high mortality rates. Prior to COVID-19, ARDS accounted for 10% of intensive care unit admissions, representing more than 3 million patients globally each year. ARDS has historically affected approximately 200,000 patients each year in the United States, resulting in nearly 75,000 deaths annually, according to medical literature.

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Countering the exaggerated innate immune response in ARDS has been a key area of interest among researchers. One of the most studied targets has been Toll-like receptor 4 (TLR4) - a key component of the innate immune system and an important mediator of inflammation. Since TLR4 detects molecules found in pathogens and also binds to endogenous molecules produced as a result of injury, it is a key receptor on which both infectious and noninfectious stimuli converge to induce a proinflammatory response. Specifically, TLR4 signaling activates leukocytes to secrete proinflammatory cytokines (i.e., CXCL10, IL-6, IFN-b, IL-1b, TNF-a), which under certain circumstances can result in a “cytokine storm” - a severe immune reaction in which the body releases too many cytokines into the blood too quickly.

Such upregulation of TLR4 and its associated cytokines has been observed in SARS-CoV-2 as well as other respiratory infections such as influenza. In multiple third-party studies, high serum levels of alarmins, such as calprotectin (S100A8/A9) and HMGB1(high mobility group protein B1), that bind to

and activate TLR4 are associated with poor outcomes and disease progression in COVID-19 patients. In addition, TLR4 inhibition (antagonism) prevents cytokine production at a very early stage and has been shown to have a protective effect. For example, in preclinical studies in mice, it was demonstrated that administration of a TLR4 antagonist blocked influenza-induced lethality and ameliorated virus-induced acute lung injury. Antagonism of TLR4 has also been shown to modulate the secretion of proinflammatory cytokines (IL-6, CRP, IFNb, TNF-a, CXCL-10, IL8 and MIP-1b). Based on this data as well as previous clinical results, we believe that the modulation of the TLR4 provides a compelling opportunity to treat ARDS.

EB05

Overview and Status

EB05 is a potentially first-in-class monoclonal antibody (mAb) that has been engineered to alter inflammatory signaling by binding to and blocking the activation of TLR4. Specifically, EB05 dampens TLR4 signaling by blocking receptor dimerization (and subsequent intracellular signaling cascades). The drug has demonstrated the ability to block signaling irrespective of the presence or concentration of the various molecules that frequently bind with TLR4, known as ligands. Based on this broad mechanism of action, we believe that EB05 could ameliorate TLR4-mediated inflammation cascades in ARDS patients, thereby reducing lung injury, ventilation rates and mortality. EB05 has demonstrated the ability to resolve fever and stabilize heart and breathing rates in human subjects that were injected with lipopolysaccharide (LPS) - a potent inducer of acute systemic inflammation. In previous Phase 1 and Phase 2 clinical studies, EB05 has demonstrated favorable safety and tolerability profiles.

In November 2020, we initiated patient enrollment for an international Phase 2/3 clinical study evaluating the safety and efficacy of EB05 as a therapy for adult hospitalized COVID-19 patients. Following a single intravenous infusion of EB05 or placebo, patients were evaluated for disease progression, mortality, side effects and other critical care measurements. Standard-of-care COVID-19 treatment is given to all patients. Phase 2 enrollment and treatment were completed in September 2021. Approximately 360 subjects were included in the Phase 2 dataset, and more than 600 subjects have been enrolled as of December 27, 2021.

In September 2021, an independent Data and Safety Monitoring Board (DSMB) identified an important signal between the treatment arms for 28-day mortality and requested that the study be pre-emptively unblinded. While the Phase 2 portion was primarily designed to refine patient stratification and statistical powering for the Phase 3 study, the DSMB concluded that "a clinically important efficacy signal" was detected and that the study has "met its objective." The DSMB recommended continuation of the study into a Phase 3 confirmatory trial.

Among the findings, the DSMB reported a 28-day death rate of 14.3% (2/14) in the EB05 arm versus 36.8% (7/19) in the placebo arm in critically ill patients receiving extracorporeal membrane oxygenation (ECMO) therapy and/or invasive mechanical ventilation plus organ support. Survival Analysis using Cox's Proportional Hazard Model showed that the patients treated with EB05 plus standard of care had a 68.5% reduction in the risk of dying when compared to placebo plus standard of care at 28 days (HR: 3.17 placebo vs. EB05; 95% CI: 0.66- 15.35; p=0.15). In this cohort, approximately 90% of patients received dexamethasone (or other steroids), and more than 45% received both an IL-6 inhibitor drug and a steroid.

The DSMB noted another mortality benefit in 136 hospitalized COVID-19 patients receiving supplemental oxygen (28-day mortality rate of 8.2% (5/61) in the EB05 + SOC arm versus 12.0% (9/75) in the placebo + SOC arm; HR: 1.52 placebo vs. EB05, n=136). Within this group, an important signal was seen in patients with severe ARDS at baseline. The DSMB reported a 28-day mortality rate of 16.7% (2/12) in the EB05 + SOC arm versus 42.9% (6/14) in the placebo + SOC arm. Survival Analysis using Cox's Proportional Hazard Model in this group showed that the subjects treated with EB05 + SOC had a 66.0% reduction in the risk of dying when compared to placebo + SOC at 28 days (HR: 2.94 placebo vs. EB05; 95% CI: 0.59-14.60; p=0.19).

There were confirmatory efficacy signals detected in other patient groups as well. In addition, the safety data demonstrated that there were no meaningful differences observed between the two treatment groups with respect to the incidence of treatment emergent serious and non-serious adverse events.

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Based on the Phase 2 interim results and the monitoring board’s recommendations, we plan to focus the Phase 3 portion of the EB05 study on critically ill hospitalized patients receiving extracorporeal membrane oxygenation (ECMO) therapy and/or invasive mechanical ventilation plus organ support. We may also evaluate other subgroups of hospitalized patients, subject to funding and the timely availability of sufficient number of subjects who meet enrollment criteria.

Federal Reimbursement Grant from the Canadian Government

On February 2, 2021, our wholly owned subsidiary Edesa Biotech Research, Inc. entered into a multi-year contribution agreement with the Canadian government’s Strategic Innovation Fund, or SIF. Under this agreement, the Government of Canada committed up to C$14.05 million ($11 million) in nonrepayable funding toward (i) the Phase 2 portion of our ongoing Phase 2/3 study of our investigation therapy EB05 in hospitalized COVID-19 patients, and (ii) certain pre-clinical research intended to potentially broaden the application of our experimental therapy. On a quarterly basis, we may submit claims to the SIF for 75% of eligible reimbursable expenses. Under the agreement, Edesa has agreed to certain obligations in relation to the completion of the clinical and pre-clinical project. In the event that we breach our obligations under the agreement, subject to applicable cure, the SIF may exercise a number of remedies, including suspending or terminating funding under the Agreement, demanding repayment of funding previously received and/or terminating the Agreement. The performance obligations of Edesa Biotech Research under the contribution agreement are guaranteed by the Company. As of December 27, 2021, we have met all of our performance and reporting requirements under the grant agreement.

Previous Phase 1 and Phase 2 Clinical Studies of EB05

In a previous Phase 1 study, EB01 demonstrated the ability to regulate inflammation in humans. EB05 was administered in healthy volunteers (HV) as a single intravenous infusion using a single ascending (from 0.001 mg/kg to 15 mg/kg) pharmacokinetic/pharmacodynamic dose design in Part 1 of the study. In Part 2 of the study, EB05 was administered at different dose levels and was followed by an *in vivo* LPS challenge where HVs were administered LPS on Day 1, Day 22 or Day 40 after EB05 administration (0.01mg/kg or 0.25 mg/kg). In subjects receiving an EB05 dose of 0.01 or 0.25 mg/kg and exposed to the LPS challenge immediately after the infusion, IL-6, TNFα and CXCL10 release was inhibited. In subjects administered EB05 0.25 mg/kg and exposed to the LPS challenge 22 days after the infusion, the release of IL6, TNFα and CXCL10 was also inhibited. In subjects who received the LPS challenge 40 days after EB05 infusion, the cytokine response to LPS was restored. In all subjects receiving placebo, the cytokine response to LPS was observed.

Vital signs (temperature and heart rate) were also measured during the *in vivo* LPS challenge in HV following EB05 or placebo administration. Similar to the trend in the cytokine levels, in subjects receiving an EB05 dose of 0.01 or 0.25 mg/kg and exposed to the LPS challenge immediately after the infusion, rise in baseline temperature and change in heart rate was inhibited. In subjects administered EB05 0.25 mg/kg and exposed to the LPS challenge 22 days after the infusion rise in baseline temperature and change in heart rate was also inhibited. In subjects who received the LPS challenge 40 days after EB05 infusion, the rise in baseline temperature and change in heart rate to LPS was restored.

EB05 has demonstrated a favorable safety profile in the Phase 1 study in health volunteers as well as a multiple-infusion Phase 2 study in subjects with rheumatoid arthritis (RA). In the Phase 1 study, doses ranged from 0.001 mg/kg up to 15mg/kg. The Phase 2 RA study was a multiple dose study where patients received one dose of EB05 5 mg/kg every two weeks for 12 weeks. In the Phase 1 study, a total of 60 subjects received EB05, and in the Phase 2 RA study, 61 patients were randomized to the EB05 group. There were no meaningful differences observed between the placebo and EB05 treatment groups with respect to the incidence of treatment emergent serious and non-serious adverse events either of these studies.

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).

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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.

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.

Current treatment plans begin by attempting to identify and remove exposure to the allergen. However, the offending allergen(s) is frequently not identified, and even when it is, avoiding exposure is often not possible (e.g., present in the workplace), 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, 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. Finally, patients may be treated with 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

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 sPLA2. 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 sPLA2 enzyme family plays a key role in initiating inflammation associated with many diseases, and we believe that targeting the sPLA2 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. 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.

In June 2021, an independent data and safety monitoring board (DSMB) completed an interim review of blinded data from the first cohort of our Phase 2b study of EB01 and determined that our drug candidate met key interim study parameters. The DSMB assessed the blinded comparable data for safety as well as pre-assigned statistical thresholds used to determine the number of subjects for the final part of the Phase 2b study. The initial cohort analyzed

consisted of a population of 46 subjects, of whom 36 completed the study follow-up and were used in the interim analysis. Based on the interim findings and the safety monitoring board's recommendations, we plan to enroll a total population of approximately 170 evaluable subjects in the primary cohort who will be provided with either 2% EB01 cream or placebo cream. In addition to the primary cohort, the company plans to complete a dose-ranging cohort, which will evaluate lower-strength concentrations of EB01 in an additional 40 subjects.

Since March 2020, we have implemented a number of measures designed to respond to and mitigate disruptions to patient care and enrollment caused by the COVID-19 pandemic. These measures include protocol amendments that reduce the number of in-person office visits and allow for remote telehealth appointments; the implementation of virtual investigational sites; patient recruitment campaigns; and new investigational sites. Due to physician and patient interest, the company has also added a voluntary open-label extension for study patients once they complete their treatment in the main study. This guarantees that participants in the placebo arm have access to treatment with the active ingredient. The open label extension is also designed to provide longer term usage data, since ACD often reoccurs, or is chronic. While these measures have been largely successful to date to increase the pace of enrollment, due to the changing nature of the pandemic and potential for new waves of infections to disrupt clinical sites, we are unable to predict with certainly the timing for the completion of the Phase 2b study.

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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 total 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).

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

Our EB02 drug candidate represents a potential extension of our sPLA2 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, sPLA2 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. 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. In light of our focus on the development of EB05 and EB01, we are currently evaluating the timing for the initiation of this planned study of EB02.

Other Product Candidates

We are also seeking to advance additional product candidates, including EB06, which is a monoclonal antibody candidate that binds specifically and selectively to chemokine ligand 10 (CXCL10) and inhibits the interaction of CXCL10 with its receptor(s). 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 inflammatory and immune-related diseases.

Intellectual Property and Key Licenses

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 and an affiliate of Yissum, have been issued for use in dermatologic and gastrointestinal conditions and infections that will expire in 2024. We expect to seek patent term extension in the United States related to time under IND, which could add up to three to five years of additional 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 hold an exclusive license from NovImmune SA, for patents and patent applications that cover our product candidates EB05 and EB06 in the United States, Canada and various other countries. Composition of matter patents, for which we hold an inbound license from NovImmune, have been issued that will expire as late as 2033 and 2028, respectively. We expect to seek patent term extension in the United States related to time under IND, which could extend protection. We have also filed additional method of use patent applications which we believe, if issued, could potentially prevent biosimilar substitution until as late as 2041.

In the event we are successful in commercializing a new drug candidate, we believe we would be eligible for data/market exclusivity, in addition to exclusivity rights granted through patent protection. We would be eligible for up to five years of exclusivity for EB01 and EB02 and up to twelve years of exclusivity for EB05 or EB06 after approval in the United States, and eight years of exclusivity after approval in Canada and ten years of exclusivity after approval in the European Union in any case.

We expect patents and other proprietary intellectual property rights to be an essential element of our business. We intend to protect our proprietary positions by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements. We also rely on trade secrets, know-how, continuing technological innovation and other in-licensing opportunities to develop and maintain our proprietary position. 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.

License Agreement with NovImmune SA

On April 17, 2020, our wholly owned subsidiary Edesa Biotech Research, Inc. entered into an exclusive license agreement with NovImmune SA, which operates under the brand Light Chain Bioscience, whereby we obtained exclusive rights throughout the world to certain know-how, patents and data relating to the monoclonal antibodies targeting TLR4 and CXCL10 (the Constructs). Edesa will use the exclusive rights to develop products containing these Constructs (the Licensed Products) for therapeutic, prophylactic and diagnostic applications in humans and animals. Unless earlier terminated, the term of the license agreement will remain in effect for twenty-five years from the date of first commercial sale of Licensed Products. Subsequently, the license agreement will automatically renew for five (5) year periods unless either party terminates the agreement in accordance with its terms.

