Edesa Biotech®

2025 Annual Report

Developing Host-Directed Therapeutics for Immuno-Inflammatory Diseases

Edesa Biotech®

Dear Fellow Shareholders,

2025 has been a year of strategic advancement and validation for Edesa's clinical development pipeline. Our plans to advance a high-impact dermatology asset alongside our first-in-class respiratory therapeutic are progressing, and we believe Edesa is well positioned for our mission to deliver transformative therapies for patients with serious immune and inflammatory conditions.

Among our 2025 accomplishments, we strengthened our balance sheet, initiated manufacturing activities for our vitiligo clinical program, extended our government support, and closed out the year with positive Phase 3 clinical results for our anti-TLR antibody. Time and time again, our small Edesa team has demonstrated their entrepreneurial spirit and their ability, when needed, to deliver results for patients and stakeholders alike.

I am pleased to share with you this year-end update on our progress:

- **February 2025 capital raise.** In February 2025, we completed a capital raise led by institutional investors and company insiders, including myself. This show of support from institutional investors has opened new doors for us as we seek to broaden our shareholder base and establish relationships with strategic partners. Most importantly, it provided us the opportunity to launch manufacturing and regulatory activities for our vitiligo program.

- **First-in-class treatment**. Vitiligo significantly impacts the lives of millions worldwide, yet there are few approved drugs that address the systemic nature of the disease. We believe that the favorable safety profile of Edesa's antibody, EB06, and its ability to target the immune system mechanisms impacting both lesional and non-lesional skin, has the potential to make it a preferable option for vitiligo patients – especially for those with large lesions or those patients concerned about the safety risks of other treatments. This year we initiated manufacturing activities to support U.S. regulatory approval of a Phase 2 study, and we are looking forward to initiating recruitment. In parallel to our clinical activities, we are engaging potential strategic partners to accelerate development and maximize value of this program.

- **Positive Phase 3 results.** This year marked a pivotal moment for our respiratory program. Our Phase 3 clinical study of paridiprubart (EB05) in Acute Respiratory Distress Syndrome (ARDS) patients met its primary and secondary endpoints with statistical significance. We believe that these findings not only provide important validation of our host-directed approach but also support paridiprubart's potential use as a standard of care treatment for ARDS, and potentially other acute and chronic indications.

- **Validation from two governments.** This year, we extended our Canadian government funding agreement to support manufacturing and development for our respiratory program. We also announced that the $117 million U.S. government-funded study evaluating three novel therapeutics (including Edesa's paridiprubart) enrolled their first patients. In light of our positive Phase 3 results, we are engaging with potential strategic and government partners to seek additional non-dilutive support and collaborative arrangements that advance our programs.

- **Fiscal discipline.** In FY2025, we once again demonstrated this flexibility and our prudent use of working capital, and ended the fiscal year with $10.8 million in cash and cash equivalents, with subsequent $3.4 million in net proceeds from our at-the-market offering program.

Looking ahead, our priorities for the coming year include executing the Phase 2 vitiligo study, advancing respiratory assets toward partnering and potential commercialization, expanding manufacturing, and maintaining financial discipline.

While challenges remain, our differentiated science and disciplined approach give us confidence in delivering meaningful outcomes for patients and stakeholders alike. On behalf of the board of directors, management and employees — many of whom are investing alongside you — thank you for your continued support and trust in Edesa Biotech.

Sincerely,

Par Nijhawan, MD, FRCPC, AGAF
Chief Executive Officer

December 2025

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, 2025

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to Section 240.10D-1(b). ☐

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, 2025, 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 nonaffiliates was approximately $13,978,238, which was calculated based on 7,022,678 common shares outstanding as of that date, of which 5,728,786 common shares were held by nonaffiliates at the closing price of the registrant's common shares on The Nasdaq Capital Market on such date.

As of December 12, 2025, the registrant had 8,333,823 common shares issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

EDESA BIOTECH, INC.

ANNUAL REPORT ON FORM 10-K
Year Ended September 30, 2025

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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 comply with the continued listing requirements of Nasdaq;
- our ability to identify, develop and commercialize additional products or product candidates;
- reliance on key personnel; and
- general changes in economic or business conditions.

Except as required by law, we undertake no obligation to update forward-looking statements. You should review the factors and risks and other information we describe in the reports we will file from time to time with the SEC.

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.

PART 1

Item 1. BUSINESS.

Overview

We are a biopharmaceutical company developing innovative ways to treat inflammatory and immune-related diseases. Our approach is to acquire, develop and commercialize drug candidates based on mechanisms of action that have demonstrated proof-of-concept in human subjects. We prioritize our efforts on disease indications where there is compelling scientific rationale, no approved therapies or where there are unmet medical needs, and where there are large addressable market opportunities, among other factors. Our clinical pipeline is focused on two therapeutic areas: Medical Dermatology and Respiratory.

In Medical Dermatology we are developing EB06, an anti-CXCL10 monoclonal antibody candidate, as a therapy for vitiligo, a common autoimmune disorder that causes skin to lose its color in patches. CXCL10 has been shown to play a key role in the disease, and neutralization of CXCL10 has been demonstrated to both prevent and reverse depigmentation in animal models. To date, EB06 has demonstrated a favorable safety and tolerability profile. We have received regulatory approval from Health Canada to conduct a Phase 2 proof of concept study of EB06 in patients with moderate-to-severe nonsegmental vitiligo and we are in discussions with the U.S. Food and Drug Administration ("FDA") for the same study. Subject to regulatory approval, we anticipate initiating enrollment by midyear 2026. Our Medical Dermatology assets also include EB01 (1.0% daniluromer cream), a Phase 3-ready asset developed for use as a potential therapy for moderate-to-severe chronic Allergic Contact Dermatitis ("ACD"), a common occupational skin condition. This asset is at the partnering stage.

Our most advanced Respiratory drug candidate is EB05 (paridiprubart). Paridiprubart represents a new class of emerging therapies called Host-Directed Therapeutics ("HDTs") that are designed to modulate the body's own immune response when confronted with infectious diseases or even chemical agents. In October 2025, we reported that paridiprubart met primary and secondary endpoints with statistical significance, providing clinically meaningful improvement in survival and recovery, in a truncated Phase 3 clinical study of hospitalized patients with Acute Respiratory Distress Syndrome ("ARDS"), a life-threatening form of respiratory failure. Paridiprubart is also being evaluated in an ongoing U.S. government-funded platform study investigating three novel threat-agnostic HDTs in hospitalized patients with ARDS. Certain development expenses, including manufacturing scale-up, for our EB05 program are also eligible for reimbursement from the Government of Canada under a 2023 grant and funding award. We are also pursuing additional uses for paridiprubart in chronic diseases.

Competitive Strengths

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

- *Validated technology and drug development capabilities.* We believe that the strength of our technologies and our drug development capabilities have been validated by our favorable clinical data, our multiple arrangements with third parties to develop and commercialize their clinical-stage drug candidates, more than C$37 million in competitive government grant and funding awards, and selection for a U.S. government-funded clinical study by experts from the Biomedical Advanced Research and Development Authority ("BARDA"), the Centers for Disease Control and Prevention, Department of Defense, FDA and National Institutes of Health.

- *Innovative 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, vitiligo affects up to 2% of the world's population and ARDS is associated with approximately 10% of ICU admissions globally, yet both diseases have limited treatment options.

- *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 U.S. and in various foreign jurisdictions. In addition to patent protection, we intend to utilize trade secrets and market exclusivity afforded to new chemical entities and biologics, 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 and 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 Exzell Pharma Inc., which was sold to BioLab Pharma in 2022, and 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.

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:

- *Prioritize the development and commercialization of later-stage product candidates.* Our goal is to obtain regulatory approval and commercialize multiple clinical assets in our pipeline. We focus on disease indications that we believe have clear regulatory pathways and interest from potential licensing or development partners. Given the high capital requirement for pivotal clinical studies, our preferred strategy is to seek public and private partners for Phase 3 clinical testing and scale-up. We also plan to evaluate opportunities to apply, as applicable, for expedited regulatory review and orphan drug programs, which could potentially lead to accelerated clinical development and commercialization timelines for our product candidates.

- *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 believe that our monoclonal antibody candidates have potential utility in additional indications, including chronic conditions like pulmonary fibrosis.

- *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 or regions outside North America where a partner may contribute additional resources, infrastructure and expertise.

- *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. We do not currently intend to invest significant capital in basic research, which can be expensive and time-consuming.

Medical Dermatology

Vitiligo

Vitiligo is a chronic autoimmune disease that causes the loss of skin pigmentation in patches. It occurs when melanocytes, the pigment-producing skin cells, die or stop producing melanin. The extent of color loss from vitiligo is unpredictable and can affect the skin on any part of the body. It is estimated that vitiligo prevalence is between 0.5 to 2% of the global population. Vitiligo patients are not born with lesioned skin. Rather, unpigmented spots appear over time, with about 50% of patients having symptom onset before 20 years of age. There are two main forms of vitiligo: segmental, where depigmentation is limited to one area and side of the body, and nonsegmental (generalized), where patches of pale skin occur on both sides of the body, often symmetrically. Nonsegmental vitiligo is the most common type of vitiligo.

At present, there is only one FDA-approved therapeutic indicated for repigmentation in vitiligo, a Janus Kinase ("JAK") inhibitor cream (ruxolitinib); however, there is an increased risk of serious infections and malignancies associated with ruxolitinib. Similarly, off-label non-surgical therapies tend to be time-consuming, expensive, or prone to causing side effects. Common treatments include topical drugs, phototherapies and surgical interventions. Based on the availability and limitations of current treatments, we believe there is a significant need for well targeted and systemic immunotherapies.

EB06

EB06 is a fully human monoclonal antibody candidate that binds specifically and selectively to chemokine ligand 10 ("CXCL10") and inhibits the interaction of CXCL10 with its receptors, CXCR3A and CXCR3B. CXCL10 plays an important role in both the innate and adaptive immune responses in patients with vitiligo. EB06 is currently formulated for intravenous administration, with plans for a potential subcutaneous formulation.

We believe that there is a significant scientific rationale to target CXCL10 in order to reduce disease symptoms and progression in vitiligo patients. CXCL10 is highly expressed in vitiligo patients and has been shown to play both a key role in the trafficking of anti-melanocytic T-cells to the epidermis (adaptive immune system response) as well as in inducing apoptosis (death) of melanocytes (innate immune response). Furthermore, neutralization of CXCL10 has been demonstrated to both prevent and reverse depigmentation in animal models.

We believe that EB06 has a number of anticipated advantages compared to other treatments available and under development for vitiligo, including: a) EB06's mechanism of action addresses both the adaptive and innate immune systems' roles in disease maintenance and progression; b) EB06 is designed to treat both lesional and non-lesional skin; c) as a systemic therapy, EB06 can treat larger body surface areas, including patients with lesions on >10% of their body surface area; d) EB06 is administered less frequently than topicals and oral medications; and e) targeted immunotherapies, like EB06, are designed to provide patients a safer and more effective option than drugs with known off-target effects or even Black Box warnings.

We have approval from Health Canada to conduct a Phase 2 study of EB06 in moderate to severe nonsegmental vitiligo patients. As planned, the double-blind, placebo-controlled trial will evaluate the safety and efficacy of EB06 in approximately 150 subjects, who will be administered intravenous infusions of either EB06 or placebo during the treatment period, followed by a follow-up period. The primary efficacy outcome measurement will be the percentage of patients achieving ≥50% decrease (improvement) from baseline in facial Vitiligo Area Scoring Index ("F-VASI50"). F-VASI is a composite measurement of the overall area of facial vitiligo patches and degree of depigmentation within patches. Before proceeding with enrollment in Canada, we may modify our current Canadian study design with Health Canada to conform the protocol with other jurisdictions. To conduct the planned study at U.S. investigational centers, we must first complete the manufacturing of the drug and submit related data to the FDA as part of an investigational new drug application ("IND"). To date, we have completed a process confirmation batch of EB06 and intend to initiate engineering and clinical-grade ("GMP") manufacturing runs in the coming weeks. We anticipate data from these activities to be submitted to the FDA once the work is completed. Subject to regulatory approval, we anticipate initiating recruitment by midyear 2026. We anticipate topline results for this Phase 2 study could be available within as few as 9 to 12 months following regulatory clearance in the U.S.