Under the license agreement, we are exclusively responsible, at our expense, for the research, development manufacture, marketing, distribution and commercialization of the Constructs and Licensed Products and to obtain all necessary licenses and rights. Edesa is required to use commercially reasonable efforts to develop and commercialize the Constructs in accordance with the terms of a development plan established by the parties. In exchange for the exclusive rights to develop and commercialize the Constructs, we issued to NovImmune $2.5 million of newly designated Series A-1 Convertible Preferred Shares pursuant to the terms of a securities purchase agreement entered into between the parties concurrently with the license agreement. In addition, Edesa is committed to payments of various amounts to NovImmune upon meeting certain development, approval and commercialization milestones as outlined in the license agreement up to an aggregate amount of $356 million. We also have a commitment to pay NovImmune a royalty based

on net sales of Licensed Products in countries where Edesa directly commercializes Licensed Products and a percentage of sublicensing revenue received by Edesa in the countries where Edesa does not directly commercialize Licensed Products.

The license agreement provides that Light Chain will remain the exclusive owner of existing intellectual property in the Constructs and that Edesa will be the exclusive owner of all intellectual property resulting from the exploitation of the Constructs pursuant to the license. Subject to certain limitations, Edesa is responsible for prosecuting, maintaining and enforcing all intellectual property relating to the Constructs. During the term of the agreement, Edesa also has the option to purchase the licensed patents and know-how at a price to be negotiated by the parties. If Edesa defaults or fails to perform any of the terms, covenants, provisions or its obligations under the license agreement, Light Chain has the option to terminate the license agreement, subject to providing Edesa an opportunity to cure such default. The license agreement is also terminable by Light Chain upon the occurrence of certain bankruptcy related events pertaining to Edesa. In connection with the license agreement and pursuant to a purchase agreement entered into by the parties on April 17, 2020, we acquired from NovImmune its inventory of the TLR4 antibody for an aggregate purchase price of $5.0 million, payable in two installments - the first in 2021 and the second in 2022.

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 certain gastrointestinal conditions. 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 certain license agreements that Edesa has with third parties. Pendopharm also has the right to terminate the license and development agreement for any reason upon 120 days notice to us.

License Agreements with Yissum and Inventor

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 for the following fields of use: 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.

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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 for 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, in the event of a 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.

On March 16, 2021, through Edesa Biotech Research, Inc., we entered into a license agreement with the inventor of the same pharmaceutical product to acquire global rights for all fields of use beyond those named under the 2016 license agreement with Yissum. As a result of the license agreement entered into with inventor, Edesa now holds exclusive global rights to the pharmaceutical product that forms the basis of our EB01 and EB02 drug candidates for all fields of use in humans and animals. We are required to use commercially reasonable efforts to develop and commercialize the product in accordance with the terms of a development plan established by the parties. Edesa is exclusively responsible, at its expense, for the development of the product. We are committed to remaining payments of up to an aggregate amount of $69.1 million, primarily relating to future potential commercial approval and sales milestones. In addition, if we fail to file an investigational new drug application or foreign equivalent (IND) for the product within a certain period of time following the date of the agreement, we are required to remit to the inventor a fixed license fee annually as long as the requirement to file an IND remains unfulfilled. Edesa also has a commitment to pay the inventor a royalty based on net sales of the product in countries where Edesa, or an affiliate, directly commercializes the product and a percentage of sublicensing revenue received by Edesa and its affiliates in the countries where the company does not directly commercialize the product. Subject to certain exceptions, we have undertaken to indemnify Licensor 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.

Manufacturing and Marketing

We rely, and expect to continue to rely for the foreseeable future, on third-party contract manufacturing organizations, or CMOs, to produce both our synthetic chemical and biological product candidates for clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. Additional contract manufacturers are used to fill, label, package and distribute investigational drug products. 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 current arrangements with our manufacturers are subject to customary industry terms and conditions, and manufacturing is performed on an as-requested basis. While we have not experienced significant shortages of raw materials to date, as a result of the pandemic and increased demand for production, CMOs have generally reported that supplies of raw materials and critical components necessary for our manufacturing processes have been more challenging and expensive to obtain, and longer lead times may be required for scheduling future production runs. We believe that we have sufficient supplies on hand or in the process of being manufactured, filled and packaged to complete our clinical studies of EB05 and EB01.

To supply future clinical studies and potential commercialization of our product candidates, we are engaged in discussions with various CMOs regarding long-term supply agreements. These supply agreements typically require significant financial commitments, including upfront amounts prior to commencement of manufacturing, progress payments through the course of the manufacturing process as well as payments for technology transfer and other start-up costs. Based on our discussions with CMOs and industry announcements regarding future expansion plans, we believe there will be sufficient supplies of raw materials and manufacturing capacity to service our near-term and future product needs.

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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 or emergency use authorization in the United States, Canada or Europe for a product candidate, we plan to either build the capabilities to commercialize the product candidate in the applicable region with our own focused, specialized sales force, or alternatively, outsource the sales and marketing infrastructure necessary to market and sell our products. We also plan to utilize strategic licensing, collaboration, distribution or other marketing arrangements with third parties for the further development or commercialization of our products and product candidates, where applicable, such as in areas where a partner may contribute additional resources, infrastructure and expertise.

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, among others, Aclaris Therapeutics, Inc., Brickell Biotech, Inc., Citius Pharmaceuticals Inc., Dermavant Sciences, Inc. and Leo Pharma A/S. For our EB05 product candidate, there are hundreds of competing therapies under evaluation, including prophylactic vaccines for the SARS-Cov2 virus, experimental stem cell therapies, novel therapeutics and repurposed commercial drugs. Our potential competitors include, among others: Aqualung Therapeutics Corporation, Athersys, Inc., Enzychem Lifesciences Corp., Humanigen, Inc., Kiniksa Pharmaceuticals, Ltd., Merck & Co, Inc., Mesoblast Limited, Pfizer Inc., Regeneron Pharmaceuticals, Inc. and Roche Holding AG. 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 conduct clinical studies and seek approvals for our product candidates in the United States, Canada and other jurisdictions. 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 is conducted in accordance with our investigational plan or research protocol, as well as International Conference on Harmonization Good Clinical Practices, or GCP, which include guidelines for conducting, recording and reporting the results of clinical trials.

The FDA in the United States, Health Canada in Canada, the European Medicines Agency (EMA) in the European Union and comparable regulatory agencies in foreign countries impose substantial requirements on the clinical development, manufacture and marketing of pharmaceutical products and product candidates. These agencies and other federal, state, provincial and local entities regulate research and development activities and the testing, manufacture, packaging, importing, distribution, quality control, safety, effectiveness, labeling, storage, record-keeping, approval and promotion of our products and product candidates. All of our product candidates will require regulatory approval before commercialization. In particular, therapeutic product candidates for human use are subject to rigorous preclinical and clinical testing and other statutory and regulatory requirements of the United States, Canada, the EU and foreign countries. Obtaining these marketing approvals and subsequently complying with ongoing statutory and regulatory requirements require substantial time, effort and financial resources.

United States

In the United States, the FDA regulates drugs under the federal Food, Drug and Cosmetic Act as well as the Public Health Service (PHS) Act for biological drugs. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

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- *Pre-clinical testing*. Drug developers complete 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. These studies typically assess efficacy, toxicology and pharmacokinetics.

- *Submission to the FDA of an Investigational New Drug application (IND), which must become effective before human clinical trials may begin.* As part of an IND application to the FDA, trial sponsors submit the results of pre-clinical tests, together with manufacturing information and analytical data. The IND automatically becomes effective 30-days after receipt by the FDA, unless the FDA, within the 30- day time frame, has questions or concerns about the proposed study. In such a case, the IND sponsor and the FDA must resolve any outstanding items before the clinical trial can begin. A separate submission to an existing IND must also be made for each successive phase of a clinical trial conducted during product development.

- *Approval by a central or institutional review board (IRB), or ethics committee at each clinical trial site before each trial may be initiated.* An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completion. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

- *Multiple Phases of Human Clinical Trials.* Drug developers conduct adequate and well-controlled human clinical trials that establish the safety and efficacy of the product candidate for the intended use, typically in the following three stages, which are often sequential but 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 before 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.

- *Manufacturing Facilities.* Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with Current Good Manufacturing Practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity.

- *New Drug Application (NDA) or Biologics License Application (BLA).* The results of the nonclinical studies and clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the drug for one or more specified indications. The FDA reviews an application to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. FDA approval of an NDA or BLA must be obtained before a drug may be offered for sale in the United States. The FDA may deny approval of an NDA or BLA 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 application 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 (post-marketing), 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 BLA or a supplement, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials. In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers.

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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.

Expedited Development and Review Programs

The FDA has several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and

Accelerated Approval.

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the agency may review portions of the marketing application before the sponsor submits the complete application.

In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review, once an NDA or BLA is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Emergency Use Authorizations

While, in most cases, a therapeutic must be approved by FDA before the product may be sold, when there is a public health emergency involving chemical, biological, radiological, or nuclear agents, including infectious diseases like COVID-19, new therapeutics may be distributed pursuant to an Emergency Use Authorization, or EUA. Under an EUA, FDA may authorize the emergency use of an unapproved medical product or an unapproved use of an approved product for certain emergency circumstances to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, and after the Secretary of the Department of Health and Human Services has issued a declaration of emergency or threat justifying emergency use.

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To receive an EUA, the product sponsor must demonstrate that the product "may be effective" in the prevention, diagnosis, or treatment of an applicable disease or condition. Additionally, FDA must determine that the product's known and potential benefits outweigh the known and potential risks. Further there must be no adequate, approved, and available alternative product for the indication. Potential alternative products may be unavailable if there are insufficient supplies to meet the emergency need. FDA may establish additional conditions on an EUA that are necessary to protect public health, including conditions related to information that must be disseminated to health care providers and patients, the monitoring and reporting of adverse events, and record keeping. Conditions may also relate to how a product is distributed and administered and how a product is advertised. Importantly, EUAs are not full marketing approvals. Rather, EUAs are only effective for the duration of the applicable EUA declaration. Full approval of the product under applicable standards would be necessary to continue to distribute the product absent an EUA. EUAs may also be revised or revoked by FDA at any 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.

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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.

Canada

Health Canada is the Canadian federal authority that regulates, evaluates and monitors the safety, effectiveness, and quality of drugs, medical devices, and other therapeutic products available to Canadians. Health Canada's regulatory process for review, approval and regulatory oversight of products is similar to the regulatory process conducted by the FDA. To initiate clinical testing of a drug candidate in human subjects in Canada, a Clinical Trial Application (CTA) must be filed with and approved by Health Canada. In addition, all federally regulated trials must be approved and monitored by research ethics boards. The review boards study and approve study-related documents and monitor trial data.

Prior to being given market authorization for a drug product, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act (Canada) and its associated regulations, including the Food and Drug Regulations. This information is usually submitted in the form of a New Drug Submission (NDS). Health Canada reviews the submitted information, sometimes using external consultants and advisory committees, to evaluate the potential benefits and risks of a drug. If after of the review, the conclusion is that the patient benefits outweigh the risks associated with the drug, the drug is issued a Drug Identification Number (DIN), followed by a Notice of Compliance (NOC), which permits the market authorization holder (i.e., the NOC and DIN holder) to market the drug in Canada. Drugs granted an NOC may be subject to additional postmarket surveillance and reporting requirements.

All establishments engaged in the fabrication, packaging/labeling, importation, distribution, and wholesale of drugs and operation of a testing laboratory relating to drugs are required to hold a Drug Establishment License to conduct one or more of the licensed activities unless expressly exempted under the Food and Drug Regulations. The basis for the issuance of a Drug Establishment License is to ensure the facility complies with cGMP as stipulated in the Food and Drug Regulations and as determined by cGMP inspection conducted by Health Canada. An importer of pharmaceutical products manufactured at foreign sites must also be able to demonstrate that the foreign sites comply with cGMP, and such foreign sites are included on the importer's Drug Establishment License.

Regulatory obligations and oversight continue following the initial market approval of a pharmaceutical product. For example, every market authorization holder must report any new information received concerning adverse drug reactions, including timely reporting of serious adverse drug reactions that occur in Canada and any serious unexpected adverse drug reactions that occur outside of Canada. The market authorization holder must also notify Health Canada of any new safety and efficacy issues that it becomes aware of after the launch of a product.

Employees

As of December 27, 2021, we have 16 full-time employees: nine employees are primarily engaged in research and development, and seven employees are engaged in management, administration, business development and finance. All employees are located in Canada or the U.S. None of our employees are members of any labor unions.

We take pride in the diversity of our workforce and being an equal opportunity employer. As a growth-oriented company focused on innovation, we strive to foster diversity and inclusion. As of December 27, 2021, women represented more than 50% of all employees, and individuals from underrepresented racial or ethnic groups, or who are foreign born, represented more than 50% of our employees.

Legal Proceedings

We are not currently subject to any material legal proceedings.

Corporate Information

We are incorporated under the laws of British Columbia, Canada, in 2007 and operate through our wholly owned subsidiaries, Edesa Biotech Research, Inc. an Ontario, Canada corporation and Edesa Biotech USA, Inc., a California, USA corporation founded in 1999 (formerly known as Stellar Biotechnologies, Inc. prior to November 2020). 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.

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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 or social media postings are not part of our SEC reports 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. Investors and other interested parties should note that we may also use our website and our social media channels to publish information about Edesa that may be deemed material to investors. We encourage investors and other interested parties to review the information we may publish through our website and social media channels.

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.

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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. In addition, many of the following risk factors could be exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. 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. At September 30, 2021, we had an accumulated deficit of $26.50 million. We have historically financed operations primarily through issuances of common shares, the exercise of common share purchase warrants, convertible preferred shares, convertible loans, government grants and tax incentives. 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.

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.

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 drug product candidates. If we are unable to obtain regulatory approval or commercialize one or more of these experimental treatments, or experience significant delays in doing so, our business will be materially harmed.

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 our drug product candidates. The success of our product candidates 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;
- our timing to obtain applicable regulatory approvals;
- 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 any of our 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.

Public health threats could have an adverse effect on our operations and financial results.

Public health threats, such as the novel coronavirus (COVID-19), influenza and other highly communicable diseases or viruses could adversely impact our operations and disrupt our ongoing or planned research and development activities. At present, the COVID-19 pandemic, and preventative measures taken to contain or mitigate this pandemic, are causing disruptions to almost every industry directly or indirectly. Governments in affected regions have implemented and may continue to implement safety precautions, including quarantines, travel restrictions and shelter in place orders, resulting in business closures, work stoppages, slowdowns and delays, cancellation of events and other measures. These measures may disrupt normal business operations and may have significant negative impacts on businesses and financial markets worldwide.

We continue to monitor our operations and applicable government recommendations, and we have made modifications to our normal operations because of the COVID-19 pandemic, including limiting travel, working from home and implementing new procedures in the workplace. The risk of cyber-attacks or other data security incidents may be heightened as a result of our remote or hybrid working environment, which may be less secure and more susceptible to security breaches. Operating requirements may continually change due to the COVID-19 pandemic and we may experience unpredictability in our expenses. Since we rely on third-party CMOs to manufacture our drug candidates we may be more susceptible to supply chain disruptions than companies with in-house manufacturing. While we have not experienced significant shortages of raw materials to date, as a result of the pandemic and increased demand for production, CMOs have generally reported that supplies of raw materials and critical components necessary for our manufacturing processes have been more challenging and expensive to obtain, and longer lead times may be required for scheduling future production runs. We cannot presently predict the scope and severity of any potential future business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

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 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.

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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.

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.

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 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 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. 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. If we are not in compliance, we 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.

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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 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, including damage from cyber attacks, ransomware attacks, computer viruses, unauthorized access, human error and technological errors, natural disasters 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 our 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.

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 drug 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. 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.

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If clinical trials for our product candidates are prolonged or delayed, we may incur additional costs, and may not be able to commercialize our product candidates on a timely basis or at all.

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;
- delays in establishing the appropriate dosage levels;
- 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 or continue 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 for our drug candidates are uncertain. We may never receive marketing approval for our drug candidates.

To our knowledge, there are currently no FDA-approved drug treatment options specifically approved for many of the disease indications we are targeting with our drug candidates. Accordingly, there may not be well-established development paths and outcomes. The FDA, Health Canada or any other regulatory authority may determine that the designs or endpoints of any trial that we conduct, or that the outcome shown on any particular endpoint in any trial that we conduct, are not sufficient to establish a clinically meaningful benefit for our drug candidates, or otherwise, to support approval, even if the primary endpoint(s) of the trial is met with statistical significance. If this occurs, our business could be materially harmed. Moreover, if the regulatory authorities require us to conduct additional clinical trials beyond the ones that we currently contemplate, our finances and results from operations will be adversely impacted. If our clinical studies meet their respective primary endpoints, we plan to seek marketing approval. We cannot predict whether each of these regulatory agencies will agree that our study data and information will be sufficient to meet the requirements for filing a marketing application or the standards for approval. If the regulatory agencies determine that more data and information are needed, it could delay and/or negatively impact our ability to obtain regulatory approval to market and sell a particular product candidate.

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If the commercial opportunity in chronic ACD or COVID-19-induced ARDS is smaller than we anticipate, our future revenue from EB01 or EB05, as applicable, 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 or COVID-19-induced ARDS. Our estimates of the number of people who have these conditions as well as the subset who have the potential to benefit from treatment with EB01 or EB05, 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 these drug candidates. The effort to identify patients for 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 our drug candidates may be limited or may not be amenable to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the commercial opportunity for these conditions is smaller than we anticipate, 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 sPLA2 or anti-TLR4 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 sPLA2 and anti-TLR4 product candidates employ novel mechanisms of action. To our knowledge no drug companies have successfully commercialized an sPLA2 inhibitor or an anti-TLR4 antibody 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 sPLA2 inhibitor or anti-TLR4 therapy, 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. 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.

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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 than we do. 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, ARDS, or any other indications for which we may receive government approval.

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, EB05 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 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. 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, and 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 manufacturing, including optimization, technology transfers and scaling up of clinical scale quantities of all of our product candidates.

We have no direct experience in manufacturing any of our product candidates, and currently lack the resources or capability to manufacture any of our product candidates on a clinical or commercial scale. As a result, we will be dependent on third parties for 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. We may compete with other companies 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.

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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 suppliers 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.

The manufacturing of our monoclonal antibody candidates is complex and subject to a multitude of risks. These manufacturing risks could substantially increase our costs and limit supply of these drug candidates for clinical development, and commercialization.

The manufacture of our monoclonal antibody candidates requires processing steps that are more complex than those required for most small molecule drugs. As a result of the complexities in manufacturing biologics, the cost to manufacture biologics in general, and our cell product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing processes are less reliable and are more difficult to reproduce. Although we are working with third parties to develop reproducible and commercially viable manufacturing processes for our product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials.

We may make changes as we continue to evolve the manufacturing processes for our product candidates for advanced clinical trials and commercialization, and we cannot be sure that even minor changes in these processes will not cause our product candidates to perform differently and affect the results of our ongoing clinical trials, future clinical trials, or the performance of the product once commercialized. In some circumstances, changes in manufacturing operations, including to our protocols, processes, materials or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements may lead to delays in our clinical development and commercialization plans for our product candidates, and may increase our development costs substantially.

We may also decide to transfer certain manufacturing process know-how and certain intermediates to other contract manufacturing organizations. Transferring manufacturing testing and processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. We and any CMOs or third parties that we engage for manufacturing our product candidates will need to conduct significant development work to transfer these processes and manufacture each of our product candidates for clinical trials and commercialization. In addition, we may be required to demonstrate the comparability of material generated by any CMO or third parties that we engage for manufacturing our product candidates with material previously produced and used in testing. The inability to manufacture comparable drug product by us or our CMO could delay the continued development of our product candidates.

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 and clinical investigators, 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 complies with standards, commonly referred to as Good Clinical Practice, and is conducted in accordance with the general investigational plan and protocols for the trial.

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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 our product candidates. Collaborations are complex and time-consuming to negotiate and document and we face significant competition in seeking appropriate 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 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. 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, Health Canada 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, EB05 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 consultants 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, EB05 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.

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, quality assurance and documentation. 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.

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We may not qualify for or ultimately benefit from various expedited regulatory review programs or designations.

In the event that our Phase 2/3 study of EB05 in hospitalized COVID-19 patients is successful, we intend to apply for various regulatory incentives in the United States, such as breakthrough therapy designation, fast track designation, accelerated approval and priority review, where available, that provide for expedited review and/or other benefits, and we may also seek similar designations elsewhere in the world. Often, regulatory agencies have broad discretion in determining whether or not product candidates qualify for such regulatory incentives and benefits and we cannot guarantee we would be successful in obtaining beneficial regulatory designations by FDA or other regulatory agencies. Even if approved, expedited designations may not result in faster development processes, reviews or approvals compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may later decide that any of our development programs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. If we are not able to obtain or maintain such designations for EB05 or other product candidates, it could delay and/or negatively impact our ability to obtain regulatory approval.

The FDA has broad discretion regarding Emergency Use Authorizations for COVID-19 medical products, and such authorizations are only valid during the COVID-19 public health emergency.

While, in most cases, a therapeutic must be approved by FDA before the product may be sold, when a public health emergency is declared, subject to certain conditions, FDA may authorize the emergency use of an unapproved medical product under an Emergency Use Authorization (EUA). In the event that our Phase 2/3 clinical study of EB05 is successful, and if we believe we meet eligibility requirements, we intend to submit an application with the FDA for EUA. FDA does not have review deadlines with respect to such submissions and, therefore, the timing of any potential approval of an EUA submission would be uncertain. We would not be able to guarantee that the FDA would review our data in a timely manner, or that the FDA would accept the data when reviewed. The FDA may decide that our data are insufficient for an EUA and require additional studies and refuse to approve our application. In addition, even if granted, the FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization. If we are unsuccessful in obtaining an EUA, or if any granted EUA is revoked after a short period of time, it could have a material adverse effect on our future business, financial condition and operating results.

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. 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.

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. In addition, our employees or third parties with whom we contract, such as our CROs or CMOs, may knowingly or inadvertently make use of social media in a manner that may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others or information regarding our product candidates or clinical trials. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common shares.

Risks Related to Our Intellectual Property

We are dependent on license relationships with third parties for our key drug development 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. In 2021, we also entered into a license agreement with the inventor of the same pharmaceutical product to acquire global rights for all fields of use beyond those named under the 2016 license agreement with Yissum. 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.

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In April 2020, we entered into an exclusive license agreement with NovImmune SA to obtain exclusive rights throughout the world to certain know- how, patents and data relating to the monoclonal antibodies targeting TLR4 and CXCL10. We are using these rights to develop EB05 as a potential treatment for ARDS resulting from COVID-19. If we default or fail to perform any of the terms, covenants, provisions or our obligations under the License Agreement, NovImmune 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.

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. 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.

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If we are found to infringe a third party's intellectual property rights, we could incur substantial monetary damages. A finding of infringement could also prevent us from commercializing our product candidates, lose market exclusivity, require substantial license payments, or force us to cease some of our business operations, which could materially harm our business.

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 securities. 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. 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;
- actual or anticipated fluctuations in our results of operations;

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- hedging or arbitrage trading activity that may develop regarding our common shares;
- regional or worldwide recession;
- sales of our common shares by our executive officers, directors and significant shareholders;
- 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. As a smaller reporting company as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, we are currently exempt from the auditor attestation requirement of Section 404(b). If we lose this eligibility, we will incur increased personnel and audit fees in connection with the additional audit requirements. 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.

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We may be deemed a passive foreign investment company, and as a result, U.S. 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, 2021 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.

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.

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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 27, 2021, we had 13,518,799 common shares outstanding, with 22 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.

Canadian Federal Income Tax Consequences Applicable to Holders in the United States

The following summary of the material Canadian federal income tax consequences is stated in general terms and is not intended to be legal or tax advice to any particular shareholder. Management urges holders to consult their own tax advisor with respect to the income tax consequences applicable to them based on their own particular circumstances.

This summary is applicable only to holders who are resident in the United States for income tax purposes, have never been resident in Canada for income tax purposes, deal at arm's length with the company, hold their Common Shares as capital property and who will not use or hold the Common Shares in carrying on business in Canada. This summary does not discuss any non-Canadian income or other tax consequences of acquiring, holding or disposing of Common Shares.

This summary is based upon the provisions of the Income Tax Act (Canada) and the regulations thereunder (collectively, the Tax Act or ITA) and the Canada-United States Tax Convention (1980) as amended (the Tax Convention) at the date of this Annual Report on Form 10-K and the current administrative practices of the Canada Revenue Agency. This summary does not take into account provincial income tax consequences. The comments in this summary that are based on the Tax Convention are applicable to U.S. Holders only if they qualify for benefits under the Tax Convention.

Dividends

A Holder will be subject to Canadian withholding tax (Part XIII Tax) equal to 25%, or such lower rates as may be available under an applicable tax treaty, of the gross amount of any dividend paid or credited or deemed to be paid or credited to the Holder on the Common Shares. For example, under the Tax Convention, where dividends on the Common Shares are considered to be paid to a Holder that is the beneficial owner of the dividends and is a resident of the United States for the purposes of, and is entitled to all the benefits of, the Tax Convention, the applicable rate of Canadian withholding tax is generally reduced to 15%. The company will be required to withhold the applicable amount of Part XIII Tax from each dividend so paid and remit the withheld amount directly to the Receiver General for Canada for the account of the Holder. 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.

Disposition of Common Shares

A Holder who is a resident of the United States and realizes a capital gain on a disposition of Common Shares will generally be exempt from Canadian income tax on that capital gain, unless the shares are taxable Canadian property.

Provided the Common Shares are listed on a "designated stock exchange" (as defined in the Tax Act) (which currently includes the Nasdaq Capital Market) at the time of disposition, the Common Shares will generally not constitute taxable Canadian property of a Holder at that time, unless any of the following conditions are met: (a) at the time of disposition more than 50% of the fair market value of the Common Shares is derived directly or indirectly from real property situated in Canada, which generally includes certain Canadian natural resource properties; (b) the Common Shares formed part of the business property of a permanent establishment that the Holder has or had in Canada within the 12 months preceding disposition; or (c) the Holder is an individual who (i) was a resident of Canada at any time within the ten years immediately preceding the disposition, and for a total of 120 months during any period of 20 consecutive years, preceding the disposition, (ii) owned the Common Shares when the individual ceased to be resident in Canada, and (iii) the Common Shares were not subject to a deemed disposition on the Holder's departure from Canada.. Notwithstanding the foregoing, a Common Share may otherwise be deemed to be taxable Canadian property to a Holder for purposes of the Tax Act in particular circumstances.

Inclusion in Taxable Income

A Holder who is subject to Canadian income tax in respect of a capital gain realized on a disposition of Common Shares must include one half of the capital gain ("taxable capital gain") in computing the Holder's taxable income earned in Canada. The Holder may, subject to certain limitations, deduct one half of any capital loss ("allowable capital loss") arising on a disposition of taxable Canadian property from taxable capital gains realized in the year of disposition in respect of taxable Canadian property and, to the extent not so deductible, from such taxable capital gains of any of the three preceding years or any subsequent year. Subject to certain exceptions, a non-resident person who disposes of taxable Canadian property must notify the Canada Revenue Agency either before or after the disposition (within ten days of the disposition).

Item 6. [RESERVED.]

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 Edesa Biotech USA, Inc. (formerly known as Stellar Biotechnologies, Inc.).