In three previous clinical studies of 65 healthy volunteers and non-vitiligo subjects in total, EB06 has demonstrated a favorable safety and tolerability profile. The first Phase 1 study was a double-blind, placebo-controlled, ascending, single-dose study in 20 healthy subjects. Participants received single intravenous doses of EB06, ranging from 0.1 to 20 mg/kg. No deaths or serious adverse events ("AEs") were reported. EB06 was generally safe and well tolerated at doses up to 20 mg/kg. A second Phase 1 study evaluated the effect of single doses of EB06 to generate proof-of-principle data on the neutralization of CXCL10 in an inflammatory setting in humans using an experimentally nickel-induced allergic contact dermatitis model. For this double-blind, placebo-controlled study, 16 subjects were exposed to single intravenous doses of 180 and 720 mg of EB06. No deaths or serious AEs were reported, and EB06 was generally safe and well tolerated. A third, open-label, single-arm Phase 2 study investigating multiple administrations of EB06 in patients with primary biliary cirrhosis with an incomplete response to ursodeoxycholic acid ("UDCA") was also completed. A total of 29 patients were treated with 10 mg/kg intravenous doses of EB06 every two weeks, for a total of 6 doses. No serious treatment-related AEs were reported. In addition, in a variety of pre-clinical in vitro and in vivo experiments, EB06 demonstrated the ability to neutralize the biological activity of CXCL10. In animal toxicology studies, EB06 was well-tolerated.

Allergic Contact Dermatitis

Contact dermatitis is a common occupational and work-related skin condition. The disease can be either irritant contact dermatitis or ACD. Based on market research, we believe that together these conditions cost up to $2 billion annually in the U.S. as a result of lost work, reduced productivity, medical care and disability payments. Based on the prevalence data of contact allergy in the general population, which we sourced from scientific literature and market reports, we estimate that there are as many as 30 million people in the seven major markets (US, UK, Germany, France, Spain, Italy, Japan) and Canada with ACD, and of these, we estimate that 40% have chronic exposure or frequent recurring exposure to a causative allergen. Based on the mechanism of action and topical delivery, we believe that the total addressable patient population for EB01 is as high as five million people in the seven major markets and Canada.

ACD is caused by an allergen interacting with skin and usually occurs on areas of the body that are open to the environment, with a high prevalence on the hands and face. Common allergens associated with ACD include plants, metals, plastics and resins, rubber additives, dyes, biocides, and various cosmetics. The disease is characterized by inflammation, erythema (redness), pruritus (itchiness), and blistering of the skin. Inflammation can vary from mild irritation and redness to open sores, depending on the type of irritant, the body part affected and the degree of sensitivity. ACD can become chronic if not treated or if the causative allergen is not removed. In many chronic cases, the causative allergen is unknown or difficult to avoid (as an example, the allergen is present in the workplace). The immune mechanisms involved in ACD are well documented. During the initial contact with the offending allergen, the immune system is sensitized. Upon subsequent contact, a delayed-type hypersensitivity reaction (Type IV) occurs at the point of contact between the skin and the allergen. As a cell-mediated response, the immune reaction primarily involves the interaction of T cells with antigens rather than an antibody response.

EB01 (daniluromer)

EB01 is a potential first-in-class, topical vanishing cream containing a novel, non-steroidal anti-inflammatory compound. Daniluromer 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. Our ACD development program is at the partnering stage following completion of a Phase 2b clinical study.

Respiratory

Acute Respiratory Distress Syndrome

ARDS is a life-threatening form of respiratory failure characterized by an exaggerated and dysfunctional immune response, rapid onset of widespread inflammation in the lungs, and hypoxia (an absence of enough oxygen in the tissues to sustain bodily functions). ARDS can be precipitated by a number of conditions including viral and bacterial pneumonia, sepsis, chest injury and even mechanical ventilation, among other causes. ARDS has historically accounted for 10% of ICU admissions, representing more than 3 million patients globally each year. Based on the prevalence data of ARDS, we estimate that there are as many as 600,000 ARDS-related admissions to ICUs each year in the seven major markets (U.S, UK, Germany, France, Spain, Italy, Japan) and Canada. According to medical literature, ICU stays for ARDS patients in the U.S. range from 7 to 21 days on average, at an average cost of more than $100,000 per patient.

For moderate to severe cases of ARDS, treatments remain limited and patients suffer high mortality rates. Countering the exaggerated innate immune response in ARDS patients 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.

EB05 (paridiprubart)

EB05 is an intravenous formulation of paridiprubart, a first-in-class monoclonal antibody (mAb) that has been engineered to alter inflammatory signaling by binding to and blocking the activation of TLR4. Specifically, paridiprubart 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 and clinical results to date, we believe that paridiprubart could ameliorate TLR4-mediated inflammation cascades in ARDS patients, thereby reducing lung injury, ventilation rates and mortality. We are currently exploring development and commercialization partnerships for paridiprubart as well as expedited regulatory pathways that may be available in certain jurisdictions.

Positive Phase 3 Results

In a Phase 3 clinical study, we evaluated paridiprubart (EB05) as a treatment for ARDS. Participants were 18 years or older, receiving Invasive Mechanical Ventilation ("IMV") with or without additional organ support at the time of hospitalization. They were randomly assigned (1:1) to standard of care treatment ("SOC") with paridiprubart (n=56), or SOC with placebo (n=48). Efficacy outcomes were 28-day and 60-day mortality and proportion of patients with a decrease of ≥ 2 points in the WHO Covid-19 Severity Scale ("WCSS") at 28-days. We opted to discontinue enrollment early for business reasons.

The data from the Phase 3 study demonstrated that paridiprubart met primary and secondary endpoints with statistical significance. Paridiprubart led to a clinically significant reduction in mortality through 60 days, as well as a significant reduction in the proportion of patients requiring IMV.

Paridiprubart in the most conservative intention-to-treat ("ITT") population met the primary endpoint, demonstrating a statistically significant and clinically meaningful benefit for reduced mortality at 28 days. Patients treated with paridiprubart + SOC had a lower risk of death (39%) compared to those receiving placebo (52%), representing an absolute improvement in survival of 13% at 28 days with paridiprubart demonstrating a relative reduction in the risk of death of 25% compared to placebo (n=104; $p<0.001$). A durable survival benefit was also demonstrated at 60 days, with patients treated with paridiprubart plus SOC demonstrating a lower risk of death (46%) compared to those receiving placebo (59%), representing an absolute improvement in survival of 13% with a relative risk reduction of 22% for paridiprubart compared to placebo (n=104; $p=0.003$). In addition, subjects receiving paridiprubart + SOC demonstrated a 41% higher relative rate of clinical improvement, meaning patients no longer required IMV and/or organ support at Day 28.

The results from a safety population of more than 275 subjects, which included patients enrolled during the interim between the Phase 2 and Phase 3 study, demonstrated that EB05 was generally well-tolerated and consistent with the observed safety profile to date.

Previous Phase 2 Clinical Study

In a signal-finding Phase 2 clinical study evaluating paridiprubart in hospitalized Covid-19 patients at various disease severity levels, paridiprubart demonstrated a statistically significant and clinically meaningful trend for 28-day mortality for all randomized subjects in the critically ill cohort (the intent to treat, or ITT, population). The 28-day death rate in the EB05 plus SOC arm was 7.7% versus 40% in the placebo + SOC arm in critically severe patients on ECMO therapy (extracorporeal membrane oxygenation) IMV plus organ support with ARDS at baseline ($p=0.04$). The Survival Analysis using Cox's Proportional Hazard Model also demonstrated that patients treated with paridiprubart + SOC had an 84% reduction in the risk of dying when compared to placebo + SOC at 28 days. The Phase 2 study demonstrated that paridiprubart appears to be well-tolerated and consistent with the observed safety profile.

U.S. Government Funded Study

In June 2024, EB05 was selected through a competitive process by BARDA, part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, as one of three drug candidates for evaluation in a U.S. government-funded Phase 2 platform study. The randomized, double-blinded, placebo-controlled, multi- center clinical trial is investigating novel threat-agnostic host-directed therapeutics, including EB05, in hospitalized adult patients with ARDS due to a variety of causes. The BARDA-funded study is being managed under a BARDA contract with PPD Development, LP, a clinical research business of Thermo Fisher Scientific, Inc. For the EB05 cohort of the study, patients are being randomized one-to-one to either EB05 + SOC or to a placebo + SOC control arm. We are providing drug products to the study as well as technical support at our own expense.

Federal Funding from the Government of Canada

Our wholly owned subsidiary Edesa Biotech Research, Inc. ("Edesa Biotech Research") is party to a multi- year contribution agreement with the Canadian government's Strategic Innovation Fund, or SIF, dated October 12, 2023, and an Amendment Agreement No. 1 to the agreement, dated September 30, 2025 (together, the "2023 SIF Agreement"). Under the 2023 SIF Agreement, the Government of Canada committed up to C$23 million in partially repayable funding toward (i) conducting and completing a Phase 3 clinical study of our investigational therapy EB05 in critical-care patients with

ARDS, and (ii) submitting EB05 for governmental approvals and manufacturing scale-up, following, and subject to, completing the Phase 3 study and (iii) conducting two non-clinical safety studies to assess the potential long-term impact of EB05 exposure. Of the C$23 million committed by SIF, up to C$5.75 million is not repayable. The remaining C$17.25 million is conditionally repayable starting in 2032 only if and when we earn gross revenue. Edesa Biotech Research has agreed to complete the project by December 31, 2028. In the event that we or Edesa Biotech Research breach our obligations under the 2023 SIF Agreement, subject to applicable cure, the SIF may exercise a number of remedies, including suspending or terminating funding under the 2023 SIF Agreement, demanding repayment of funding previously received and/or terminating the 2023 SIF Agreement. The performance obligations of Edesa Biotech Research under the 2023 SIF Agreement are guaranteed by us.

Our previously completed Phase 2 study of EB05 was also funded, in part, by SIF. Under a February 2021 agreement (the "2021 SIF Agreement" and together with the 2023 SIF Agreement, the "SIF Agreements"), the Government of Canada committed C$14.1 million in nonrepayable funding for an international Phase 2 study and certain pre-clinical experiments. In the event that we or Edesa Biotech Research breach our obligations under the 2021 SIF Agreement, subject to applicable cure, the SIF may exercise a number of remedies, including 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 us. All potential funding available under the 2021 SIF Agreement has been received.

As of the date of this filing, we have met all of our performance and reporting requirements under our SIF Agreements.

Other Future Product Candidates

We are seeking to advance additional product candidates as well as add new disease indications for current product candidates, and from time to time we may request approval from regulators in various jurisdictions to initiate new clinical studies or amend the scope of current clinical studies. 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. For instance, there is significant evidence that targeting TLR4 in chronic respiratory conditions, such as pulmonary fibrosis, could result in therapeutic benefit for patients. In light of our other development priorities, we are evaluating the timing for the next steps in our EB07 program for the treatment of pulmonary fibrosis. Initiating recruitment in the EB07 study is subject to, among other limitations, funding, regulatory approvals, drug manufacturing and activation of clinical investigational sites.

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 EB01 in the U.S., 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 and expired in 2024. We did not seek patent term extension in the U.S. for these patents, and they no longer provide patent protection for EB01. 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 that utilize our anti-TLR4 and anti-CXCL10 monoclonal antibody technology in the U.S., 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 U.S. 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. We have also filed provisional patent applications for use of these monoclonal antibody technologies in vitiligo (EB06) and systemic sclerosis and pulmonary fibrosis (EB07).

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 up to 12 years of exclusivity for EB05/EB07 and EB06 after approval in the U.S., and, for any of these drug products, eight years of exclusivity after approval in Canada and ten years of exclusivity after approval in the European Union ("EU").

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

In April 2020, through Edesa Biotech Research, we entered into an exclusive license agreement (the "NovImmune License Agreement") with NovImmune SA ("NovImmune"), 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"). We 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 NovImmune License Agreement will remain in effect for 25 years from the date of first commercial sale of Licensed Products. Subsequently, the NovImmune License Agreement will automatically renew for 5- year periods unless either party terminates the agreement in accordance with its terms.

Under the NovImmune 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. We are 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 (all of which were subsequently converted into common shares) pursuant to the terms of a securities purchase agreement entered into between the parties concurrently with the NovImmune License Agreement. In addition, we are committed to payments of various amounts to NovImmune upon meeting certain development, approval and commercialization milestones as outlined in the NovImmune 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 we directly commercialize Licensed Products and a percentage of sublicensing revenue received by us in the countries where we do not directly commercialize Licensed Products. As of the date of this 10-K, the commercialization milestones have not been achieved.

The NovImmune License Agreement provides that NovImmune will remain the exclusive owner of existing intellectual property in the Constructs and that we will be the exclusive owner of all intellectual property resulting from the exploitation of the Constructs pursuant to the license. Subject to certain limitations, we are responsible for prosecuting, maintaining and enforcing all intellectual property relating to the Constructs. During the term of the agreement, we also have the option to purchase the licensed patents and know-how at a price to be negotiated by the parties. If we default or fail to perform any of the terms, covenants, provisions or its obligations under the NovImmune License Agreement, NovImmune has the option to terminate the NovImmune License Agreement, subject to providing us with an opportunity to cure such default. The NovImmune License Agreement is also terminable by NovImmune upon the occurrence of certain bankruptcy related events pertaining to us.

In connection with the NovImmune License Agreement and pursuant to a purchase agreement entered into by the parties in April 2020, we acquired from NovImmune its inventory of the TLR4 antibody for an aggregate purchase price of $5.0 million.

License and Development Agreement with Pendopharm

In August 2017, Edesa Biotech Research entered into an exclusive license and development agreement with Pendopharm, a division of Pharmascience Inc. (the "Pendopharm License Agreement"). Pursuant to the Pendopharm License 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 Pendopharm License 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 Pendopharm License Agreement shall also terminate upon the termination of certain other license agreements that we have with third parties. Pendopharm also has the right to terminate the Pendopharm License Agreement for convenience upon 120 days' notice to us.

License Agreements with Yissum and Inventor

In June 2016, Edesa Biotech Research, entered into an exclusive license agreement with Yissum, which was subsequently amended in April 2017, May 2017 and October 2022 (collectively, the "Yissum License Agreement"). Pursuant to the Yissum 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 Yissum License Agreement will expire on a country by country basis on the later of (i) the date of expiry of the last valid licensed patent in such country; (ii) the date of expiry of any period of exclusivity granted to a product by a regulatory authority in such country or (iii) the date that is 15 years after the first commercial sale of a product in such country.

Under the Yissum 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 Yissum License Agreement up to an aggregate amount of $18.4 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. As of the date of this 10-K, the commercialization milestones have not been achieved.

The Yissum 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 Yissum License Agreement, Yissum has the option to terminate the Yissum License Agreement, subject to providing us with an opportunity to cure such default. We have the right to terminate the Yissum License 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.

In March 2021, through Edesa Biotech Research, we entered into a license agreement with the inventor of the same pharmaceutical product, which was subsequently amended in September 2023 (together, the "Inventor License Agreement"), to acquire global rights for all fields of use beyond those named under the Yissum License Agreement. As a result of the Inventor License Agreement, we now hold exclusive global rights to the pharmaceutical product that forms the basis of EB01 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. We are exclusively responsible, at our 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 IND application or foreign equivalent 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 on a quarterly basis as long as the requirement to file an IND remains unfulfilled. We also have a commitment to pay the inventor a royalty based on net sales of the product in countries where we, or an affiliate, directly commercialize 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. Unless earlier terminated, the term of the Inventor 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 or (ii) the date that is 15 years after the first commercial sale of a product in such country. If we default or fail to perform any of the terms, covenants, provisions or our obligations under the Inventor License Agreement, the inventor has the option to terminate the Inventor License Agreement, subject to providing us with an opportunity to cure such default. We have the right to terminate the Inventor License 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 the inventor 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 increased industry demand, CMOs have generally reported that supplies of raw materials and critical components necessary for manufacturing processes have been more challenging and expensive to obtain, and longer lead times may be required for scheduling future production runs.

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.

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 U.S., 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 or regions outside North America 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 product candidate, our potential competitors include, among others, Aclaris Therapeutics, Inc., Dermavant Sciences, Inc., Incyte Corporation, Leo Pharma A/S, Pfizer Inc., Sanofi S.A., Astria Therapeutics, Inc. and Sun Pharmaceutical Industries Ltd. For our EB05 product candidate, there are numerous competing therapies, including prophylactic vaccines for the SARS-Cov2 and influenza viruses, experimental stem cell therapies, novel therapeutics and repurposed commercial drugs. Our potential competitors include, among others: Aqualung Therapeutics Corporation, Eli Lilly and Company, InflaRx N.V., Enzychem Lifesciences Corp., Merck & Co, Inc., Mesoblast Limited, Pfizer Inc., Regeneron Pharmaceuticals, Inc., Roche Holding AG and Veru Inc. For any future product for vitiligo or fibrotic diseases, potential competitors, include, among others: Bausch Health, Eli Lilly and Company, Incyte Corporation, Boehringer Ingelheim AG, UCB, Chemomab Therapeutics Ltd., F. Hoffmann-La Roche AG, GlaxoSmithKline plc., Leo Pharma A/S, Merck & Co., Inc., Mitsubishi Tanabe Pharma Corporation, Vyne Therapeutics Inc, and Sanofi S.A. 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 U.S., Canada, EU 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 U.S., 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 U.S., 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.

U.S. Regulations

In the U.S., 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 U.S. generally involves the following:

- *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 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 human volunteers 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.

- *Product Candidate Chemistry, Controls and Manufacturing.* Concurrent with clinical trials, companies typically complete additional animal and laboratory studies, develop additional information about the chemistry and physical characteristics of the drug, and finalize a process for manufacturing the product in commercial quantities in accordance with FDA's current Good Manufacturing Practices ("cGMP") requirements. The manufacturing process must consistently produce quality batches of the drug, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of an investigational drug or biologic product, an NDA or BLA is prepared and submitted to the FDA. FDA approval must be obtained before commercial marketing and distribution of the product may begin in the U.S. The NDA or BLA must include results of product development, laboratory, and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will file the NDA or BLA and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each NDA or BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes annual program fees on prescription drugs, including biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. No user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the application also includes a non-orphan indication.

Within 60 days following submission, the FDA reviews the NDA or BLA to determine if it is substantially complete before the agency files it. The FDA may request additional information or may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to an initial filing review before the FDA files it. Once the submission is filed, the FDA begins an in-depth substantive review of the NDA or BLA. Under PDUFA, FDA has agreed to performance goals to review 90% of original standard NDAs or BLAs within 10 months of the 60-day filing date and 90% of original priority NDAs or BLAs within 6 months of the 60-day filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs and BLAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA/BLA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA or BLA submission. The FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP to assure and preserve the product's identity, safety, strength, quality, potency and purity.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations when making decisions. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to assure that the benefits of the biologic outweigh the potential risks of the product to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use ("ETASU"). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient- specific

registries. If the FDA concludes that a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving an NDA or BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in substantial compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites, to assure that the clinical trials were conducted in compliance with GCP requirements. To assure GMP, GLP and GCP compliance, an applicant must incur significant expenditure of time, money, and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA or BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently from how we interpret the same data. If the agency decides not to approve the NDA or BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may resubmit, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing.

If a product candidate receives regulatory approval, the FDA will issue an approval letter. The approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to assess further a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the U.S., or a patient population greater than 200,000 individuals in the U.S. and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the U.S. will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA or NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product marketing exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA or NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

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.

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.

U.S. Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our current and potential product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be highly similar to, or interchangeable with, an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

The BPCIA includes, among other provisions: A 12-year exclusivity period from the date of first licensure, or BLA approval, of the reference product, during which approval of a 351(k) application referencing that product may not be made effective; a 4-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted; and, an exclusivity period for certain biological products that have been approved through the 351(k) pathway as interchangeable biosimilars. The BPCIA also establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHSA.

The BPCIA is complex and its interpretation and implementation by the FDA remains unpredictable. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate effect, implementation, and meaning of the BPCIA is subject to uncertainty.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to a BLA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act ("BPCA") provides a six-month extension of any non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug or biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

FDA Post-Approval Requirements

Once an NDA or BLA is approved, maintaining post-approval compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register the establishments where the approved products are made with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP and other laws. Rigorous and extensive FDA regulation of products continues after approval, particularly with respect to GMP. We rely, and expect to continue to rely, on third parties for the production and distribution of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable U.S. requirements after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Other Regulatory Requirements

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

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

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

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

Canada Regulations

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 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 the date of this filing, we have 17 full-time employees: ten 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 the date of this filing, 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.

Corporate Information

We are a British Columbia, Canada corporation founded 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. In June 2019, we acquired the Ontario corporation through a reverse acquisition and changed our name to Edesa Biotech, Inc.

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 Securities and Exchange Commission ("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 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 us 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 Exchange Act, and are thus allowed to provide simplified executive compensation disclosures in our filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting and have certain other reduced disclosure obligations with respect to our SEC filings.

Item 1A. RISK FACTORS.

Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes, before deciding to invest in our securities. 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 and cause the market price of our securities to decline. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects could be materially and adversely affected. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward- looking statements. See "*Forward-Looking Statements And Other Matters*" *for a discussion of some of the forward-looking statements that are qualified by these risk factors.*

Summary of Risks

The following summarizes key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed description of each risk factor contained below.

- We are a late-stage biopharmaceutical company with no products approved for commercial sale, and 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.
- 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, commercialization efforts or other operations.
- 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. We cannot give any assurance that we will receive regulatory approval for such product candidates or any other product candidates, which is necessary before they can be commercialized.
- We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.
- A successful anti-sPLA2, anti-TLR4 or anti-CXCL10 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.
- 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 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.

- 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.
- 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.
- 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.
- 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 and our ability to access the capital markets could be negatively impacted.

Risks Related to Our Business, Financial Position and Capital Requirements

We are a late-stage biopharmaceutical company with no products approved for commercial sale, and 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, 2025, we had an accumulated deficit of $65.9 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 without corresponding revenue 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 U.S. 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. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our securities and our ability to raise capital.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

We have recognized recurring losses, and at September 30, 2025, we had an accumulated deficit of $65.9 million. We anticipate operating losses to continue for the foreseeable future due to, among other things expenses related to ongoing activities to research, develop and commercialize our product candidates. We expect that our cash and cash equivalents at September 30, 2025, net proceeds from the HCW ATM (as defined below) and reimbursements of eligible R&D expenses under the 2023 SIF Agreement may not be sufficient to fund our operating expenses for one year after the date of the filing of this Form 10-K, unless we delay spending on our EB-06 program or raise additional capital. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative and research and development activities are forward- looking statements and involve risks and uncertainties. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials. These factors among others create a substantial doubt about our ability to continue as a going concern.

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, commercialization efforts or other operations.

We expect our research and development expenses to increase substantially in the future, particularly for any drug candidates beyond Phase 2 clinical development or if we 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.

We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, future debt financing into which we may enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our shares, make certain investments and engage in certain merger, consolidation or asset sale transactions. In addition, any debt financing would require us to dedicate a portion of our cash resources to the payment of interest and principal, thereby reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, share price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

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. To the extent that 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, would result in increased fixed payment obligations and 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. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing shareholders. 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 fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development of our product candidates.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, clinical trials of our product candidates, and other operations and potential product acquisitions and in-licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in-licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in-licensing or similar strategic business transaction.

Changes in the U.S. political and regulatory environment could affect availability of government funding that we or our third party collaborators may rely on, which could negatively impact the development of our product candidates.

We and our current and future third party collaborators may rely on government programs or agencies, such as the National Institutes for Health ("NIH"), as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which

is often unpredictable. For example, on February 7, 2025, the NIH issued Notice Number NOT-OD-25-068, a guidance document pronouncing that funding in NIH grants to cover certain indirect costs would be capped at 15% for existing and future grant recipients, a rate that is substantially lower than the existing rates. There is ongoing litigation challenging this policy change. Reductions in NIH grants to us and our third party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates.