Our operations have been funded primarily through issuances of common shares, exercises of common share purchase warrants, convertible preferred shares, convertible loans, government grants and tax incentives. 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 believe our working capital, remaining grant funds and available equity distribution sales are 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. To fund operations, we may seek additional financing through the sale of equity, government grants, debt financings or other capital sources, including potential future licensing, collaboration or similar arrangements with third parties or other strategic transactions.

Results of Operations

Fiscal Year Ended September 30, 2021 Compared to the Fiscal Year Ended September 30, 2020

There were no revenues for the year ended September 30, 2021 compared to $0.33 million for the prior year, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

Our total operating expenses increased by $16.95 million to $23.68 million for the year ended September 30, 2021 compared to $6.73 million for the prior year:

- There was no cost of sales for the year ended September 30, 2021 compared to $0.02 million for the prior year, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

- Research and development expenses increased by $14.62 million to $17.95 million for the year ended September 30, 2021 compared to $3.33 million for the prior year primarily due to milestone payments related to advancement of our EB05 clinical program, increased external research expenses related to accelerated activity in our ongoing clinical studies, increased investigational drug product expenses and an increase in noncash share-based compensation. Higher salary and related personnel expenses and patent fees also contributed to the increase.

- General and administrative expenses increased by $2.35 million to $5.73 million for the year ended September 30, 2021 compared to $3.38 million for the prior year primarily as a result of higher salary and related personnel expenses, noncash share-based compensation and increased headcount. Higher legal and other professional services also contributed to the increase.

Total other income increased by $10.30 million to $10.34 million for the year ended September 30, 2021 compared to $0.04 million for the prior year primarily due to increased grant income under our federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the year ended September 30, 2021, our net loss was $13.34 million, or $1.10 per common share, compared to a net loss of $6.36 million, or $0.74 per common share, for the year ended September 30, 2020.

Capital Expenditures

Our capital expenditures primarily consist of computer and office equipment. There were no significant capital expenditures for the years ended September 30, 2021 and 2020.

Liquidity and Capital Resources

As a clinical-stage company we have not generated significant revenue, and we expect to incur operating losses as we continue our efforts to acquire, develop, seek regulatory approval for and commercialize product candidates and execute on our strategic initiatives. Our operations have historically been funded through issuances of common shares, exercises of common share purchase warrants, convertible preferred shares, convertible loans, government grants and tax incentives. For the years ended September 30, 2021 and 2020, we reported net losses of $13.34 million and $6.36 million, respectively.

Under our contribution agreement with the Canadian government's Strategic Innovation Fund (SIF), we are eligible to receive cash reimbursements up to C$14.05 million ($11 million USD) in the aggregate for certain research and development expenses related to our EB05 clinical development program. For the year ended September 30, 2021, we recorded $10.34 million in grant income.

On March 2, 2021, we completed a registered public offering of an aggregate of 1,562,500 common shares, no par value, of the Company at an offering price of $6.40 per share for net proceeds of $8.89 million, after deducting underwriter fees and related offering expenses.

For the year ended September 30, 2021, the exercise of warrants and options as well as sales under our equity distribution agreement with RBC Capital Markets, LLC resulted in the issuance of 987,859 common shares and net cash proceeds to the Company of $5.12 million.

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On November 22, 2021, we entered into a new equity distribution agreement with RBC Capital Markets, LLC (RBCCM), as sales agent, pursuant to which the Company may offer and sell, from time to time, common shares through an at-the-market equity offering program for up to $15 million in gross cash proceeds. RBCCM will use commercially reasonable efforts to sell the common shares from time to time, based upon our instructions. We have no obligation to sell any of the shares, and may at any time suspend sales under the distribution agreement or terminate the agreement in accordance with its terms. The total amount of cash that may be generated under this distribution agreement is uncertain and depends on a variety of factors, including market conditions and the trading price of our common shares.

At September 30, 2021, the Company had cash and cash equivalents of $7.84 million, working capital of $10.63 million, shareholders' equity of $13.06 million and an accumulated deficit of $26.50 million. Subsequent to the fiscal year end, we sold 223,396 common shares under the current distribution agreement with RBCCM for gross proceeds of approximately $1.29 million.

We plan to finance company operations over the course of the next twelve months with cash and cash equivalents on hand, equity sales under the at-the-market offering program and reimbursements of eligible research and development expenses under our contribution agreement with the Canadian government. 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. To help fund our operations and meet our obligations in the future, we may also seek additional financing through the sale of equity, government grants, debt financings or other capital sources, including potential future licensing, collaboration or similar arrangements with third parties or other strategic transactions. If we determine it is advisable to raise additional funds, there is no assurance that adequate funding will be available to us or, if available, that such funding will be available on terms that we or our shareholders view as favorable. Market volatility, inflation and concerns related to the COVID-19 pandemic may have a significant impact on the availability of funding sources and the terms at which any funding may be available.

Research and Development

Our primary business is the development of innovative therapeutics for inflammatory and immune-related diseases with clear unmet medical needs. We focus our resources on research and development activities, including the conduct of clinical studies and product development, and expense such costs as they are incurred. Our research and development expenses have primarily consisted of employee-related expenses, including salaries, benefits, taxes, travel, and share-based compensation expense for personnel in research and development functions; expenses related to process development and production of product candidates paid to contract manufacturing organizations, including the cost of acquiring, developing, and manufacturing research material; costs associated with clinical activities, including expenses for contract research organizations; and clinical trials and activities related to regulatory filings for our product candidates, including regulatory consultants.

Research and development expenses, which have historically varied based on the level of activity in our clinical programs, are significantly influenced by study initiation expenses and patient recruitment rates, and as a result are expected to continue to fluctuate, sometimes substantially. Our research and development costs were $17.95 million and $3.33 million for the years ended September 30, 2021 and 2020, respectively. The increase was due primarily to increased activities and preparations related to the ongoing Phase 2/Phase 3 clinical study of our EB05 drug candidate as a potential treatment for hospitalized COVID-19 patients.

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, 2021, we had assets denominated in Canadian dollars of approximately C$9.8 million and the U.S. dollar exchange rate as at this date was equal to 1.2711 Canadian dollars. Based on the exposure at September 30, 2021, a 10% annual change in the Canadian/U.S. exchange rate would impact our net loss and other comprehensive loss by $0.77 million.

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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 US Treasury bills, money market mutual funds of U.S. government securities or financial institutions believed to be credit worthy and perform periodic evaluations of their relative credit standing. There were no Treasury bills outstanding at September 30, 2021 and 2020. 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 and reimbursements receivable from the Canadian government's Strategic Innovation Fund (SIF). As of September 30, 2021 and 2020, 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

Accounts and other receivable include Harmonized Sales Tax (HST) refunds receivable and reimbursements receivable from the Canadian government's Strategic Innovation Fund (SIF). As of September 30, 2021, all outstanding amounts were deemed to be fully collectible, and therefore, no allowance for doubtful accounts was recorded.

Intangible assets

Intangible assets represent the exclusive world-wide rights to know-how, patents and data relating to certain monoclonal antibodies (the Constructs), including sublicensing rights, acquired by entering into a license agreement with a pharmaceutical development company. Unless earlier terminated, the term of the license agreement will remain in effect for 25 years from the date of first commercial sale of licensed products containing the Constructs. Subsequently, the license agreement will automatically renew for five-year periods unless either party terminates the agreement in accordance with its terms. We recognize intangible assets at their historical cost, amortized on a straight-line basis over their expected useful lives, which is 25 years, and subject to impairment review at the end of each reporting period.

Right-of-Use assets

We adopted Accounting Standards Codification (ASC) Topic 842 Leases for the year ended September 30, 2020 using the modified retrospective transition method. We elected the package of practical expedients in transition and the ongoing practical expedient not to recognize operating lease right-of-use assets and operating lease liabilities for short-term leases. As a result of adopting the new standard, we recognized operating lease right-of-use (ROU) assets and operating lease liabilities on the balance sheet for one operating lease with a term longer than 12 months at adoption. There was no impact to opening accumulated deficit. There were three short-term operating leases upon adoption that did not follow the ROU model. The ROU assets are initially measured at cost and amortized using the straight-line method through the end of the lease term. The lease liabilities are initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using our incremental borrowing rate.

Share-based compensation

We measure 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.

We grant options to buy common shares of the Company to our directors, officers, employees and consultants, and grant 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 our share-based compensation plans do not require the Company to settle any options by transferring cash or other assets, and therefore we classify 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.

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Translation of foreign currency transactions

Our reporting currency is the U.S. dollar. The financial statements of our wholly owned Canadian subsidiary is measured using the Canadian dollar as the functional currency. Assets and liabilities of the Canadian operation 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 operation 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 our 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 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.

Not applicable.

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, 2021. Our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures as of September 30, 2021, 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.

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, 2021.

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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 a “smaller reporting company” as defined by Rule 12b-2 of the Exchange Act, and are subject to reduced public company reporting requirements. We are not required to have the effectiveness of our internal control over financial reporting audited by our external auditors.

Limitations on the Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION.

Not applicable.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Directors

Our directors and their ages as of December 27, 2021 are set forth below.

Name	Age	Position(s) Held	Director Since
Lorin Johnson, PhD (2)	69	Director	June 7, 2019
Sean MacDonald (1)(2)(3)	45	Chairman of Board of Directors	June 7, 2019
Pardeep Nijhawan, MD	51	Director, Chief Executive Officer and Corporate Secretary	June 7, 2019
Frank Oakes	71	Director	April 9, 2010
Paul Pay (1)(2)	67	Director	June 7, 2019
Carlo Sistilli, CPA, CMA (1)(3)	65	Director	June 7, 2019
Peter van der Velden (3)	60	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 cofounded 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 9Meters Biopharma, Inc. (Nasdaq: NMTR), Glycyx MOR, Inc., Intact Therapeutics, Inc., Kinisi Therapeutics, Ltd. and NeVAP, Inc. 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 coauthor of 76 journal articles and book chapters and is the coinventor 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 chaired our Board since June 2019, having previously served as a director of the company's principal operating subsidiary, Edesa Biotech Research, Inc., since September 2017. In his career, he has led and closed multiple licensing transactions, financings, acquisitions and divestments, and corporate strategy for several pharmaceutical and biotechnology companies. Mr. MacDonald is currently Chief Business Officer of iOnctura SA, a Swiss clinical-stage oncology company, a position he has held since August 2021. From April 2019 to August 2021, he was the Head of Business

Development for Cosmo Pharmaceuticals NV, a European gastroenterology focused pharmaceutical company; and from October 2018 to August 2021 he was the chief executive of Corbin Therapeutics, a Montreal-based biotech company focused on treating neuroinflammation. Mr. MacDonald held various operational and executive leadership roles from October 2012 to October 2018 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.

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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 over 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 May 2021, he led all business development activity at Norgine. He is currently Senior Advisor, Corporate & Business Development at Norgine reporting to the CEO. 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. He is a past director at Arc Medical Design, a medical device development company and a portfolio company of Norgine; Norgine Ltd., an affiliate of Norgine; and Merus Labs Inc., a Norgine wholly owned subsidiary. 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. He currently serves on the board of directors and audit committee of Aleafia Health Inc. (TSX: AH). 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 Lava Medtech Acquisition Corp (Nasdaq: LVACU), Exact Imaging, Medexus Pharmaceuticals (TSX: MDP.TO) 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.

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Executive Officers

Set forth below is certain information with respect to the names, ages, and positions of our executive officers as of December 27, 2021. 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	51	Director, Chief Executive Officer and Corporate Secretary	June 7, 2019
Kathi Niffenegger, CPA	64	Chief Financial Officer	November 1, 2013
Michael Brooks, PhD	43	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 Postdoctoral 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 year ended September 30, 2021, 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 inadvertently filed late by Mr. 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 officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of our Code of Ethics and Business Conduct is available on the Investor Relations section of our website at 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.

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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 year ended September 30, 2021 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 years ended September 30, 2021 and September 30, 2020.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Pardeep Nijhawan, MD	2021	$ 315,000	$ 120,000	$ 820,526	$ 63,773(2)	$ 1,319,299
Director, Chief Executive Officer and Corporate Secretary	2020	300,000	56,000	-	55,204(2)	411,204
Kathi Niffenegger, CPA	2021	305,016	100,000	605,857	30,908(3)	1,041,781
Chief Financial Officer	2020	234,069	31,354	214,275	25,613(3)	505,311
Michael Brooks, PhD	2021	293,750	110,000	605,857	42,339(4)	1,051,946
President	2020	275,000	51,333	166,658	36,220(4)	529,211

(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 9 to our audited consolidated financial statements for the year ended September 30, 2021 included in this Annual Report.

(2) Represents (i) $30,453 in car allowance (ii) $2,054 in health insurance and (iii) $31,266 in vacation payout in 2021 and (i) $32,435 in car allowance (ii) $2,187 in health insurance and (iii) $20,582 in vacation payout in 2020. All compensation to Dr. Nijhawan was paid in Canadian dollars and was converted to US dollars using the average foreign exchange rate for the year from oanada.com.

(3) Represents (i) $18,758 in health insurance and (ii) $12,150 in 401(k) company contributions in 2021 and (i) $17,650 in health insurance and (ii) $7,963 in 401(k) company contributions in 2020.

(4) Represents (i) $22,548 in car allowance (ii) $2,597 in health insurance and (iii) $17,194 in vacation payout in 2021 and (i) $24,015 in car allowance (ii) $2,213 in health insurance and (iii) $9,992 in vacation payout in 2020. All compensation to Dr. Brooks was paid in Canadian dollars and was converted to US dollars using the average foreign exchange rate for the year from oanda.com.

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Narrative Disclosure to Summary Compensation Table Employment Agreements

Upon completion of our business combination transaction with Edesa Research, Dr. Nijhawan, Dr. Brooks and Kathi Niffenegger each entered into new employment agreements with us which are described below. Kathi Niffenegger entered into a new employment agreement with us on December 1, 2020 as described below and the employment agreement she entered into upon completion of our business combination transaction with Edesa Research was superseded. All three employment agreements were amended on March 19, 2021.