We partially rely on government grants to contribute to our EB05 (paridiprubart) development program. If we are unable to satisfy our contractual obligations and manage our covenants or meet expected milestones, the development of EB05 may be extended, delayed, modified, or terminated and we may be required to repay all or part of the grant earlier than expected.

In February 2021, we and Edesa Biotech Research signed the 2021 SIF Agreement whereby the Government of Canada agreed to contribute C$14.1 million in nonrepayable funding for an international Phase 2 study and certain pre-clinical experiments. In the event that we or Edesa Biotech Research breach our obligations under the 2021 SIF Agreement, subject to applicable cure, the SIF may exercise a number of remedies, including 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 us. All potential funding available under the 2021 SIF Agreement has been received. As of the date of this filing, we have met all of our performance and reporting requirements under the 2021 SIF Agreement.

On October 12, 2023, we and Edesa Biotech Research signed the 2023 SIF Agreement whereby the Government of Canada agreed to contribute up to C$23 million from the SIF in partially repayable funding toward of the development and commercialization of our investigational therapy EB05. Under the 2023 SIF Agreement, we agreed to complete the project, to be conducted exclusively in Canada except as permitted otherwise under certain circumstances, on or before December 31, 2028. We also have agreed to certain financial and non-financial covenants and other obligations in relation to EB05, including the achievement of certain headcount requirements in Canada, the maintenance of a collaboration with a Canadian research institute or post-secondary institutions, and the maintenance of certain research and development expenditures in Canada. In an event of default, such as our breach of our covenants and obligations under either the 2023 SIF Agreement or the 2021 SIF Agreement, the Government of Canada may suspend or terminate its contribution to the project, or require repayment. As a result, if we default on our obligations under the SIF Agreements, we may not have sufficient funds available to continue the Phase 3 clinical study of our investigational therapy EB05, and we cannot be certain that we will be able to obtain additional capital to fund the program. We are currently not in default of our obligations per the terms of either SIF Agreement.

In June 2024, EB05 was selected through a competitive process by BARDA, as one of three drug candidates for evaluation in a U.S. government-funded Phase 2 platform study. We are providing drug products to the study as well as technical support at our own expense.

Any failures on our part to satisfy any of our obligations under the above agreements could adversely affect or terminate our development of EB05.

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. We cannot give any assurance that we will receive regulatory approval for such product candidates or any other product candidates, which is necessary before they can be commercialized.

We have not completed development of and/or obtained regulatory approval for any of our product candidates. Development will require the commitment of substantial financial resources, extensive product candidate development, and clinical trials. This process takes years of effort without any assurance of ultimate success.

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, but not limited to:

- 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.

Our product development efforts with respect to our product candidates may fail for many reasons, including but not limited to:

- the failure of the product candidate in clinical studies;
- adverse patient reactions to the product candidate or indications of other safety concerns;
- insufficient clinical trial data to support the effectiveness or superiority of the product candidate;
- the inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; and
- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive.

Deterioration in general economic conditions in the U.S., Canada and globally, including the effect of prolonged periods of inflation on our suppliers, third-party service providers and potential partners, could harm our business and results of operations.

Our business and results of operations could be adversely affected by changes in national or global economic conditions. These conditions include but are not limited to inflation, rising interest rates, availability of capital markets, energy availability and costs, the negative impacts caused by pandemics and public health crises, negative impacts resulting from the military conflict between Russia and the Ukraine, and the effects of governmental initiatives to manage economic conditions. Impacts of such conditions could be passed on to our business in the form of higher costs for labor and materials, higher investigator fees, possible reductions in pharmaceutical industry-wide spending on research and development and acquisitions and higher costs of capital.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our current and future business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in certain countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our

ability to establish cost-effective production capabilities and international operations, negatively impacting our growth prospects.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

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 are exposed to risks related to currency exchange rates.

We conduct a significant portion of our operations outside of the U.S. 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, privacy 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 (“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

U.S. and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations. 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. Similarly, compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and our failure to comply with data protection laws and regulations could lead to government enforcement actions, which would cause our business and reputation to suffer.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations produce hazardous waste products. We expect to contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or

future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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. Such actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 material and adverse impact on our business, financial condition, results of operations and prospects including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, loss of eligibility to obtain marketing approvals from the FDA, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our operating results.

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. If we are not able to effectively manage our growth and expand our organization, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

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 CEO 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 executives, these agreements do not prevent our executives from terminating their employment 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. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result.

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. We could have difficulty attracting experienced personnel to our Company and may be required to expend significant financial resources in our employee recruitment and retention efforts. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

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. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition,

our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

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

Despite the implementation of security measures, our computer systems and those of third parties with which we contract are vulnerable to damage, including damage from cyberattacks, 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 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.

Any product candidate we advance into and through clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by our product candidates in clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale. We have not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our product candidates. If

any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product or, if such product candidate is approved for marketing, future adverse events could cause us to withdraw such product from the market.

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;
- 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.

If the commercial opportunity in vitiligo, chronic ACD, ARDS, or pulmonary fibrosis is smaller than we anticipate, our future revenue from our drug candidates 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 vitiligo, chronic ACD, ARDS or pulmonary fibrosis. 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 EB06, EB01, EB05 or EB07, 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, anti-TLR4 or anti-CXCL10 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, anti-TLR4 and anti-CXCL10 product candidates employ novel mechanisms of action. To our knowledge no drug companies have successfully commercialized an sPLA2 inhibitor, an anti-TLR4 antibody or an anti-CXCL10 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 any of these therapies, 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 U.S., Canada, the EU 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.

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 commercialize. 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, vitiligo, pulmonary diseases 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, EB06, EB07 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. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products manufactured and distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

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.

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 monoclonal antibody 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 also must develop satisfactory methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we fail at any of these tasks, we may not be able to obtain approval or successfully commercialize 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.

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

The development of our product candidates and clinical programs and the potential commercialization will require substantial additional capital. Given the high capital requirement for pivotal clinical studies, our preferred strategy is to seek public and private partners for Phase 3 clinical testing and scale-up. We face significant competition in seeking appropriate partners and collaborators. Whether we reach additional definitive agreements for a collaboration or partnership will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or Health Canada, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator or partner may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may not be able to negotiate collaborations or partnerships 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 product candidates, reduce or delay one or more of our development programs, delay potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may 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, EB06, EB07 or any other Edesa product candidate from regulatory authorities in any jurisdiction.

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, EB06, EB07 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.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We may seek orphan drug designation for some of our product candidates in the United States. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently

profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application for orphan drug designation with respect to any product candidate will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Increasing use of social media platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage.

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 the Yissum License Agreement 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. In 2021, we also entered into the Inventor License Agreement to acquire global rights for all fields of use beyond those named under the Yissum License Agreement. If we default or fail to perform any of the terms, covenants, provisions or our obligations under the Yissum License Agreement, Yissum has the option to terminate the Yissum 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.

In April 2020, we entered into the NovImmune License Agreement 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 and other disease indications. If we default or fail to perform any of the terms, covenants, provisions or our obligations under the NovImmune License Agreement, including milestone payments, NovImmune has the option to terminate the NovImmune 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 U.S. and other countries with respect to our proprietary technology and products. We intend to protect our proprietary position by filing patent applications in the U.S., 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 U.S. 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. 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. 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 U.S. 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 clinical-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;

- 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 and our ability to access the capital markets could be negatively impacted.

Our common shares are listed on The Nasdaq Capital Market. We must satisfy the continued listing requirements of Nasdaq, to maintain the listing of our common shares on The Nasdaq Capital Market.

There can be no assurance that we will be able to continue to maintain compliance with the Nasdaq continued listing requirements, and if we are unable to maintain compliance with the continued listing requirements, our securities may be delisted from Nasdaq, which could reduce the liquidity of our common shares materially and result in a corresponding material reduction in the price of our common shares. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees, suppliers and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common shares when you wish to do so. Further, if we were to be delisted from Nasdaq, our common shares may no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common shares.

We do not currently intend to pay dividends on our common shares in the foreseeable future, and consequently, any gains from an investment in our common shares will likely depend on appreciation in the price of our common shares.

We have never declared or paid cash dividends on our common shares and do not anticipate paying any cash dividends to holders of our common shares in the foreseeable future. Consequently, investors must rely on sales of their common shares and warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that our common shares will appreciate in value or even maintain the price at which the shareholders have purchased their shares.

A sale of a substantial number of our common shares in the public market could cause the market price of our common shares to drop significantly, even if our business is doing well.

The price of our common shares could decline as a result of sales of a large number of our common shares or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

In addition, in the future, we may issue additional common shares, warrants or other equity or debt securities convertible into common shares in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause the price of our common shares to decline.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common shares, the price of our common shares could decline.

The trading market for our common shares relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common shares could decline if one or more equity analysts downgrade our common shares or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Our directors, executive officers and certain other holders of our securities have control over us and could delay or prevent a change of corporate control.

As of December 12, 2025, Dr. Nijhawan, our Chief Executive Officer, beneficially owns 19.99% of our outstanding common shares and all of our executive officers and directors, including Dr. Nijhawan, beneficially own 23.6% of our

common shares. As a result of the foregoing, such individuals will have the ability, acting together, to significantly influence the election of our directors and the outcome of corporate actions requiring shareholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our Articles.

In addition, on February 12, 2025, we entered into an Investor Rights Agreement with, among other parties, Velan Capital Master Fund LP, Velan Horizon Fund LP and Velan Capital Opportunity Fund II LLC (collectively, "Velan"), pursuant to which Velan has the right to designate a director nominee for election to our Board (as defined below), so long as Velan maintains certain beneficial ownership of the Company, as set forth in the Investor Rights Agreement. As of December 12, 2025, Velan beneficially owns 9.99% of our outstanding common shares.

This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other shareholders and be disadvantageous to our shareholders with interests different from those individuals.

See "Security Ownership of Certain Beneficial Owners and Management" below for more information regarding the ownership of our outstanding common shares by our executive officers, directors and holders of more than 5% of our common shares, together with their affiliates.

Our Articles allow for our board of directors to create new series of preferred shares without further approval by the shareholders, which could adversely affect the rights of the holders of our common shares.

As previously approved by our shareholders, our board of directors ("Board") has the authority to authorize up to an unlimited number of a new series of our preferred shares and to fix and determine the special rights and restrictions of that series without further shareholder approval, subject to the terms set out in the Articles and unless otherwise required by the Business Corporations Act (British Columbia). As a result, our Board could authorize the creation of a series of our preferred shares that would grant to holders of the preferred shares a right to our assets upon liquidation before a distribution to the holders of our common shares. In addition, our Board could authorize the creation of a new series of our preferred shares that is convertible into our common shares, which could result in dilution to existing shareholders.

On October 30, 2024, we filed Amended Articles to amend the rights, preferences, restrictions and other matters pertaining to our newly designated Series A-1 Convertible Preferred Shares (the "Series A-1 Preferred Shares"). The Series A-1 Preferred Shares have no par value and a stated value of $10,000 per share and rank, with respect to redemption payments, rights upon liquidation, dissolution or winding-up of the Company, or otherwise, senior in preference and priority to our common shares.

On October 30, 2024, we filed Amended Articles to amend the rights, preferences, restrictions and other matters pertaining to our newly designated Series B-1 Convertible Preferred Shares (the "Series B-1 Preferred Shares"). The Series B-1 Preferred Shares have no par value and a stated value of $10,000 per share and rank, with respect to redemption payments, rights upon liquidation, dissolution or winding-up of the Company, or otherwise, senior in preference and priority to our common shares and each other class or series of shares ranking junior to the Series B-1 Preferred Shares.

Our common shares rank junior to our preferred shares in the event of a liquidation, dissolution or winding-up of the Company.

In the event of any liquidation, dissolution or winding-up of the Company, (i) a holder of the Series A-1 Preferred Shares will be entitled to receive, before any distribution or payment may be made with respect to the holders of our common shares, an amount equal to 100% of the stated value, plus a return equal to 10% of the stated value per Preferred Share per annum, calculated daily and (ii) a holder of the Series B-1 Preferred Shares will be entitled to receive, before any distribution or payment may be made with respect to common shares, an amount equal to 100% of the stated value.

Any issuance of our common shares upon conversion of our preferred shares will cause dilution to our then existing stockholders and may depress the market price of our common shares.

The Series A-1 Preferred Shares accrue an annual return equal to 10% of the stated value per Preferred Share payable by the issuance of our common shares at the conversion price upon a buy-back by the Company, liquidation or on conversion at the conversion price (calculated daily). Each Series A-1 Preferred Share is convertible into a number of our common shares calculated by dividing (i) the sum of the stated value of such Series A-1 Preferred Share plus a return equal to 10% of the stated value per Series A-1 Preferred Share per annum, calculated daily, by (ii) a fixed conversion price of $3.445.

Each Series B-1 Preferred Share is convertible into a number of our common shares calculated by dividing (i) the sum of the stated value of such Series B-1 Preferred Share by (ii) a fixed conversion price of $1.92.

The issuance of our common shares upon conversion of our preferred shares will result in immediate and substantial dilution to the interests of holders of our common shares, and such dilution will increase over time in connection with the accrual of the annual return on the Series A-1 Preferred Shares.

We may incur future indebtedness that will rank senior to our preferred shares or issue additional series of preferred shares that rank on a parity with, or senior to, the preferred shares as to dividend payments and liquidation preference.

We may incur substantial amounts of additional debt and other obligations that will rank senior to the preferred shares, and the terms of the preferred shares do not limit the amount of such debt or other obligations that we may incur. The terms of the preferred shares will not prohibit us from issuing additional series of preferred shares that would rank on parity with the preferred shares. The Articles allow for our Board to create new series of preferred shares without further approval by our shareholders, which could adversely affect the rights of the holders of the preferred shares and our common shares. The issuances of other series of preferred shares could have the effect of reducing the amounts available to the preferred shares in the event of liquidation. If we issue preferred shares with voting rights that dilute the voting power of our common shares, the market price of our common shares could decrease, adversely affecting the value of the preferred shares. Additional issuances and sales of preferred shares, or the perception that such issuances and sales could occur, may cause prevailing market prices for our common shares to decline and may adversely affect our ability to raise additional capital in the financial markets at times and prices favorable to it.

Failure to maintain effective internal control over financial reporting 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 Exchange Act, 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. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness or significant deficiencies in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also adversely affect investor confidence in the reliability of our financial reports and restrict our future access to the capital markets.

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

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

We 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, 2025 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 a 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 1C. CYBERSECURITY.

Risk Management and Strategy

In the ordinary course of our business, we, and third parties upon which we rely, collect, use, store and transmit confidential, sensitive, proprietary, personal and protected health information. The secure maintenance of this information is important to our operations and business strategy. To this end, we have implemented various cybersecurity plans and processes designed to manage cybersecurity risks relating to our third party hosted services, communications systems, hardware and software, and our critical data, including data related to our clinical trials and investigational products.

One of our strategies to mitigate cybersecurity risks is to utilize expert third-party software-as-a-service, human resource, and clinical providers to store and manage personally identifiable information, rather than maintaining and processing such data within our enterprise. We select reliable, reputable service providers that maintain cybersecurity programs of their own and other measures to comply with privacy and security requirements, including when applicable Canada's Personal Information Protection and Electronic Document Act ("PIPEDA") and the U.S. Health Insurance Portability and Accountability Act ("HIPAA"). Depending on the nature of the services provided, the sensitivity and quantity of information processed and the identity of the service provider, we may also contractually impose certain security obligations on the provider.

Our executive leadership exerts operational oversight of our cybersecurity as part of our overall risk management function. We engage an expert IT and security provider to assist us with managing security risk and responding to cybersecurity threats or incidents. We have designed our business applications and hosting services to minimize the impact that cybersecurity incidents could have on our business and utilize back-up and recovery systems where appropriate. We also use other technology-based tools that are designed to mitigate and detect cybersecurity risks. In addition, we provide our employees with cybersecurity training, including topics such as phishing, password protection and reporting cyber incidents.

Governance

Our Board oversees our risk management strategy with respect to cybersecurity threats. The Board, through its audit committee, holds regular meetings, at least quarterly, to discuss issues including our cybersecurity threats. The meetings involve presentations and reports from our executive leadership and security provider, concerning our cybersecurity risk management activities, including any critical cybersecurity risks, ongoing cybersecurity initiatives and strategies, and applicable regulatory requirements and industry standards. Management also notifies the audit committee of any cybersecurity incidents (suspected or actual) and provides updates on the incidents as appropriate.

Material Effects of Cybersecurity Incidents

As of the date of this report, we have not identified any cybersecurity event or risks from cybersecurity threats that, individually or in the aggregate, would materially affect us. Notwithstanding, we, or third parties upon which we relay, may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us or our business strategy, results of operations or financial condition. For further information, refer to Section 1A, Risk Factors, for a discussion of risks related to cybersecurity and technology, including, without limitation, the risk factor under the heading "We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively"

Item 2. PROPERTIES.

We currently lease approximately 2,800 square feet of office space for our executive offices in Markham, Ontario, from 1968160 Ontario Inc., an entity affiliated with Dr. Nijhawan. Pursuant to the lease, as amended and extended on December 31, 2022, the term of the lease expired on December 31, 2024. The lease was subsequently extended to November 30, 2025 and thereafter, the arrangement continues on a month-to-month basis and either party may terminate on 30 days' notice. We believe our current offices are sufficient to meet our needs. We may seek to negotiate new leases or evaluate additional or alternate space to accommodate operations. We believe that appropriate alternative space is readily available on commercially reasonable terms.

Item 3. LEGAL PROCEEDINGS.

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

Item 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

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

Holders

As of December 12, 2025, we had 8,333,823 common shares outstanding, with 41 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. Any future determination to pay dividends will be made at the discretion of our Board.

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.

Overview

We are a biopharmaceutical company developing innovative ways to treat inflammatory and immune-related diseases. Our approach is to acquire, develop and commercialize drug candidates based on mechanisms of action that have demonstrated proof-of-concept in human subjects. We prioritize our efforts on disease indications where there is compelling scientific rationale, no approved therapies or where there are unmet medical needs, and where there are large addressable market opportunities, among other factors. Our clinical pipeline is focused on two therapeutic areas: Medical Dermatology and Respiratory.

In Medical Dermatology we are developing EB06, an anti-CXCL10 monoclonal antibody candidate, as a therapy for vitiligo, a common autoimmune disorder that causes skin to lose its color in patches. CXCL10 has been shown to play a key role in the disease, and neutralization of CXCL10 has been demonstrated to both prevent and reverse depigmentation in animal models. To date, EB06 has demonstrated a favorable safety and tolerability profile. We have received regulatory approval from Health Canada to conduct a Phase 2 proof of concept study of EB06 in patients with moderate-to-severe nonsegmental vitiligo and we are in discussions with the U.S. Food and Drug Administration ("FDA") for the same study. Subject to regulatory approval, we anticipate initiating enrollment by midyear 2026. Our Medical Dermatology assets also include EB01 (1.0% daniluromer cream), a Phase 3-ready asset developed for use as a potential therapy for moderate-to-severe chronic Allergic Contact Dermatitis ("ACD"), a common occupational skin condition. This asset is at the partnering stage.

Our most advanced Respiratory drug candidate is EB05 (paridiprubart). Paridiprubart represents a new class of emerging therapies called Host-Directed Therapeutics ("HDTs") that are designed to modulate the body's own immune response when confronted with infectious diseases or even chemical agents. In October 2025, we reported that paridiprubart met primary and secondary endpoints with statistical significance, providing clinically meaningful improvement in survival and recovery, in a truncated Phase 3 clinical study of hospitalized patients with Acute Respiratory Distress Syndrome ("ARDS"), a life-threatening form of respiratory failure. Paridiprubart is also being evaluated in an ongoing U.S. government-funded platform study investigating three novel threat-agnostic HDTs in hospitalized patients with ARDS.

Certain development expenses, including manufacturing scale-up, for our EB05 program are also eligible for reimbursement from the Government of Canada under a 2023 grant and funding award. We are also pursuing additional uses for paridiprubart in chronic diseases.

Operating and Financial Review and Prospects

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.

Our operations have been funded primarily through issuances of common shares and preferred 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 expect that our cash and cash equivalents at September 30, 2025, which include proceeds from our 2025 equity financings, together with net proceeds from the HCW ATM (as defined below) and reimbursements of eligible R&D expenses under the 2023 SIF Agreement may not be sufficient to fund our operating expenses for one year after the date of this filing, unless the Company raises additional capital or delays its current EB06 development program. Accordingly, management has concluded that substantial doubt exists about our ability to continue as a going concern. We will need to raise additional capital and/or reduce our operating expenses 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, 2025 Compared to the Fiscal Year Ended September 30, 2024

Our total operating expenses increased by $0.9 million to $7.9 million for the year ended September 30, 2025 compared to $7.0 million for the prior year.

- The following table summarizes our R&D expenses incurred for the years ended September 30, 2025 and 2024, together with the dollar increase or decrease in those items:

	Fiscal Year End		Change
	September 30, 2025	**September 30, 2024**	
Program-specific external costs:			
EB06	**$ 339,816**	$ -	$ 339,816
EB05	**1,929,023**	1,444,949	484,074
Other development and discovery programs	**133,347**	218,391	(85,044)
Total program-specific costs	**2,402,186**	1,663,340	738,846
Unallocated internal costs			
Non-program specific external costs	**1,206**	9,652	(8,446)
Unallocated internal costs	**1,265,346**	1,208,975	56,371
Total unallocated internal costs	**1,266,552**	1,218,627	47,925
Total research and development costs	**3,668,738**	2,881,967	786,771

- Research and development ("R&D") expenses increased by $0.8 million to $3.7 million for the year ended September 30, 2025 compared to $2.9 million for the prior year primarily due to increased expenses for manufacturing-related activities and other preparations for the planned Phase 2 clinical study of EB06 in vitiligo patients, as well as increased research expenses related to the completion of the Phase 3 study of paridiprubart (EB05) and supply costs for the ongoing United States government-funded study of paridiprubart, partially offset by lower spend on other development programs. Our R&D expenses consist primarily of employee-related

expenses, including salaries, benefits, taxes, travel, and share-based compensation expense for personnel in R&D 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.

- General and administrative ("G&A") expenses increased by $0.1 million to $4.2 million for the year ended September 30, 2025 compared to $4.1 million for the prior year primarily due to an increase in noncash share-based compensation, which was partially offset by a decrease in professional fees. Our G&A expenses consist primarily of salaries and related costs for our employees in administrative, executive and finance functions. G&A expenses also include professional fees for legal, accounting, audit, tax and consulting services, insurance, office, and travel expenses.

Total other income decreased by $0.1 million to $0.7 million for the year ended September 30, 2025 compared to $0.8 million for the prior year, and was composed of the following:

- Grant income increased by $0.1 million to $0.8 million for the year ended September 30, 2025 compared to $0.7 million for the year ended September 30, 2024, reflecting an increase in grant income associated with reimbursable expenses under the 2023 SIF Agreement.
- Interest income decreased to $3,000 for the year ended September 30, 2025 from $0.2 million for the prior year, primarily due to lower interest earned on cash balances.
- No miscellaneous other income was recorded in the year ended September 30, 2025 compared to $15,000 in the year ended September 30, 2024 related to loan forgiveness on the Canada Emergency Business Account ("CEBA") loan that was repaid during the year.
- Foreign exchange loss increased to $59,000 in the year ended September 30, 2025 compared to $21,000 in the year ended September 30, 2024.

For the year ended September 30, 2025, our net loss was $7.2 million, or $1.27 per common share, compared to a net loss of $6.2 million, or $1.93 per common share, for the year ended September 30, 2024.

Capital Expenditures

Our capital expenditures primarily consist of computer and office equipment. There were no significant capital expenditures for the years ended September 30, 2025 and 2024.

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.

Our primary use of cash is to fund our operating expenses, which consist of R&D and G&A expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in accounts payable and accrued expenses. Net cash used in operating activities was $7.3 million and $4.9 million for the years ended September 30, 2025 and 2024, respectively. We incurred net losses of $7.2 million and $6.2 million for those same years. We ended fiscal 2025 with $10.8 million in cash and cash equivalents and working capital of $10.4 million, compared to $1.0 million in cash and cash equivalents and a working capital deficit of approximately $0.2 million as of September 30, 2024.