Employment Agreement with Pardeep Nijhawan effective as of June 7, 2019 and amended March 19, 2021

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. The base salary increased to $320,000 per year effective January 1, 2021. 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.

Employment Agreement with Michael Brooks effective as of June 7, 2019 and amended March 19, 2021

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. The base salary increased to $300,000 per year effective January 1, 2021. 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.

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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.

Employment Agreement with Kathi Niffenegger effective as of June 7, 2019

On June 7, 2019, we entered into an employment agreement with Ms. Niffenegger which has subsequently been superseded by the employment agreement with Ms. Niffenegger described below. Pursuant to the employment agreement, Ms. Niffenegger served as our Chief Financial Officer with 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 and such other employee benefits as are generally provided to similarly situated employees of the company.

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Employment Agreement with Kathi Niffenegger effective as of December 1, 2020 and amended March 19, 2021

On December 1, 2020, we entered into an employment agreement with Ms. Niffenegger. Pursuant to the employment agreement, Ms. Niffenegger will continue to serve as our Chief Financial Officer. Both Ms. Niffenegger and we 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 $275,000 per year retroactive to June 1, 2020, a discretionary bonus in an amount up to 40% of her base salary based on her performance and the company's performance and such other employee benefits as are generally provided to similarly situated employees of the company. The base salary increased to $290,000 per year effective January 1, 2021. 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 the independent members of our Board of Directors 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 defined in the employment agreement) or if Ms. Niffenegger resigns from her employment at any time, our only obligation is to provide Ms. Niffenegger with: (i) her accrued salary and accrued unused vacation pay 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 Ms. Niffenegger is terminated by us without "Cause", our only obligations are (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 (the "Severance Amount"), (i) a lump sum payment equal to twelve months of Ms. Niffenegger's then current base salary, plus one additional month of base salary for every completed year of service since June 2019, not to exceed an aggregate of twenty-four months, (ii) a lump sum payment of any discretionary bonus for the prior calendar year already determined by our Board of Directors, but not yet paid; and (iii) a lump sum payment equal to Ms. Niffenegger's potential discretionary bonus for the calendar year in which the Separation Date occurs, prorated over Ms. Niffenegger's length of service in the calendar year in which her employment is terminated, calculated in accordance with the terms of the employment agreement. If Ms. Niffenegger's 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), Ms. Niffenegger shall be entitled to the Severance Amount described above, except that the portion of the Severance Payment established by (b)(i) shall be equal to twenty four months of Ms. Niffenegger's base salary.

The Agreement provides that during the term of Ms. Niffenegger's employment with us and for a period of one year thereafter, Ms. Niffenegger is prohibited from soliciting for employment certain of our employees. The Agreement also provides that both during and after Ms. Niffenegger's employment with us, she is prohibited from (i) making use of our trade secrets to solicit on behalf of Ms. Niffenegger or any other person business from any of our customers and (ii) inducing or attempting to induce any person to sever any existing contractual relationship they have with us.

Outstanding Equity Awards at September 30, 2021

		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	47,490	-	C$	2.16	9/26/27
	12/28/18	1,485	135(2)	C$	2.16	12/28/28
	10/13/20	20,004	39,996(4)	$	7.44	10/13/30
	4/22/21	19,998	100,002(4)	$	5.45	4/22/31
Kathi Niffenegger, CPA	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
	2/12/20	60,640	28,059(3)	$	3.16	2/12/30
	10/13/20	16,668	33,332(4)	$	7.44	10/13/30
	4/22/21	13,332	66,668(4)	$	5.45	4/22/31
Michael Brooks, PhD	8/28/17	136,416	-	C$	2.16	8/28/27
	9/26/17	24,299	-	C$	2.16	9/26/27
	12/28/18	1,485	135(2)	C$	2.16	12/28/28
	2/12/20	47,162	21,826(3)	$	3.16	2/12/30
	10/13/20	16,668	33,332(4)	$	7.44	10/13/30
	4/22/21	13,332	66,668(4)	$	5.45	4/22/31

(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.

(3) The option will vest over a period of three years, with one-third vesting on the date of grant and the remainder vesting on a pro-rata basis monthly thereafter.

(4) The option will vest over a period of three years, with monthly vesting on a pro-rata basis beginning on the date of grant.

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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 2,625,951, 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 1,776,219 common shares at prices ranging from C$2.16 to C$638.40 and $3.16 to $304.08 are outstanding at September 30, 2021. No restricted shares or restricted share units have been granted as of September 30, 2021.

Options granted during the year ended September 30, 2021 to directors, officers and employees under the 2019 Plan totaled 1,145,000 options to purchase common shares at exercise prices ranging from $5.25 to $7.44. Options granted during the year ended September 30, 2020 to directors, officers and employees under the 2019 Plan totaled 366,365 options to purchase common shares at exercise prices ranging from $3.16 to $8.07.

Options Vesting Policy

Vesting requirements for option awards are determined by the independent members of the Board of Directors. Options granted by the Company during the year ended September 30, 2021 generally had monthly vesting for directors in equal proportions over 12 months beginning on the grant date, monthly vesting for officers and current employees in equal proportions over 36 months beginning on the grant date and monthly vesting for new employees in equal proportions over 36 months beginning on the monthly anniversary of the grant date following 90 days of employment. Options granted by the Company during the year ended September 30, 2020 generally vested one-third upon the date of grant and monthly thereafter until the third anniversary of the date of grant. Substitute options under the 2019 Plan 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.

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 years ended September 30, 2021 and 2020 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 year ended September 30, 2021.

Name	Fees Earned or Paid in Cash ($)	Option Awards($) (1)	All Other Compensation($)	Total ($)
Lorin Johnson, PhD	$ 33,500	$ 195,595	-	$ 229,095
Sean MacDonald	50,000(2)	195,595	-	245,595
Frank Oakes	30,000	195,595	-	225,595
Paul Pay	42,500(2)	195,595	-	238,095
Carlo Sistilli, CPA, CMA	43,500(2)	195,595	-	239,095
Peter van der Velden	37,500(2)(3)	195,595	-	233,095

(1) The amounts shown in this column represent the aggregate grant date fair value of the share option awards computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification 718, not the actual amounts paid to or realized by the directors during the covered fiscal year. The assumptions used in determining grant date fair value of these awards are set forth in Note 9 to our audited consolidated financial statements for the year ended September 30, 2021 included in this Annual Report.

(2) The compensation was paid in Canadian dollars or British pounds and was converted from US dollars using the average foreign exchange rate for each month of the year from oanda.com.

(3) Fees of $34,326 and $3,174 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.

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Outstanding Equity Awards at September 30, 2021

The following table summarizes the equity awards made to our directors that were outstanding at September 30, 2021.

	Outstanding Options (#)
Lorin Johnson, PhD	51,389
Sean MacDonald	51,389
Frank Oakes	52,341
Paul Pay	83,788

Carlo Sistilli, CPA, CMA	51,389
Peter van der Velden	51,389

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, 2021 about our common shares that may be issued under our equity compensation plans, which consists of our 2019 Equity Incentive Compensation Plan in effect at September 30, 2021:

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)
Equity compensation plans approved by security holders	1,776,219	$ 5.06	849,732
Equity compensation plans not approved by security holders	N/A	N/A	N/A
Total	1,776,219	$ 5.06	849,732

Warrants and other equity held by directors, officers and employees outside of the compensation plans are not included in the table above.

Security Ownership of Certain Beneficial Owners and Management

The following tables sets forth certain information as of December 27, 2021, 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 27, 2021 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 13,518,799 common shares outstanding as of December 27, 2021.

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Directors and Officers

Name and Address of Beneficial Owner (1)	Beneficial Ownership	Beneficially Owned
Lorin Johnson, PhD	55,814(2)	*
Sean MacDonald	51,004(3)	*
Pardeep Nijhawan, MD	3,392,839(4)	24.9%
Frank Oakes	38,501(5)	*
Paul Pay	74,515(6)	*
Carlo Sistilli, CPA, CMA	42,116(7)	*
Peter van der Velden	2,214,987(8)	16.2%

Michael Brooks, PhD	278,584(9)	2.0%
Kathi Niffenegger, CPA	121,000(10)	*
All directors and executive officers as a group (9 persons)	**6,269,360(11)**	**45.6%**

* 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 (i) 12,786 Common Shares, (ii) 6,393 Common Shares issuable upon exercise of Class A Warrants and (iii) 36,635 Common Shares issuable upon exercise of options that are exercisable within sixty days of December 27, 2021.

(3) Consists of (i) 14,369 Common Shares and (ii) 36,635 Common Shares issuable upon exercise of options exercisable within sixty days of December 27, 2021.

(4) Consists of (A)(i) 547,312 Common Shares and (ii) 114,112 Common Shares issuable upon exercise of options exercisable within sixty days of December 27, 2021 held by Pardeep Nijhawan; (B)(i) 2,128,652 Common Shares and (ii) 6,942 Common Shares issuable upon exercise of Class A Warrants held by Pardeep Nijhawan Medicine Professional Corporation for which Pardeep Nijhawan has sole voting and dispositive power over all such shares; (C) 224,094 Common Shares held by The Digestive Health Clinic Inc. for which Pardeep Nijhawan has sole voting and dispositive power over all such shares and (D) 371,727 Common Shares held by 1968160 Ontario Inc. for which Pardeep Nijhawan has sole voting and dispositive power over all such shares.

(5) Consists of (A)(i) 37,587 Common Shares issuable upon exercise of options that are exercisable within sixty days of December 27, 2021 held by Frank Oakes and (B)(i) 914 Common Shares issuable upon exercise of Class A Warrants held by Frank and Dorothy Oakes Family Trust for which each of Frank Oakes and Dorothy Oakes, as trustees, have voting and dispositive power over all such shares.

(6) Consists of (i) 3,654 Common Shares, (ii) 1,827 Common Shares issuable upon exercise of Class A Warrants and (iii) 69,034 Common Shares issuable upon exercise of options exercisable within sixty days of December 27, 2021.

(7) Consists of (A) 36,635 Common Shares issuable upon exercise of options exercisable within sixty days of December 27, 2021 held by Carlo Sistilli and (B)(i) 3,654 Common Shares and (ii) 1,827 Common Shares issuable upon exercise of Class A Warrants held by York-Cav Enterprises Inc. for which Carlo Sistilli, as President and Director, has sole voting and dispositive power over all such shares.

(8) Consists of (A) 36,635 Common Shares issuable upon exercise of options exercisable within sixty days of December 27, 2021 held by Peter van der Velden; (B)(i) 1,897,425 Common Shares and (ii) 96,542 Common Shares issuable upon exercise of Class A Warrants held by Lumira Capital II, L.P. and (C)(i) 175,454 Common Shares and (ii) 8,928 Common Shares issuable upon exercise of Class A Warrants 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. Peter van der Velden is an executive officer of Lumira GP Inc., Lumira GP Holdings Co. and Lumira Capital Investment Management Inc.

(9) Consists of (i) 13,241 Common Shares, (ii) 1,371 Common Shares issuable upon exercise of Class A Warrants and (iii) 263,972 Common Shares issuable upon exercise of options exercisable within sixty days of December 27, 2021.

(10) Consists of (A) 118,259 Common Shares issuable upon exercise of options that are exercisable within sixty days of December 27, 2021 held by Kathi Niffenegger and (B) (i) 1,827 Common Shares and (ii) 914 Common Shares issuable upon exercise of Class A Warrants held by the Kathi Niffenegger Trust for which Kathi Niffenegger, as trustee, has sole voting and dispositive power over all such shares.

(11) Consists of (i) 5,394,198 Common Shares, (ii) 125,658 Common Shares issuable upon exercise of Class A Warrants and (iii) 749,504 Common Shares issuable upon exercise of options that are exercisable within sixty days of December 27, 2021.

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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
Lumira Capital II, L.P. (1)	2,178,352(1)	16.3%

(1) Consists of (A)(i) 1,897,428 Common Shares and (ii) 96,542 Common Shares issuable upon exercise of Class A Warrants held by Lumira Capital II, L.P. and (B)(i) 175,454 Common Shares and (ii) 8,928 Common Shares issuable upon exercise of Class A Warrants 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 during the term range from C$8,320 to C$9,020 plus HST. Rents of approximately $81,000 and $76,000 were incurred in the years ended September 30, 2021 and 2020, respectively. No rent was payable at September 30, 2021 or 2020.

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.

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Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The following table shows the aggregate fees billed for audit and other services provided for the years ended September 30, 2021 and 2020 rendered by MNP LLP.

Principal Accountant Fees and Services

Type of Service	Year Ended 2021	Year Ended 2020
Audit Fees	$ 237,605	$ 166,712
Tax Fees	10,519	24,166
Total	$ 248,124	$ 190,878

Audit Fees

Audit fees consisted of fees incurred for professional services rendered for audits and interim reviews of the years ended September 30, 2021 and 2020 and include procedures related to registrations and offerings.

Tax Fees

Tax fees consisted of fees incurred for professional services rendered for tax compliance related to tax returns during the years ended September 30, 2021 and 2020.

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 years ended September 30, 2021 and 2020.

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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.

(3) 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	Certificate of Change of Name of the Company, dated June 7, 2019 (included as Exhibit 3.6 to the Company's Annual Report on Form 10-K filed on December 12, 2019, and incorporated herein by reference).
3.6	Amended and Restated Articles of Edesa Biotech, Inc. (included as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 23, 2020, and incorporated herein by reference).
3.7	Notice of Articles of Edesa Biotech, Inc. (included as Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2020, and incorporated herein by reference)
4.1	Specimen of common share certificate (included as Exhibit 4.1 to the Company's Registration Statement on Form S-3 filed on August 30, 2019 and incorporated herein by reference)
4.2	Form of Class A Purchase Warrant issued to investors (included as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 6, 2020 and incorporated herein by reference)
4.3	Form of Class B Purchase Warrant issued to investors (included as Exhibit 4.2 to the Company's Current Report on Form 8-K filed on January 6, 2020 and incorporated herein by reference)
4.4	Form of Warrant issued to Brookline Capital Markets, a division of Arcadia Securities, LLC (included as Exhibit 4.3 to the Company's Current Report on Form 8-K filed on January 6, 2020 and incorporated herein by reference)
4.5	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)

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4.6	Form of Underwriter Warrant (included as Exhibit 4.1 to the Company's Current Report on Form 8-K/A filed on February 26, 2021 and incorporated herein by reference).
10.1	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).
10.2@	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).
10.3@	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).
10.4@	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).