On February 12, 2025, we entered into a Securities Purchase Agreement (the "Series B-1 Purchase Agreement") with a lead investor and several additional investors signatory thereto (the "Series B-1 Investors"), pursuant to which we sold to the Series B-1 Investors in a private placement, an aggregate of (i) 834 Series B-1 Preferred Shares, each of which is initially convertible into approximately 5,208 common shares (the "Series B-1 Conversion Shares") at a conversion price of $1.92 per Series B-1 Conversion Share, and (ii) 3,468,746 common shares. The purchase price per Series B-1 Preferred Share was $10,000 and the purchase price per common share was $1.92. The gross proceeds were approximately $15.0 million, prior to deducting offering expenses payable by us. A holder of Series B-1 Preferred Shares will not have the right to convert any portion of its Series B-1 Preferred Shares if, together with its affiliates, it would beneficially own in excess of 4.99% (or, at the option of the holder, 9.99%) of the number of common shares outstanding immediately after giving effect to such conversion, provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 19.99%.

In October 2024, we entered into an At The Market Offering Agreement with H.C. Wainwright & Co., LLC as a sales agent ("HCW ATM") pursuant to which we may offer and sell, from time to time, common shares through an at-the-market equity offering program for up to $4.0 million in gross proceeds. For the year ended September 30, 2025, the Company sold 394,057 Common Shares pursuant to the HCW ATM for net proceeds of approximately $1.0 million after deducting sales agent commissions. Subsequent to September 30, 2025, we sold an additional 1,177,568 common shares under the HCW ATM for net proceeds of approximately $3.4 million after deducting sales agent commissions.

A new shelf registration statement on Form S-3, allowing for the offer and sale of up to $4.0 million of securities, was filed and declared effective by the SEC on September 9, 2025.

In October 2024, we entered into a Securities Purchase Agreement (the "Series A-1 Purchase Agreement") with Pardeep Nijhawan Medicine Professional Corporation (the "Series A-1 Purchaser"), an entity controlled by Pardeep Nijhawan, our Chief Executive Officer, Secretary and member of our Board, pursuant to which we agreed to issue and sell to the Series A-1 Purchaser in a private placement, up to $5 million of Series A-1 Preferred Shares, each of which is initially convertible into approximately 2,903 common shares (the "Series A-1 Conversion Shares"), at a conversion price of $3.445 per Series A-1 Conversion Share, and warrants (the "Warrants") to purchase common shares (the "Warrant Shares") at an exercise price of $3.445 per Warrant Share. The Series A-1 Preferred Shares and the Warrants were being sold together in a fixed combination of one Series A-1 Preferred Share and a Warrant to purchase a number of common shares equal to 75% of the underlying Series A-1 Conversion Shares at a combined purchase price of $10,272.13 per Series A-1 Preferred Share and related Warrants. Under the Series A-1 Purchase Agreement, the Series A-1 Purchaser has purchased 150 Series A-1 Preferred Shares initially convertible into an aggregate of 435,414 Series A-1 Conversion Shares and Warrants to purchase up to an aggregate of 326,560 Warrant Shares for an aggregate purchase price of $1,540,819. The Warrants expire five years from the issuance date. We have the right to require the Series A-1 Purchaser to purchase additional Series A-1 Preferred Shares and Warrants (up to an aggregate investment of $5.0 million); provided however, no more than an aggregate of $2.0 million of Series A-1 Preferred Shares and Warrants may be issued and sold pursuant to the Series A-1 Purchase Agreement without shareholder approval in accordance with applicable Canadian securities laws.

In October 2023, we entered into the 2023 SIF Agreement with the Canadian Government's SIF. Under the 2023 SIF Agreement, the Government of Canada committed up to C$23 million in partially repayable funding. Of the C$23 million committed by SIF, up to C$5.8 million is not repayable by us. The remaining C$17.2 million is conditionally repayable starting in 2032 only if and when we earn gross revenue. For the years ended September 30, 2025 and 2024, we recorded grant income of $0.8 million and $0.7 million, respectively, related to the 2023 SIF Agreement. On September 30, 2025, the 2023 SIF Agreement was amended to, among other things, extend the program period to December 31, 2028 from December 31, 2025 and defer the start of the conditional repayment period from 2029 to 2032.

In October 2023, we entered into a $10.0 million revolving credit agreement with PN MPC, an entity controlled by Pardeep Nijhawan, our Chief Executive Officer and Secretary and member of our Board ("Credit Agreement"), providing an unsecured revolving credit facility, with a credit limit of $3.5 million ("Credit Limit") which was available immediately. The line of credit bore interest at the Canadian Imperial Bank of Commerce US Base-Interest Rate plus 3% per annum and has a maturity date of March 31, 2026, unless terminated earlier by either party with 90 days' notice. Advances under the line of credit were tied to a borrowing base ("Borrowing Base") consisting of eligible grant receivables from SIF, future potential license fee receivables and any other accounts receivable. At no time could the aggregate principal amount of all advances outstanding have exceeded the lesser of (i) the Credit Limit and (ii) an amount equal to 85% of the Borrowing Base. The Credit Agreement was terminated in October 2024. Prior to the termination of the Credit Agreement, we had not borrowed any funds thereunder. We incurred no termination penalties in connection with the termination of the Credit Agreement.

In August 2022, we filed a $150.0 million shelf registration statement that expired in August 2025. In March 2023, we entered into an equity distribution agreement with Canaccord, as sales agent, pursuant to which we may offer and sell, from time to time, common shares through an at-the-market equity offering program for up to $20 million in gross proceeds, subject to certain offering limitations that currently allow us to offer and sell common shares having an aggregate gross sales price of up to $8.4 million ("Canaccord ATM"). For the fiscal year ended September 30, 2024, we sold a total of 171,916 common shares pursuant to the agreement for net proceeds of $0.6 million after deducting commissions and costs of $0.1 million. The Canaccord ATM was terminated in October 2024.

At September 30, 2025, we had an accumulated deficit of $65.9 million and working capital of $10.4 million, including $10.8 million in cash and cash equivalents. Subsequent to September 30, 2025, we received net proceeds of $3.4 million from the sale of common shares under the HCW ATM. We expect that our cash and cash equivalents at September 30, 2025, future sales of common shares pursuant to the HCW ATM and reimbursements of eligible R&D expenses under the 2023 SIF Agreement will not be sufficient to fund our operating expenses including the advancement of the vitiligo program through the end of fiscal 2026. 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 and manufacturing campaigns, 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 plan to 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 raise additional funds by issuing equity securities, our shareholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and 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. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing shareholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development of our product candidates.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company. To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, clinical trials of our product candidates, and other operations and potential product acquisitions and in licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in licensing or similar strategic business transaction.

Cash Flows

Net cash used in operating activities

Net cash used in operating activities was $7.3 million for the year ended September 30, 2025 compared to $4.9 million for the year ended September 30, 2024 primarily due to an increase in R&D and G&A expenses.

Net cash used in investing activities

There was no cash used in investing activities for the years ended September 30, 2025 and September 30, 2024.

Net cash provided by financing activities

Net cash provided by financing activities was $17.0 million for the year ended September 30, 2025 as compared to $0.6 million for the year ended September 30, 2024. In the current year, we received proceeds of $15.0 million from the private placement of Series B-1 Preferred Shares, $1.5 million from the private placement of Series A-1 Preferred Shares and Warrants, and approximately $1.0 million of net proceeds from sales under the HCW ATM, partially offset by approximately $0.6 million of offering costs. In the prior year, we received approximately $0.6 million of net proceeds from sales under the Canaccord ATM.

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 R&D activities, including the conduct of clinical studies and product development, and expense such costs as they are incurred.

R&D 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 R&D expenses were $3.7 million and $2.9 million for the years ended September 30, 2025

and 2024, respectively. The increase primarily reflects manufacturing-related activities and other preparations for the planned Phase 2 study of EB06 (vitiligo) and manufacturing support and wind-down activities for paridiprubart (EB05), including BARDA-related work, partially offset by lower spend on other discovery programs.

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 that are subject to foreign currency fluctuations when translated to U.S. dollars for financial statement 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 impacts 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, 2025, we had assets denominated in Canadian dollars of approximately C$3.0 million and the U.S. dollar exchange rate as of this date was equal to 1.3918 Canadian dollars. Based on this exposure at September 30, 2025, a 10% annual change in the Canadian/U.S. exchange rate would impact our net loss and other comprehensive loss by approximately $0.2 million.

Concentration of Credit Risk

We are potentially subject to financial instrument concentration of credit risk through our cash and cash equivalents and accounts and other receivables. We place our cash and cash equivalents in money market mutual funds of U.S. government securities or with financial institutions believed to be creditworthy and perform periodic evaluations of their relative credit standing.

Accounts and other receivables primarily include Harmonized Sales Tax ("HST") refunds receivable from the Canada Revenue Agency, reimbursements receivable from the Canadian government's SIF and other miscellaneous receivables. We assess the collectability of our accounts and other receivables through a review of our current aging and payment terms, as well as an analysis of our historical collection rate, general economic conditions and the credit status of the relevant counterparties. As of September 30, 2025 and 2024, all outstanding accounts and other receivables were deemed to be fully collectible, and therefore, no allowance for doubtful accounts was recorded.

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 receivables

Accounts and other receivables include HST refunds receivable and reimbursements receivable from the Canadian government's SIF. As of September 30, 2025, all outstanding accounts, grants and HST refunds receivable 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 the NovImmune License Agreement. Unless earlier terminated, the term of the NovImmune License Agreement will remain in effect for 25 years from the date of first commercial sale of licensed products containing the Constructs. Subsequently, the NovImmune License Agreement will automatically renew for 5-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 recognize operating lease right-of-use ("ROU") assets and operating lease liabilities on the balance sheet for operating leases with terms longer than 12 months. We follow the ongoing practical expedient not to recognize operating lease right-of-use assets and operating lease liabilities for short-term leases. 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 have equity incentive plans under which various types of equity-based awards including share options, restricted shares and restricted share unit awards may be granted to employees, non-employee directors and non-employee consultants and warrants that may be granted as compensation to non-employees.

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.

We recognize compensation expense for all share-based awards based on the estimated grant-date fair values. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

The fair value of share options is determined using the Black-Scholes option pricing model. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention of paying cash dividends. We elected an accounting policy to record forfeitures as they occur. See Note 7 for a discussion of the assumptions used by us in determining the grant date fair value of options granted under the Black-Scholes option pricing model, as well as a summary of the share option activity under our share-based compensation plan for all years presented.

The provisions of our share-based compensation plans do not require us to settle any options or restricted share units by transferring cash or other assets, and therefore we classify the awards as equity.

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.

For 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 Exchange Act) as of September 30, 2025. 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. Our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures as of September 30, 2025, 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. Our Board is responsible for ensuring that management fulfills its responsibilities. The audit committee of our Board 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, 2025.

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

Attestation Report of Our Registered Public Accounting Firm

Because we are a non-accelerated filer, this Annual Report does not include an attestation report from our independent registered public accounting firm. We are not required to provide an attestation report on our internal control over financial reporting until such time as we are an accelerated filer or large accelerated filer.

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, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION.

None of the Company's directors or officers adopted, modified, or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the Company's fiscal quarter ended September 30, 2025 (each as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, as amended).

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

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Directors

Our directors and their ages as of the date of this filing are set forth below. Each director is elected annually to serve until the next annual meeting of shareholders, or until his or her successor is duly elected.

Name	Age	Position(s) Held	Director Since
Joan Chypyha (1) (2)	59	Director	May 23, 2023
David Liu (2) (4)	40	Director	February 12, 2025
Sean MacDonald	49	Director	June 7, 2019
Patrick Marshall (1) (3)	54	Director	May 23, 2023
Pardeep Nijhawan, MD	55	Director and Chief Executive Officer	June 7, 2019
Charles Olson, DSc (2) (3)	68	Director	May 23, 2023
Carlo Sistilli, CPA, CMA (1)	69	Chairman of the Board of Directors	June 7, 2019

(1) Member of Audit Committee.