10.5@	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).
10.6@	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).
10.7@	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).
10.8@	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).
10.9	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).
10.10+	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).
10.11	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).
10.12	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).
10.13+	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).
10.14	Form of Securities Purchase Agreement between Edesa Biotech, Inc. and certain investors (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 6, 2020 and incorporated herein by reference)
10.15	Form of Subscription Agreement between Edesa Biotech, Inc. and certain investors (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 6, 2020 and incorporated herein by reference)
10.16+	License Agreement by and between Edesa Biotech Research, Inc. and NovImmune SA dated April 17, 2020 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 23, 2020, and incorporated herein by reference).
10.17+	Purchase Agreement by and between Edesa Biotech Research, Inc. and NovImmune SA dated April 17, 2020 (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 23, 2020, and incorporated herein by reference).
10.18+	Securities Purchase Agreement by and between Edesa Biotech, Inc. and NovImmune SA dated April 17, 2020 (included as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on April 23, 2020, and incorporated herein by reference).
10.19@	Employment Agreement by and between the Company and Kathi Niffenegger, dated December 1, 2020 (included as Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on December 7, 2020, and incorporated herein by reference).

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10.20+	Strategic Innovation Fund Agreement among Edesa Biotech Research, Inc., Edesa Biotech, Inc., and her Majesty the Queen in right of Canada as represented by the Minister of Industry, dated February 2, 2021 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 3, 2021, and incorporated herein by reference).
10.21+	Exclusive License Agreement, dated as of March 16, 2021, by and between the Edesa Biotech Research, Inc. and Dr. Saul Yedgar (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 22, 2021, and incorporated herein by reference).
10.22@	Amendment No. 1 to Edesa Biotech, Inc. 2019 Equity Incentive Compensation Plan (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 23, 2021, and incorporated herein by reference).
10.23@	Amendment to Employment Agreement, entered into on March 19, 2021, by and between Par Nijhawan and Edesa Biotech, Inc. (included as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 14, 2021, and incorporated herein by reference).
10.24@	Amendment to Employment Agreement, entered into on March 19, 2021, by and between Kathi Niffenegger and Edesa Biotech USA, Inc. (included as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 14, 2021, and incorporated herein by reference).
10.25@	Amendment to Employment Agreement, entered into on March 19, 2021, by and between Michael Brooks and Edesa Biotech, Inc. (included as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on May 14, 2021, and incorporated herein by reference).
14.1	Code of Ethics and Business Conduct (included as Exhibit 14.1 to the Company's Annual Report on Form 10-K filed on December 12, 2019, and incorporated herein by reference).

21	Subsidiaries of Edesa Biotech, Inc. (included as Exhibit 21 to the Company's Annual Report on Form 10-K filed on December 7, 2020, and incorporated herein by reference).
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.

** The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of Edesa Biotech, Inc. under the Securities Act of 1933, as amended, or the Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

@ 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.

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SIGNATURES

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

EDESA BIOTECH, INC.

Date: December 28, 2021

/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 28, 2021
/s/ Kathi Niffenegger **Kathi Niffenegger**	Chief Financial Officer (Principal Financial and Accounting Officer)	December 28, 2021
/s/ Lorin Johnson **Lorin Johnson**	Director	December 28, 2021
/s/ Sean MacDonald **Sean MacDonald**	Chairman of the Board of Directors	December 28, 2021
/s/ Frank Oakes **Frank Oakes**	Director	December 28, 2021
/s/ Paul Pay **Paul Pay**	Director	December 28, 2021
/s/ Carlo Sistilli **Carlo Sistilli**	Director	December 28, 2021
/s/ Peter van der Velden **Peter van der Velden**	Director	December 28, 2021

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders 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, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for each of the years in the two-year period ended September 30, 2021, 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, 2021 and 2020, and the results of its consolidated operations and its consolidated cash flows for each of the years in the two-year period ended September 30, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that 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

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

Toronto, Canada
December 28, 2021

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EDESA BIOTECH, INC.
Consolidated Balance Sheets

	September 30, 2021	September 30, 2020
Assets:		
Current assets:		
Cash and cash equivalents	**$ 7,839,259**	$ 7,213,695
Accounts and other receivable	**3,302,827**	87,446
Prepaid expenses and other current assets	**948,645**	802,877
Total current assets	**12,090,731**	8,104,018
Non-current assets:		
Property and equipment, net	**14,989**	14,815
Intangible asset, net	**2,382,364**	2,483,536
Operating lease right-of-use assets	**96,571**	160,006
Total assets	**$ 14,584,655**	$ 10,762,375
Liabilities, shareholders' equity and temporary equity:		
Current liabilities:		
Accounts payable and accrued liabilities	**$ 1,379,842**	$ 1,460,127
Short-term operating lease liabilities	**78,808**	69,730
Total current liabilities	**1,458,650**	1,529,857
Non-current liabilities:		
Long-term payables	**47,202**	29,928
Long-term operating lease liabilities	**20,512**	94,460
Total liabilities	**1,526,364**	1,654,245
Commitments *(Note 7)*		
Temporary equity:		
Convertible preferred shares	-	2,476,955
Shareholders' equity:		
Capital shares		
Authorized unlimited common and preferred shares without par value		
Issued and outstanding:		
13,295,403 common shares (September 30, 2020 - 9,615,119)	**34,887,721**	18,500,853
Additional paid-in capital	**4,871,461**	1,550,480
Accumulated other comprehensive loss	**(205,262)**	(287,204)
Accumulated deficit	**(26,495,629)**	(13,132,954)

Total shareholders' equity	**13,058,291**	6,631,175
Total liabilities, shareholders' equity and temporary equity	**$ 14,584,655**	$ 10,762,375

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EDESA BIOTECH, INC.
Consolidated Statements of Operations and Comprehensive Loss

	Years Ended	
	September 30, 2021	**September 30, 2020**
Revenues:		
Product sales	**$ -**	$ 328,801
Expenses:		
Cost of sales	-	17,601
Research and development	**17,947,072**	3,329,451
General and administrative	**5,734,260**	3,382,591
	23,681,332	6,729,643
Loss from Operations	**(23,681,332)**	(6,400,842)
Other Income (Loss):		
Reimbursement grant income	**10,340,839**	-
Interest income	**11,165**	37,778
Foreign exchange loss	**(13,022)**	(366)
	10,338,982	37,412
Loss before income taxes	**(13,342,350)**	(6,363,430)
Income tax expense	**800**	800
Net Loss	**(13,343,150)**	(6,364,230)
Exchange differences on translation	**81,942**	54,870
Net Comprehensive Loss	**$ (13,261,208)**	$ (6,309,360)
Weighted average number of common shares	**12,077,822**	8,607,161
Loss per common share - basic and diluted	**$ (1.10)**	$ (0.74)

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EDESA BIOTECH, INC.
Consolidated Statements of Cash Flows

	Years Ended	
	September 30, 2021	**September 30, 2020**
Cash Flows from Operating Activities:		
Net loss	**$ (13,343,150)**	$ (6,364,230)
Adjustments for:		
Depreciation and amortization	**118,788**	57,563
Share-based compensation	**3,195,469**	598,359
Changes in working capital items:		
Accounts and other receivable	**(3,229,954)**	127,131
Prepaid expenses and other current assets	**(281,361)**	(404,066)
Accounts payable and accrued liabilities	**(124,724)**	998,903
Net cash used in operating activities	**(13,664,932)**	(4,986,340)
Cash Flows from Investing Activities:		

Proceeds on sales of property and equipment	-	53,412
Purchase of property and equipment	**(6,146)**	(4,856)
Purchase of intangible assets	-	(29,483)
Purchase of short-term investments	-	(500,000)
Proceeds from maturities of short-term investments	-	500,000
Net cash provided by (used in) investing activities	**(6,146)**	19,073
Cash Flows from Financing Activities:		
Proceeds from issuance of common shares and warrants	**12,662,357**	4,360,500
Proceeds from exercise of warrants	**1,658,769**	3,223,804
Proceeds from exercise of share options	**41,981**	11,571
Payments for issuance costs of common shares	**(188,366)**	(475,720)
Payments for issuance costs of convertible preferred shares	-	(57,154)
Proceeds from borrowings	-	29,748
Net cash provided by financing activities	**14,174,741**	7,092,749
Effect of exchange rate changes on cash and cash equivalents	**121,901**	57,630
Net change in cash and cash equivalents	**625,564**	2,183,112
Cash and cash equivalents, beginning of year	**7,213,695**	5,030,583
Cash and cash equivalents, end of year	**$ 7,839,259**	$ 7,213,695
Supplemental Disclosure of Non-cash Financing Activities:		
Preferred shares converted from temporary equity to common shares	**$ 2,496,480**	$ -
Issuance costs withheld from gross proceeds from issuance of common shares	**1,087,184**	-
Fair value of compensation warrants to underwriter	**407,022**	-
Issuance of convertible preferred shares to acquire license	-	2,500,000
Fair value of placement agent warrants	-	18,051

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EDESA BIOTECH, INC.
Consolidated Statements of Changes in Shareholders' Equity

	Shares #	Common Shares	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
Balance - September 30, 2019	**7,504,468**	**$12,005,051**	**$ 327,768**	**$ (342,074)**	**$ (6,734,615)**	**$ 5,256,130**
Issuance of common shares in equity offerings	1,354,691	3,070,358	1,290,142	-	-	4,360,500
Issuance costs including fair value of underwriter warrants	-	(349,756)	(125,964)	-	-	(475,720)
Issuance of common shares upon exercise of warrants	751,510	3,754,265	(530,461)	-	-	3,223,804
Issuance of common shares upon exercise of share options	4,450	20,935	(9,364)	-	-	11,571
Preferred return on convertible preferred shares	-	-	-	-	(34,109)	(34,109)
Share-based compensation	-	-	598,359	-	-	598,359
Net loss and comprehensive loss	-	-	-	54,870	(6,364,230)	(6,309,360)
Balance - September 30, 2020	**9,615,119**	**$18,500,853**	**$ 1,550,480**	**$ (287,204)**	**$ (13,132,954)**	**$ 6,631,175**
Issuance of common shares in equity offerings	2,148,963	13,749,541	-	-	-	13,749,541
Issuance costs including fair value of underwriter warrants	-	(1,841,413)	407,022	-	-	(1,434,391)
Issuance of common shares upon exercise of warrants	381,650	1,912,725	(253,956)	-	-	1,658,769
Issuance of common shares upon exercise of share options	19,746	69,535	(27,554)	-	-	41,981
Conversion of convertible preferred shares	1,129,925	2,496,480	-	-	-	2,496,480
Preferred return on convertible preferred shares	-	-	-	-	(19,525)	(19,525)
Share-based compensation	-	-	3,195,469	-	-	3,195,469
Net loss and comprehensive loss	-	-	-	81,942	(13,343,150)	(13,261,208)
Balance - September 30, 2021	**13,295,403**	**$34,887,721**	**$ 4,871,461**	**$ (205,262)**	**$ (26,495,629)**	**$ 13,058,291**

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 inflammatory and immune-related diseases with clear unmet medical needs. The Company is organized under the laws of British Columbia, Canada and is headquartered in Markham, Ontario. It operates under its wholly owned subsidiaries, Edesa Biotech Research, Inc., an Ontario, Canada corporation, and Edesa Biotech USA, Inc. (formerly known as Stellar Biotechnologies, Inc. prior to November 2020), a California, USA corporation.

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 common shares, exercises of common share purchase warrants, convertible preferred shares, convertible loans, government grants and tax incentives. For the years ended September 30, 2021 and 2020, the Company reported net losses of $13.34 million and $6.36 million, respectively.

Under the Company's contribution agreement with the Canadian government's Strategic Innovation Fund (SIF), the Company is eligible to receive cash reimbursements up to C$14.05 million ($11 million USD) in the aggregate for certain research and development expenses related to the Company's EB05 clinical development program. For the year ended September 30, 2021, the Company recorded $10.34 million in grant income.

On March 2, 2021, the Company completed a registered public offering of an aggregate of 1,562,500 common shares, no par value, of the Company at an offering prices of $6.40 per share for net proceeds of $8.89 million, after deducting underwriter fees and related offering expenses.

For year ended September 30, 2021, the exercise of warrants and options as well as sales under the Company's equity distribution agreement with RBC Capital Markets, LLC resulted in the issuance of 987,859 common shares and net cash proceeds to the Company of $5.12 million.

At September 30, 2021, the Company had cash and cash equivalents of $7.84 million, working capital of $10.63 million, shareholders' equity of $13.06 million and an accumulated deficit of $26.50 million. The Company plans to finance operations for at least the next twelve months with cash and cash equivalents on hand, equity sales under the at-the-market offering program and reimbursements of eligible research and development expenses under the Company's agreement with the Canadian government's SIF.

Impact of COVID-19

The ongoing COVID-19 pandemic has severely impacted global economic activity and has caused material disruptions to almost every industry directly or indirectly. The full impact of the pandemic remains uncertain and ongoing developments related to the pandemic may cause material impacts to the Company's future operations, clinical study timelines and financial results. While the full impact of the COVID-19 pandemic to business and operating results presents additional uncertainty, the Company's management continues to use reasonably available information to assess impacts to the Company's business plans and financial condition.

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. and Edesa Biotech USA, Inc. All intercompany balances and transactions have been eliminated upon consolidation.