(2) Member of Compensation Committee.

(3) Member of Nominating and Corporate Governance Committee.

(4) On February 12, 2025, we entered into the Investor Rights Agreement, pursuant to which Velan has the right to designate a director nominee for election to our Board, so long as Velan maintains certain beneficial ownership of the Company, as set forth in the Investor Rights Agreement (the "Nominee Period"). Dr. Liu is affiliated with Velan and was designated by Velan to be appointed to the Board in accordance with the terms and conditions of the Investor Rights Agreement. The Company also agreed to use its reasonable best efforts to solicit shareholder approval of such designee at each general or special meeting of shareholders at which an election of directors is held during the Nominee Period.

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:

Joan Chypyha has more than 30 years of experience in the pharmaceutical industry including executive and operational positions in business development, sales and marketing, and general management. She is the President of Alto Pharmaceuticals, Ltd., a specialty pharmaceutical company focused on dermatology, women's health and elder care, which she founded in 2009. Alto is also a major shareholder in Pepper and Pink Inc., a manufacturer of brand and private label personal care products for major retailers in Canada. From July 2015 to June 2017, she was the President of Cipher Pharmaceuticals, Inc., having previously served as Vice President of Marketing and Sales. Ms. Chypyha's professional career also includes executive positions at Rhei Pharmaceuticals Ltd. and Barrier Therapeutics Canada, Inc., following sixteen years at Hoffman-La Roche, where she held progressively senior positions. Since February 2018, she has served as a director and a member of the audit committee of Ovation Science Inc., a research and development company that develops topical and transdermal consumer products. She is a past advisory board member of Up Cannabis Inc (from August 2017 to January 2019). Ms. Chypyha currently served as the President of the Canadian Dermatology Industry Association, from 2015 to 2023, and is a Co-Chair of DiTiDE (Dermatology Industry Taskforce on Inclusiveness, Diversity & Equity), a group she co-founded in 2020. She has also previously served on boards of other non-profits and business organizations, including the Canadian Healthcare Licensing Association. Ms. Chypyha earned her Bachelor's Degree from the University of Toronto and a Master's Degree in Business Administration from Queen's University. Ms. Chypyha's qualifications to serve on our Board include her extensive operational experience in founding, managing and building companies, previous board experience and her extensive experience in the dermatology industry.

David Liu, PhD has over 10 years of investment experience within the biopharmaceutical industry. From January 2023 to March 2024, and since December 2024, he has served as a Senior Analyst at Velan Capital Investment Management LP, a healthcare dedicated investment firm based in Alpharetta, Georgia. Prior to his current position, he served as a Biotech Analyst at Altium Capital Management, LP, an investment firm focused on healthcare companies from January 2019 to November 2022. He received his B.S. in Biological Sciences from Stanford University and his Ph.D. in Molecular Biology from Weill Cornell Graduate School of Medical Sciences. Dr. Liu is qualified to serve on our Board because of his experience in the biopharmaceutical industry.

Sean MacDonald has been a member of our Board since June 2019, and served as Chairman of the Board from June 2019 until May 2023. He previously served on the board of our principal operating subsidiary, Edesa Biotech Research, from September 2017 to June 2019. In his career, he has led and closed multiple licensing transactions, financings, acquisitions and divestments, and led corporate strategy for several pharmaceutical and biotechnology companies. Since April 2024, Mr. MacDonald has served as the Chief Executive Officer of Domain Therapeutics Inc., a biotechnology company and from January to March 2024, Mr. MacDonald served as their Chief Business Officer. From April 2022 to February 2024, he served as an advisor to investors and biotechnology companies, including Raya Therapeutic Inc. From August 2021 to April 2022, he was the Chief Business Officer of iOnctura SA, a Swiss clinical-stage oncology company. 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 our Board include his extensive operational experience and background in the pharmaceutical/biotechnology industry.

Patrick Marshall has more than 20 years of experience raising capital, building and launching new products and services, developing strategy and completing mergers and acquisitions to support growth in private and public companies. Since 2010 he has been a managing director at VRG Capital, having previously held various executive roles in several of the firm’s portfolio companies since 2000, including Wheels Group Inc., a North American third-party logistics company acquired by Radiant Logistics, Inc. in 2015, and Thomas International Ltd., a global provider of psychometric and aptitude tests acquired by Palamon Capital Partners in 2018. Mr. Marshall is a cofounder and current board member (since 2024) of Crawford Bowman Ltd, a privately held Canadian company focused on over-the-counter and nutritional supplements markets. He is an advisor to Jouleia Inc, a start-up focused on accelerating the transition to low-carbon homes. He is a current advisor, past board member (January 2016 – January 2025), and past President (January 2016 -December 2023) of Adrem Brands Inc., a privately held Canadian company focused on the over-the-counter and nutritional supplements markets. Prior to 2000, he held fundraising, business development and strategy roles for various international enterprises and non-governmental organizations. Mr. Marshall is a cofounder, advisor and former board member of Together Project (2016-2023), a current board member of Faith & the Common Good (since 2025), and a trustee of Lakefield College School (since 2012). He received his Bachelor of Arts in Sociology from Queen's University and Master of Business Administration from the University of Exeter. Mr. Marshall’s qualifications to serve on our Board include his experience managing and building companies, strategic transactions, raising capital and prior board experience.

Pardeep Nijhawan, MD, FRCPC, AGAF has served as our Chief Executive Officer, Corporate Secretary and a member of our Board since June 2019, having previously founded and led our principal operating subsidiary, Edesa Biotech Research, since January 2015. Dr. Nijhawan is a seasoned pharmaceutical entrepreneur with more than 20 years of experience in cross- functional leadership roles in finance, marketing, corporate strategy and business development. In 2002 Dr. Nijhawan founded Medical Futures Inc., and served as its CEO. He sold Medical Futures to Tribute Pharmaceuticals in 2015. In 2014, he founded Exzell Pharma, a specialty Canadian-based pharmaceutical organization that markets and commercializes approved products. He sold Exzell Pharma to BioLab Pharma in 2022. Dr. Nijhawan also founded Digestive Health Clinic in 2000 and led it to become one of Canada’s largest provider of private endoscopy services. He continues to serve on the board of directors of Digestive Health Clinic. From January 2021 until June 2024, he served on the advisory board of Private Debt Partners, a Canadian alternative asset management firm. 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 our Board include his extensive executive leadership and experience in the life sciences industry and his knowledge of our business as its chief executive.

Charles Olson, DSc is a CMC consultant with more than 40 years of biotech experience. Since April 2024 he has also been the Senior Vice President of Technical Operations at NervGen Pharma, responsible for the process development and manufacture of their peptide product in clinical development for nerve regeneration as a result of spinal cord injury. From September 2021 to April 2023 he was Chief Operating Officer at Dendreon Corporation, where he was responsible for the commercial manufacturing of Provenge, a commercial cell-based product for prostate cancer, overseeing multiple sites and several hundred employees. From September 2017 to August 2021, he was a senior Vice President of Operations at Applied Molecular Transport. From April 2010 to August 2017, Dr. Olson held various leadership roles at Anthera Pharmaceuticals Inc., including Chief Technology Officer. He has also been a Principal Biotechnology Consultant for Compass Biotechnology LLC since 2006. Dr. Olson previously held senior and executive management positions at NGM Biopharmaceuticals Inc., Coherus BioSciences Inc., Nexbio Inc., Cell Genesys, Inc., Biomarin Pharmaceuticals, Inc, and Onyx Pharmaceuticals, Inc. From December 2016 to June 2019, Dr. Olson served on the Board of Edesa Biotech, Inc. (then operating as Stellar Biotechnologies, Inc.), having previously served on Stellar’s scientific advisory board. After graduate school, Dr. Olson was a Research Scientist at Kaiser Hospitals, followed by Scientist and Senior Scientist positions at

Genentech and Bayer, respectively. He holds a B.A. in biology and chemistry from Westmont College, an M.A. in chemistry from the University of California at Santa Barbara and a D.Sc. in biochemistry. Dr. Olson qualifications to serve on our Board include his extensive scientific, manufacturing operations, process development and senior management and board experience in the biopharmaceutical industry.

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 since June 2019, having previously served as a board observer of our principal operating subsidiary, Edesa Biotech Research, 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. From January 2021 to February 2024, he served on the board of directors and audit committee of Aleafia Health Inc. 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 our Board include his knowledge of Edesa's business and his background in accounting and finance.

Executive Officers

Set forth below is certain information with respect to the names, ages, and positions of our executive officers as of the date of this filing. 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	55	Director and Chief Executive Officer	June 7, 2019
Michael Brooks, PhD	47	President	June 7, 2019
Peter Weiler	56	Chief Financial Officer	May 1, 2025

Michael Brooks, PhD was appointed President in June 2019, having served as Vice President of Corporate Development and Strategy for our principal operating subsidiary, Edesa Biotech Research, 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 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.

Peter Weiler was appointed as our Chief Financial Officer on April 3, 2025, effective May 1, 2025. From August 2018 to May 2025, Mr. Weiler served as President of Exzell Pharma, Inc., a privately held, commercial-stage pharmaceutical company. From August 2017 to August 2018, Mr. Weiler served as Vice President of Business Development at Biosyent Inc. (TSX: RX). Prior to that, he served in various roles at Cipher Pharmaceuticals Inc. (TSX: CPH), including Vice President of Business Development from January 2015 to June 2017, Senior Director from January 2012 to January 2014, and Director from December 2008 to December 2011. Prior to Cipher, he served as Senior Director of Investment Analysis at DRI Capital Inc. and held market research and financial positions at Eli Lilly Canada Inc. Mr. Weiler holds a Master of Business Administration degree from the Ivey School of Business, University of Western Ontario, a Masters of Science in Biology degree from the University of Western Ontario, and a Bachelor of Science (Honors Biology) degree and Diploma in Accounting from Wilfrid Laurier University.

Code of Ethics and Business Conduct

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 that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions by posting such information on our website identified above. 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.

Insider Trading Policy

The Company has an insider trading policy governing the purchase, sale and other dispositions of the Company's securities that applies to all Company personnel, including directors, officers, and employees. The Company believes that its insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. A copy of the Company's insider trading policy is filed as Exhibit 19.1 to this Form 10-K.

Information about our Board Committees

Our Board has appointed an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The Board 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 SEC. The Board 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 www.edesabiotech.com/investors/governance.

Audit Committee

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

Carlo Sistilli is the Chair of our Audit Committee and has extensive financial experience. He holds a Bachelor of Arts from York University, with a major in economics, Certified Management Accountant Designation and a Chartered Professional Accountant Designation. He has held a variety of executive positions in accounting and finance during the past 35 years. The Board has determined that Mr. Sistilli is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K.

Compensation Committee

Our Compensation Committee is composed of Joan Chypyha (chair), David Liu and Charles Olson. The purpose of the Compensation Committee is to assist the Board's oversight relating to the compensation of our Chief Executive Officer and our other Named Executive Officers. It has responsibility for evaluating and 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 Patrick Marshall (chair) and Charles Olson. 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; lead the Board in its annual review of the Board and management's performance; 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, 2025 were Pardeep Nijhawan, MD, Director, Chief Executive Officer and Corporate Secretary; Peter Weiler, Chief Financial Officer; Michael Brooks, PhD, President; and Stephen Lemieux, CPA, former Chief Executive Officer.