The accompanying consolidated financial statements include the years ended September 30, 2021 and 2020.

3. Significant accounting policies

Use of estimates

The preparation of consolidated 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; intangible assets; operating lease right-of-use assets; deferred income taxes; classification of convertible preferred shares as liability or equity; the determination of fair value of share-based compensation; the determination of fair value of warrants in order to allocate proceeds from equity issuances; 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, which is the Company's and its wholly owned subsidiary's, Edesa Biotech USA, Inc., functional currency. The functional currency of the Company's wholly owned subsidiary, Edesa Biotech Research, Inc., as determined by management, is Canadian 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

There were no investments during the year ended September 30, 2021. Investments during the year ended September 30, 2020 consisted of U.S. Treasury bills with original maturities between 13 and 52 weeks. They were reported at amortized cost, which approximated fair value. The Company regularly reviewed these investments to determine whether any decline in fair value below the amortized cost basis occurred that was other than temporary. If a decline in fair value occurred that was determined to be other than temporary, the cost basis of the investment would be written down to fair value. There were no investments outstanding at September 30, 2021 and 2020.

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 reimbursement grant income for the Company's federal grant with the Canadian government's Strategic Innovation Fund (SIF) and Harmonized Sales Tax (HST) refunds receivable. As of September 30, 2021, all outstanding accounts, grants 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.

The depreciation policy for the principal asset categories are calculated as follows:

Computer equipment 30% declining balance method or straight line 3 years
Furniture and equipment 20% declining balance method

Intangible assets

Intangible assets represent the exclusive world-wide rights to know-how, patents and data relating to certain monoclonal antibodies (the Constructs), including sublicensing rights, acquired by entering into a license agreement with a pharmaceutical development company. Unless earlier terminated, the term of the license agreement will remain in effect for 25 years from the date of first commercial sale of licensed products containing the Constructs. Subsequently, the license agreement will automatically renew for five-year periods unless either party terminates the agreement in accordance with its terms. Intangible assets are stated at their historical cost, amortized on a straight-line basis over their expected useful lives, which is 25 years, and subject to impairment review at the end of each reporting period.

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 12.

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.

Reimbursement grant income is recognized based on the reimbursement rate included in the government contribution agreement when allowable expenses have been incurred.

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 wholly owned Canadian subsidiary is measured using the Canadian dollar as the functional currency. Assets and liabilities of the Canadian operation 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 operation 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 net 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 would be reflected in diluted earnings per share by application of the "if converted" method. The dilutive effect of outstanding options and warrants and their equivalents would be reflected in diluted earnings per share by application of the treasury stock method. However, conversion of outstanding convertible preferred shares, options and warrants would have an antidilutive effect on loss per share for the years ended September 30, 2021 and 2020 and are therefore excluded from the computation of diluted loss per share. See Notes 8 and 9 for outstanding convertible preferred shares, options and warrants at September 30, 2021 and 2020. See Note 14 for subsequent issuance of common shares.

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 net loss, comprehensive loss, depreciation and total assets also represent segmented amounts.

Adoption of Recent Accounting Pronouncements

On October 1, 2019, the Company adopted Accounting Standards Codification (ASC) Topic 842 Leases using the modified retrospective transition method, applying the new standard to all leases existing at the date of initial application. In addition, the Company elected the package of practical expedients in transition, which permitted the Company not to reassess prior conclusions about lease identification, lease classification and initial direct costs on leases that commenced prior to adoption of the new standard. The Company also elected the ongoing practical expedient not to recognize operating lease right-of-use assets and operating lease liabilities for short-term leases. As a result of adopting the new standard, the Company recognized operating lease right-of-use (ROU) assets of approximately $234,000 and operating lease liabilities of approximately $234,000 on the balance sheet for one operating lease with a term longer than 12 months at adoption. There was no impact to opening accumulated deficit. The Company had three short-term operating leases upon adoption that did not follow the ROU model. The ROU assets are initially measured at cost and amortized using the straight-line method through the end of the lease term. The lease liabilities are measured at the present value of the lease payments that are not paid at the commencement date, discounted using the Company's incremental borrowing rate.

On October 1, 2020, the Company adopted ASC 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 Company did not record any credit losses as a result of adoption and there was no impact to opening accumulated deficit.

Future accounting pronouncements

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes, modifying ASC Topic 740, Income Taxes. The amendments in ASU 2019-12, among other things, remove certain exceptions to the general principles in ASC 740 and seek more consistent application by clarifying and amending the existing guidance. The guidance is effective for public entities for fiscal years beginning after December 15, 2020, including interim periods within those years, with early adoption permitted for periods for which financial statements have not yet been issued. These standards are effective for the Company during the fiscal year ending September 30, 2022. Management expects that ASU 2019-12, will not have a significant impact on the Company's consolidated financial statements.

4. Property and equipment

Property and equipment, net consisted of the following:

	September 30, 2021	September 30, 2020
Computer equipment	**$ 42,855**	$ 34,651
Furniture and equipment	**5,987**	5,694
	48,842	40,345
Less: accumulated depreciation	**(33,853)**	(25,530)
Total property and equipment, net	**$ 14,989**	$ 14,815

Depreciation expense amounted to $8,323 and $9,602 for the years ended September 30, 2021 and 2020, respectively.

5. Intangible assets

Acquired License

In April 2020, the Company entered into a license agreement with a pharmaceutical development company to obtain exclusive world-wide rights to know-how, patents and data relating to certain monoclonal antibodies (the Constructs), including sublicensing rights. Unless earlier terminated, the term of the license agreement will remain in effect for 25 years from the date of first commercial sale of licensed products containing the Constructs. Subsequently, the license agreement will automatically renew for five-year periods unless either party terminates the agreement in accordance with its terms.

Under the license agreement, the Company is exclusively responsible, at its expense, for the research, development manufacture, marketing, distribution and commercialization of the Constructs and licensed products and to obtain all necessary licenses and rights. The Company is required to use

commercially reasonable efforts to develop and commercialize the Constructs in accordance with the terms of a development plan established by the parties.

The Company has determined that the license has multiple alternative future uses in research and development projects and sublicensing in other countries or for other disease indications. The value of the acquired license is recorded as an intangible asset with amortization over the estimated useful life of 25 years and evaluation for impairment at the end of each reporting period.

The required upfront license payment of $2.5 million was paid by issuance of Series A-1 Convertible Preferred Shares. The value of the license includes acquisition legal costs. See Note 7 for license commitments and Note 8 for temporary equity.

Intangible assets, net consisted of the following:

	September 30, 2021	**September 30, 2020**
The Constructs	**$ 2,529,483**	$ 2,529,483
Less: accumulated amortization	**(147,119)**	(45,947)
Total intangible assets, net	**$ 2,382,364**	$ 2,483,536

Amortization expense amounted to $101,172 and $45,947 for the years ended September 30, 2021, and 2020, respectively.

Total estimated future amortization of intangible assets for each fiscal year is as follows:

Year Ending	
September 30, 2022	$ 101,172
September 30, 2023	101,172
September 30, 2024	101,172
September 30, 2025	101,172
September 30, 2026	101,172
Thereafter	1,876,504
	$ 2,382,364

6. Leases

Related party operating lease

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 option period is not included in the operating lease right-of-use assets and liabilities.

The gross amounts of assets and liabilities related to operating leases were as follows:

	September 30, 2021	**September 30, 2020**
Assets:		
Operating lease right-of-use assets	$ 96,571	$ 160,006
Liabilities:		
Current:		
Short-term operating lease liabilities	$ 78,808	$ 69,730
Long-term:		
Long-term operating lease liabilities	20,512	94,460
Total lease liabilities	$ 99,320	$ 164,190

The components of lease cost were as follows:

	Years Ended	
	September 30, 2021	**September 30, 2020**
Operating lease cost, included in general and administrative on the Statements of Operations	$ 81,207	$ 76,331

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EDESA BIOTECH, INC.
Notes to Consolidated Financial Statements
For the Years Ended September 30, 2021 and 2020

Lease terms and discount rates were as follows:

	September 30, 2021	September 30, 2020
Remaining lease term (months):	15	27
Estimated incremental borrowing rate:	6.5%	6.5%

The approximate future minimum lease payments under operating leases at September 30, 2021 were as follows:

Year Ending	
September 30, 2022	$ 82,942
September 30, 2023	20,736
Total lease payment	103,678
Less imputed interest	4,358
Present value of lease liabilities	99,320
Less current installments	78,808
Long-term lease liabilities excluding current installments	$ 20,512

Cash flow information was as follows:

	Years Ended	
	September 30, 2021	September 30, 2020
Cash paid for amounts included in the measurement of lease liabilities, included in accounts payable and accrued liabilities on the Statements of Cash Flows	$ 81,209	$ 76,331

Other operating leases

The Company also leased facilities through its California subsidiary under two operating leases that expired in September 2020. The total rent under these leases included in general and administrative expenses was $201,421 for the year ended September 30, 2020. There was no rent under these leases during the year ended September 30, 2021.

7. Commitments

Research and other commitments

The Company has commitments for contracted research organizations who perform clinical trials for the Company's ongoing clinical studies, other service providers and the drug substance acquired in connection with a license agreement. Aggregate future contractual payments at September 30, 2021 are as follows:

Year Ending	
September 30, 2022	$ 3,315,000
September 30, 2023	201,000
September 30, 2024	57,000
September 30, 2025	38,000
	$ 3,611,000

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EDESA BIOTECH, INC.
Notes to Consolidated Financial Statements
For the Years Ended September 30, 2021 and 2020

License and royalty commitments

In April 2020, through its Ontario subsidiary, the Company entered into a license agreement with a third party to obtain exclusive world-wide rights to certain know-how, patents and data relating to certain monoclonal antibodies (the Constructs), including sublicensing rights. An intangible asset for the acquired license has been recognized. See Note 5 for intangible assets. Under the license agreement, the Company is committed to payments of up to an aggregate amount of $356 million contingent upon meeting certain milestones outlined in the license agreement, primarily relating to future potential commercial approval and sales milestones. The Company also has a commitment to pay royalties based on any net sales of products containing the

Constructs in the countries where the Company directly commercializes the products containing the Constructs and a percentage of any sublicensing revenue received by the Company and its affiliates in the countries where it does not directly commercialize the products containing the Constructs. No royalty or sublicensing payments were made to the third party during the year ended September 30, 2021. In connection with this license agreement and pursuant to a purchase agreement entered into in April 2020, the Company acquired drug substance of one of the Constructs for an aggregate purchase price of $5.0 million, payable in two future installments, the first when the Company is ready to initiate a Phase 2 trial and the second when the Company is ready to initiate a Phase 3 trial. A payment of $2.5 million was made for the drug substance during the year ended September 30, 2021. The remaining purchase commitment is included in the table above for the year ending September 30, 2022.

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. 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 years ended September 30, 2021 and 2020, respectively.

In March 2021, through its Ontario subsidiary, the Company entered into a license agreement with the inventor of the same pharmaceutical product to acquire global rights for all fields of use beyond those named under the 2016 license agreement. For the year ended September 30, 2021, the Company recorded an expense of $212,000 as a result of meeting milestones outlined in the 2021 license agreement. The Company is committed to remaining payments of up to an aggregate amount of $69.1 million, primarily relating to future potential commercial approval and sales milestones. In addition, if the Company fails to file an investigational new drug application or foreign equivalent (IND) for the product within a certain period of time following the date of the agreement, the Company is required to remit to the inventor a fixed license fee annually as long as the requirement to file an IND remains unfulfilled.

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 $23,786 and $11,936 during the years ended September 30, 2021 and 2020, respectively.

8. Temporary Equity

Series A-1 Convertible Preferred Shares

As described in Note 5, in April 2020, the Company issued 250 convertible preferred shares valued at $2.5 million designated as Series A-1 Convertible Preferred Shares (the "Series A-1 Shares") to acquire a license. The Series A-1 Shares had no par value, a stated value of $10,000 per share and ranked, with respect to redemption payments, rights upon liquidation, dissolution or winding-up of the Company, or otherwise, senior in preference and priority to the Company's common shares.

Subject to certain exceptions and adjustments for share splits, each Series A-1 Share was convertible six months after its date of issuance into a number of the Company's common shares calculated by dividing (i) the sum of the stated value of such Series A-1 Share plus a return equal to 3% of the stated value of such Series A-1 Share per annum (collectively, the "Preferred Amount") by (ii) a fixed conversion price of $2.26.

Because the convertible preferred shares were redeemable outside the control of the Company, they were presented as temporary equity rather than permanent shareholders' equity until they were converted or redeemed. At September 30, 2021 all 250 Series A-1 Shares have been converted to common shares.

Issued and outstanding Series A-1 Convertible Preferred Shares:

	Series A-1 Convertible Preferred Shares (#)	Series A-1 Convertible Preferred Shares
Balance - September 30, 2019	-	$ -
Issuance of convertible preferred shares	250	2,500,000
Convertible preferred share issuance costs	-	(57,154)
Preferred return on convertible preferred shares	-	34,109
Balance - September 30, 2020	250	$ 2,476,955
Preferred return on convertible preferred shares	-	19,525
Conversion to common shares	(250)	(2,496,480)
Balance - September 30, 2021	-	$ -

9. Capital shares

Equity offerings

On March 2, 2021, the Company closed an underwritten offering of 1,562,500 common shares, no par value, at a price to the public of $6.40 per share less underwriting discounts and commissions. Gross proceeds from the offering amounted to $10,000,000. The Company granted to the underwriters a 30-day option to purchase up to an additional 234,375 common shares, which expired with no further shares issued. On the closing date the Company issued Underwriter Warrants to purchase an aggregate of up to 109,375 common shares at an exercise price of $8.00 per share, expiring on February 26, 2026.

The direct costs related to the issuance of the common shares were $1,106,625. These direct costs were recorded as an offset against gross proceeds. The Company also recorded the fair value of underwriter warrants in the amount of $407,022 as share-based compensation to non-employees under additional paid-in capital and an offset against gross proceeds.

On January 8, 2020, the Company closed a registered direct offering of 1,354,691 common shares, no par value and a concurrent private placement of Class A Purchase Warrants to purchase an aggregate of up to 1,016,036 common shares and Class B Purchase Warrants to purchase an aggregate of up to 677,358 common shares. Gross proceeds from the offering amounted to $4,360,500.

The Class A Purchase Warrants were exercisable on or after July 8, 2020, at an exercise price of $4.80 per share and will expire on July 8, 2023. The Class B Purchase Warrants were exercisable on or after July 8, 2020, at an exercise price of $4.00 per share and expired on November 8, 2020. In connection with the offering, the Company also issued warrants to purchase an aggregate of 12,364 common shares to certain affiliated designees of the placement agent as part of the placement agent's compensation. The placement agent warrants were exercisable on or after July 6, 2020, at an exercise price of $3.20 per share, and will expire on January 6, 2025.

The warrants are considered contracts on the Company's own shares and are classified as equity. The Company allocated gross proceeds with $3,070,358 as the value of common shares and $1,008,743 as the value of Class A Purchase Warrants and $281,399 as the value of Class B Purchase Warrants under additional paid-in capital in the consolidated statements of changes in shareholders' equity on a relative fair value basis.

The direct costs related to the issuance of the common shares and warrants were $468,699. These direct costs were recorded as an offset against gross proceeds with $330,025 being recorded under common shares and $138,674 being recorded under additional paid-in capital on a relative fair value basis. The Company also recorded the fair value of placement agent warrants in the amount of $18,051 as share based compensation to nonemployees under additional paid-in capital and an offset against gross proceeds with $12,710 being recorded under common shares and $5,341 being recorded under additional paid-in capital on a relative fair value basis.

Equity distribution agreements

On September 28, 2020, the Company entered into an equity distribution agreement with RBC Capital Markets, LLC (RBCCM), as sales agent, pursuant to which the Company could offer and sell, from time to time, common shares through an at-the-market equity offering program for up to $9.2 million in gross cash proceeds. The distribution agreement was terminated on February 25, 2021. During the year ended September 30, 2021, 586,463 shares were sold under the distribution agreement, resulting in $3,749,542 in gross proceeds. The commissions and direct costs of the offering program totaled $325,199 and were recorded as an offset against gross proceeds. No shares were sold during the year ended September 30, 2020.

Subsequent to September 30, 2021, the Company entered into a new Equity Distribution Agreement with RBCCM, as sales agent, pursuant to which the company may offer and sell, from time to time, common shares through an at-the-market equity offering program for up to $15 million in gross cash proceeds. RBCCM will use commercially reasonable efforts to sell the common shares from time to time, based upon the Company's instructions. The Company has no obligation to sell any of the shares, and may at any time suspend sales under the distribution agreement or terminate the agreement in accordance with its terms. The total amount of cash that may be generated under this distribution agreement is uncertain and depends on a variety of factors, including market conditions and the trading price of the Company's common shares.

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 and the fair value of warrants issued. Option valuation models require the input of highly subjective assumptions including the expected price volatility. The Company calculates expected volatility based on historical volatility of the Company's share price. When there is insufficient data available, the Company uses a peer group that is publicly traded to calculate expected volatility. The Company adopted interest-free rates by reference to the U.S. treasury yield rates. The Company calculated the fair value of share options granted based on the expected life of 5 years considering expected forfeitures during the option term of 10 years. Expected life of warrants is based on warrant terms. The Company did not and is not expected to declare any dividends. 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 Warrant Shares (#)	Weighted Average Exercise Price
Balance - September 30, 2019	48,914	$ 11.19
Issued	1,705,758	4.47
Exercised	(761,951)	4.31
Balance - September 30, 2020	992,721	$ 4.92
Issued	109,375	8.00
Exercised	(381,650)	4.35
Balance - September 30, 2021	720,446	$ 5.69

The weighted average contractual life remaining on the outstanding warrants at September 30, 2021 is 25 months.

The following table summarizes information about the warrants outstanding at September 30, 2021:

Number of Warrants (#)	Exercise Prices	Expiry Dates
28,124	$ 15.90	May 2023
563,685	$ 4.80	July 2023
7,484	$ 4.81	June 2024
11,778	$ 3.20	January 2025
109,375	$ 8.00	February 2025
720,446		

The fair value of warrants issued during the years ended September 30, 2021 and 2020 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Year Ended September 30, 2021	Year Ended September 30, 2020		
	Underwriter Warrants	Class A Warrants	Class B Warrants	Placement Agent Warrants
Risk free interest rate	0.67%	1.61%	1.55%	1.61%
Expected life	5 years	3.5 years	0.83 years	5 years
Expected share price volatility	94.20%	103.81%	134.15%	101.89%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

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Share Options

The Company adopted an Equity Incentive Compensation Plan in 2019 (the 2019 Plan) administered by the independent members of the Board of Directors. 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 at September 30, 2021 is 2,625,951 including shares available for the exercise of outstanding options.

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 and the exercise price of each option is determined by the independent members of the Board of Directors.

Options have been granted under the 2019 Plan allowing the holders to purchase common shares of the Company as follows:

	Number of Options (#)	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value
Balance - September 30, 2019	319,645	$ 3.39	$ 2.72
Granted	366,365	3.35	2.54

Exercised	(4,450)	2.60	1.91
Forfeited	(5,790)	2.73	2.03
Expired	(333)	145.20	145.20
Balance - September 30, 2020	675,437	$ 3.30	$ 2.56
Granted	1,145,000	6.21	4.65
Exercised	(19,746)	2.10	1.35
Forfeited	(22,566)	6.02	4.02
Expired	(1,906)	102.49	101.12
Balance - September 30, 2021	1,776,219	$ 5.06	$ 3.79

In October 2020 and April 2021, the independent members of the Board of Directors granted a total of 430,000 and 603,000 options, respectively, to directors, officers and employees of the Company pursuant to the 2019 Plan. The options have a term of 10 years and an exercise price equal to the Nasdaq closing price on the grant dates. Options granted for directors in April 2021 have monthly vesting in equal proportions over 12 months beginning on the grant date. Options granted for directors in October 2020 and all options for officers and current employees have monthly vesting in equal proportions over 36 months beginning on the grant date.

During the year ended September 30, 2021, the independent members of the Board of Directors granted a total of 112,000 options to new employees of the Company pursuant to the 2019 Plan. The options have a term of 10 years with vesting in equal proportions over 36 months beginning on the monthly anniversary of the grant date following 90 days of employment, and an exercise price equal to the Nasdaq closing price on the grant dates.

In February 2020, the independent members of the Board of Directors granted a total of 352,365 options to directors, officers and employees of the Company pursuant to the 2019 Plan. The options have a term of 10 years with 33% vesting on the grant date, with a pro rata amount of the balance vesting monthly for the next 36 months and an exercise price equal to the Nasdaq closing price on the grant date.

In September 2020, the independent members of the Board of Directors granted a total of 14,000 options to new employees of the Company pursuant to the 2019 Plan. The options have a term of 10 years with vesting in equal proportions over 36 months beginning on the monthly anniversary of the grant date following 90 days of employment, and an exercise price equal to the Nasdaq closing price on the grant date.

The aggregate intrinsic values of options outstanding at September 30, 2021 and 2020 were $4.46 million and $3.71 million, respectively. The aggregate intrinsic value of options exercised during the years ended September 30, 2021 and 2020 were $0.09 million and $0.01 million, respectively.

The weighted average contractual life remaining on the outstanding options at September 30, 2021 is 103 months.

The following table summarizes information about the options under the 2019 Plan outstanding and exercisable at September 30, 2021:

Number of Options (#)	Exercisable at September 30, 2021 (#)	Range of Exercise Prices		Expiry Dates
214	214	C$	638.40	Nov 2021
238	238	$	304.08	Dec 2022
3,499	3,499	$	35.28 - 93.24	Sep 2023-Mar 2025
296,403	294,783	C$	2.16	Aug 2027-Dec 2028
335,365	229,248	$	3.16	Feb 2030
429,000	142,652	$	7.44 - 8.07	Sep 2030-Oct 2030
711,500	151,072	$	5.25 - 5.74	Jan 2031-Sep 2031
1,776,219	821,706			

The options exercisable at September 30, 2021 had a weighted average exercise price of $4.21, an intrinsic value of $2.93 million and a weighted average remaining life of 94 months. There were 954,513 options at September 30, 2021 that had not vested with a weighted average exercise price of $5.80 an intrinsic value of $1.53 million and a weighted average remaining life of 111 months.

The fair value of options granted during the years ended September 30, 2021 and 2020 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Years Ended September 30, 2021	September 30, 2020
Risk free interest rate	0.31% - 0.90%	0.28% - 1.45%
Expected life	5 years	5 years
Expected share price volatility	85.33% - 97.28%	94.42% - 104.14%
Expected dividend yield	0.00%	0.00%

The Company recorded $3,195,469 and $598,359 of share-based compensation expenses for the years ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, the Company had approximately $2.18 million of unrecognized share-based compensation expense, which is expected to be recognized over a period of 36 months.

10. Reimbursement Grant Income and Receivable

Reimbursement grant income for the Company's federal grant with the Canadian government's Strategic Innovation Fund (SIF) is recorded based on the claim period. Claims during the year ended September 30, 2021 included reimbursement of eligible costs from the eligibility date in the SIF contribution agreement through September 30, 2021. At September 30, 2021, grant reimbursements receivable of $3,030,005 were included in accounts and other receivable.

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11. Income Tax

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

	Years Ended	
	September 30, 2021	**September 30, 2020**
Net loss before recovery of income taxes	**$ (13,342,350)**	$ (6,363,430)
Canadian federal and provincial statutory income tax rate	**26.5%**	26.5%
Expected income tax recovery	**$ (3,536,000)**	$ (1,686,000)
Permanent differences	**847,000**	159,000
Effect of foreign currency and foreign tax rate differences	**(309,200)**	23,800
Share issuance cost booked through equity or capitalization	**(447,000)**	(144,000)
Change in valuation allowance	**3,446,000**	1,648,000
Income tax (recovery) expense	**$ 800**	$ 800

Components of the net deferred tax asset or liability

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 and liabilities are as follows:

	September 30, 2021	**September 30, 2020**
Non-capital losses carried forward - Canada	**$ 8,073,000**	$ 4,881,000
Non-capital losses carried forward - U.S.	**1,628,000**	1,609,000
Research and development tax credits	**1,294,000**	1,253,000
Share issuance and financing costs	**628,000**	473,000
Operating lease liabilities	**26,000**	43,000
Other temporary differences	**15,000**	16,000
Subtotal	**11,664,000**	8,275,000
Less: valuation allowance	**(11,620,000)**	(8,173,000)
Total net deferred tax assets	**$ 44,000**	$ 102,000
Property and equipment	**$ (18,000)**	$ (17,000)
Operating lease right-of-use assets	**(26,000)**	(42,000)
Deferred share issuance costs	**-**	(43,000)
Total deferred tax liabilities	**$ (44,000)**	$ (102,000)
Net deferred taxes	**$ -**	$ -

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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 Edesa Biotech USA, 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 $25.6 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, 2021 expire as follows:

2025	C$	21,000
2026		56,000
2027		114,000
2028		233,000
2029		688,000
2030		860,000
2031		685,000
2032		673,000
2033		266,000
2034		1,708,000
2035		2,207,000
2036		2,216,000
2037		2,123,000
2038		3,714,000
2039		1,732,000
2040		7,046,000
2041		14,046,000
Total	C$	38,388,000

Share issuance and financing costs will be fully amortized in 2025.

The U.S. non-capital losses carried forward at September 30, 2021 totaled approximately $7,655,000, which do not expire for federal taxes. The U.S. state research and development tax credits carried forward at September 30, 2021 totaled approximately $619,000, which do not expire for state taxes. The approximate U.S. state non-capital losses carried forward at September 30, 2021 expire as follows:

2039	$	70,000
2040		150,000
2041		68,000
Total	$	288,000

12. 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, U.S. Treasury Bills and money market mutual funds of U.S. government securities. 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 reimbursement grant and HST refunds receivable are not considered significant since amounts are due from the Canadian government's Strategic Innovation Fund (SIF) and 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, 2021, the Company and its Canadian subsidiary had assets denominated in Canadian dollars of approximately C$9.8 million and the U.S. dollar exchange rate as at this date was equal to 1.2711 Canadian dollars. Based on the exposure at September 30, 2021, a 10% annual change in the Canadian/U.S. exchange rate would impact the Company's loss and other comprehensive loss by approximately $773,000.

(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.

13. Related party transactions

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

- During the years ended September 30, 2021 and 2020, the Company incurred rent expense of $81,000 and $76,000 from a company controlled by the Company's CEO, 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.

14. Subsequent events

On November 22, 2021, the Company entered into a new Equity Distribution Agreement with RBC Capital Markets, LLC (RBCCM), as sales agent, pursuant to which the company may offer and sell, from time to time, common shares through an at-the-market equity offering program for up to $15 million in gross cash proceeds. Subsequently, 223,396 common shares were sold under the distribution agreement with RBCCM for gross proceeds of approximately $1.29 million.

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in Registration Statement Nos. 333-217480, 333-236121 and 333-255485 on Form S-8, Registration Statement No. 333-233567 on Form S-3 and Registration Statement No. 333-236608 on Form S-1 of Edesa Biotech, Inc. of our report dated December 28, 2021, relating to the consolidated financial statements of Edesa Biotech, Inc. for the years ended September 30, 2021 and 2020, which report appears in this Annual Report on Form 10-K for the year ended September 30, 2021.

/s/ MNP LLP
Chartered Professional Accountants
Licensed Public Accountants

Toronto, Canada
December 28, 2021

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 28, 2021

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 28, 2021

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 year ended September 30, 2021, 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 28, 2021

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 year ended September 30, 2021 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 28, 2021

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