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, 2025 and September 30, 2024

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	All Other Compensation ($)	Total ($)
Pardeep Nijhawan, MD	2025	$ 357,696(2)	$ 93,717	$ 522,931(3)	$ 32,415(4)	$ 1,006,759
Director, Chief Executive Officer and Corporate Secretary	2024	357,696(5)	72,434	-	34,598(4)	464,728
Michael Brooks, PhD	2025	335,340	87,859	411,671(6)	27,007(7)	861,877
President	2024	335,340	67,906	-	25,741(7)	428,987
Peter Weiler (8)	2025	125,000	-	129,143(9)	10,558(10)	264,701
Chief Financial Officer						
Stephen Lemieux, CPA (11)	2025	192,500	86,460	111,858(12)	32,054(13)	422,872
Former Chief Financial Of icer	2024	330,000	14,097	-	24,000(13)	368,097

(1) The amounts shown in this column represent the aggregate grant date fair value of the restricted share units 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 7 to our audited consolidated financial statements for the year ended September 30, 2025 included in this Annual Report.
(2) Includes 79,826 restricted share units with an aggregate grant date fair value of $178,848 issued as partial payment of salary.
(3) Includes 263,200 restricted share units with an aggregate grant date fair value of $522,931.
(4) Represents $32,415 in car allowance in 2025 and (i) $32,412 in car allowance and (ii) $2,186 in health insurance in 2024. All compensation to Dr. Nijhawan was paid in Canadian dollars and was converted from US dollars using the average foreign exchange rate for each bi-weekly pay period of the year from oanada.com.
(5) Includes 30,159 restricted share units with an aggregate grant date fair value of $144,454 issued as partial payment of salary.
(6) Includes 207,201 restricted share units with an aggregate grant date fair value of $411,671.
(7) Represents (i) $24,000 in car allowance (ii) $3,007 in health insurance in 2025 and (i) $24,000 in car allowance and (ii) $1,741 in health insurance in 2024. All compensation to Dr. Brooks was paid in Canadian dollars and was converted from US dollars using the average foreign exchange rate for each bi-weekly pay period of the year from oanda.com.
(8) Mr. Weiler was appointed Chief Financial Officer, effective May 1, 2025.
(9) Includes 65,000 restricted share units with an aggregate grant date fair value of $129,143.
(10) Represents (i) $10,000 in car allowance (ii) $558 in health insurance in 2025. All compensation to Mr. Weiler was paid in Canadian dollars and was converted from US dollars using the average foreign exchange rate for each bi-weekly pay period of the year from oanda.com.
(11) Mr. Lemieux served as Chief Financial Officer through May 1, 2025.
(12) Includes 56,300 restricted share units with an aggregate grant date fair value of $111,858.
(13) Represents (i) $14,000 in car allowance (ii) $18,054 in consulting fees for services following Mr. Lemieux's tenure as Chief Financial Officer in 2025 and $24,000 in car allowance in 2024. All compensation to Mr. Lemieux was paid in Canadian dollars and was converted from US dollars using the average foreign exchange rate for the year from oanda.com.

Narrative Disclosure to Summary Compensation Table Employment Agreements

Amended and Restated Employment Agreement with Pardeep Nijhawan effective as of August 4, 2023, as amended December 7, 2023

On August 4, 2023, the Company entered into an amended and restated employment agreement with Pardeep Nijhawan, the Company's Chief Executive Officer that superseded prior employment agreements (as amended, the "Nijhawan Employment Agreement").

Pursuant to the Nijhawan Employment Agreement, Dr. Nijhawan serves as the Company's Chief Executive Officer as well as Chief Executive Officer of each of the Company's subsidiaries, Edesa Biotech Research and Edesa Biotech USA, Inc. and a director of Edesa Biotech Research. Dr. Nijhawan's employment will continue for an indefinite term until terminated in accordance with the Nijhawan Employment Agreement.

Pursuant to the Nijhawan Employment Agreement, Dr. Nijhawan is entitled to a base salary of $357,700 per year effective May 13, 2023 and is eligible to receive a target annual bonus of 40% of his base salary, subject to the achievement of corporate and personal targets as determined by the Company and the Board. Dr. Nijhawan's base salary is subject to annual review by the Board. Dr. Nijhawan and the Board may agree that Dr. Nijhawan may receive a portion of his base salary in equity-based awards pursuant to the Company's Equity Incentive Compensation Plan, in amounts and on the terms determined by the Board. Dr. Nijhawan is also entitled to an automobile allowance of $2,701.50 per month and is eligible to participate in the Company's group insured benefits program, as may be in effect from time-to-time for employees generally, and executive employees specifically. Dr. Nijhawan is eligible for equity-based awards pursuant to the Company's Equity Incentive Compensation Plan, as determined by the Board or Compensation Committee, commensurate with Dr. Nijhawan's position and any business milestones that may be established by the Company.

If Dr. Nijhawan's employment is terminated for "Cause" (as such term is defined in the Nijhawan Employment Agreement), subject to applicable law, Dr. Nijhawan is entitled to his base salary and vacation pay earned through the date of termination, and all of Dr. Nijhawan's non-vested equity-based awards will be automatically extinguished. All vested equity-based awards shall be subject to the terms of the Company's Equity Incentive Compensation Plan.

If Dr. Nijhawan is terminated without "Cause", subject to Dr. Nijhawan signing a general release of claims, Dr. Nijhawan is entitled to: (i) a lump sum payment equal to Dr. Nijhawan's then current base salary for 12 months plus one additional month for every completed year of service since August 1, 2017 (the "Nijhawan Severance Period") which shall not exceed 24 months, inclusive of, and not in addition to, his notice and severance entitlements, if any, pursuant to applicable law, (ii) a lump sum payment of the annual bonus to which Dr. Nijhawan is entitled for the calendar 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 calendar year in which his employment is terminated, calculated in accordance with the terms of the Nijhawan Employment Agreement, (iv) payment of Dr. Nijhawan's annual bonus entitlement during the full Nijhawan Severance Period, calculated in accordance with the terms of the Nijhawan 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 Nijhawan Employment Agreement, and (vi) subject to applicable law, all vested equity-based awards granted to Dr. Nijhawan shall be exercisable in accordance with the terms of the applicable Equity Incentive Compensation Plan.

In the event that Dr. Nijhawan is terminated or constructively terminated, which includes a material change in Dr. Nijhawan's title, responsibilities, authority or status or a material reduction of his compensation, without "Cause" upon or within a 12- month period following a "Change of Control" (as such term is defined in the Nijhawan Employment Agreement), Dr. Nijhawan is entitled to (i) a change of control payment equal to 24 months of the value of Dr. Nijhawan's then current base salary as of the date of termination, (ii) a lump sum payment of the annual bonus to which Dr. Nijhawan is entitled for the calendar 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 calendar year in which his employment is terminated, calculated in accordance with the terms of the Nijhawan Employment Agreement, (iv) payment of Dr. Nijhawan's annual bonus entitlement during the full Nijhawan Severance Period, calculated in accordance with the terms of the Nijhawan 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 Nijhawan Employment Agreement, and (vi) subject to applicable law, all vested equity-based awards granted to Dr. Nijhawan shall be exercisable in accordance with the terms of the applicable Equity Incentive Compensation Plan.

Dr. Nijhawan may resign from his employment at any time by providing the Company with a minimum of 60 days advance notice, in writing. Dr. Nijhawan's notice may be waived by the Company, 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 equity based awards held by Dr. Nijhawan shall be automatically extinguished and (ii) Dr. Nijhawan shall not be entitled to any bonus or pro rata bonus payment not already awarded on or before the date of termination. All vested equity-based awards shall be subject to the terms of the applicable Equity Incentive Compensation Plan.

During the term of Dr. Nijhawan's employment and for 12 months following the cessation of Dr. Nijhawan's employment, Dr. Nijhawan is prohibited from competing with the business of the Company in North America. In addition, for 24 months following the cessation of Dr. Nijhawan's employment, Dr. Nijhawan is prohibited from soliciting customers or prospective customers for any purpose competitive with the business of the Company, encouraging any customer to cease doing business with the Company and soliciting the employment or engagement of certain of Company's employees.

Amended and Restated Employment Agreement with Michael Brooks effective as of August 4, 2023

On August 4, 2023, the Company entered into an amended and restated employment agreement with Michael Brooks, the Company's President, that superseded prior employment agreements (the "Brooks Employment Agreement").

Pursuant to the Brooks Employment Agreement, Dr. Brooks serves as the Company's President as well as President and a director of the Company's subsidiary, Edesa Biotech Research. Dr. Brooks' employment will continue for an indefinite term until terminated in accordance with the Brooks Employment Agreement.

Pursuant to the Brooks Employment Agreement, Dr. Brooks is entitled to a base salary of $335,340 per year effective May 13, 2023 and is eligible to receive a target annual bonus of 40% of his base salary, subject to the achievement of corporate and personal targets as determined by the Company and the Board. Dr. Brooks' base salary is subject to annual review by the Board. Dr. Brooks is also entitled to an automobile allowance of $2,000 per month and is eligible to participate in the Company's group insured benefits program, as may be in effect from time-to-time for employees generally, and executive employees specifically. Dr. Brooks is eligible for equity-based awards pursuant to the Company's Equity Incentive Compensation Plan, as determined by the Board or Compensation Committee, commensurate with Dr. Brooks' position and any business milestones that may be established by the Company.

If Dr. Brooks' employment is terminated for "Cause" (as such term is defined in the Brooks Employment Agreement), subject to applicable law, Dr. Brooks is entitled to his base salary and vacation pay earned through the date of termination, and all of Dr. Brooks' non-vested equity-based awards will be automatically extinguished. All vested equity-based awards shall be subject to the terms of the Company's Equity Incentive Compensation Plan.

If Dr. Brooks is terminated without "Cause", subject to Dr. Brooks signing a general release of claims, Dr. Brooks is entitled to: (i) a lump sum payment equal to Dr. Brooks' then current base salary for 12 months plus one additional month for every completed year of service since September 1, 2015 (the "Brooks Severance Period") which shall not exceed 24 months, inclusive of, and not in addition to, his notice and severance entitlements, if any, pursuant to applicable law, (ii) a lump sum payment of the annual bonus to which Dr. Brooks is entitled for the calendar 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 calendar year in which his employment is terminated, calculated in accordance with the terms of the Brooks Employment Agreement, (iv) payment of Dr. Brooks' annual bonus entitlement during the full Brooks Severance Period, calculated in accordance with the terms of the Brooks 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 Brooks Employment Agreement, and (vi) subject to applicable law, all vested equity-based awards granted to Dr. Brooks shall be exercisable in accordance with the terms of the applicable Equity Incentive Compensation Plan.

In the event that Dr. Brooks is terminated or constructively terminated, which includes a material change in Dr. Brooks' title, responsibilities, authority or status or a material reduction of the Employee's compensation, without cause upon or within a 12-month period following a "Change of Control" (as such term is defined in the Brooks Employment Agreement), Dr. Brooks is entitled to (i) a change of control payment equal to 24 months of the value of Dr. Brooks' then current base salary as of the date of termination, (ii) a lump sum payment of the annual bonus to which Dr. Brooks is entitled for the calendar 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 calendar year in which his employment is terminated, calculated in accordance with the terms of the Brooks Employment Agreement, (iv) payment of Dr. Brooks' annual bonus entitlement during the full Brooks Severance Period, calculated in accordance with the terms of the Brooks 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 Brooks Employment Agreement, and (vi) subject to applicable law, all vested equity-based awards granted to Dr. Brooks shall be exercisable in accordance with the terms of the applicable Equity Incentive Compensation Plan.

Dr. Brooks may resign from his employment at any time by providing the Company with a minimum of 60 days advance notice, in writing. Dr. Brooks' notice may be waived by the Company, 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 equity based awards held by Dr. Brooks shall be automatically extinguished and (ii) Dr. Brooks shall not be entitled to any bonus or pro rata bonus payment not already awarded on or before the date of termination. All vested equity-based awards shall be subject to the terms of the applicable Equity Incentive Compensation Plan. During the term of Dr. Brooks' employment and for 12 months following the cessation of Dr. Brooks' employment, Dr. Brooks is prohibited from competing with the business of the Company in North America. In addition, for 24 months following the cessation of Dr. Brooks' employment, Dr. Brooks is prohibited from soliciting customers or prospective customers for any purpose competitive with the business of the Company, encouraging any customer to cease doing business with the Company and soliciting the employment or engagement of certain of Company's employees.

Employment Agreement with Peter Weiler effective as of August 4, 2023

On April 3, 2025 but effective May 1, 2025, we entered into an employment agreement with Peter Weiler (the "Weiler Employment Agreement"). Pursuant to the Weiler Employment Agreement, Mr. Weiler serves as our Chief Financial Officer for an indefinite term until his employment is terminated in accordance with the Weiler Employment Agreement. As compensation for his services to the Company, Mr. Weiler is entitled to a base salary of $300,000 per annum. Mr. Weiler is also eligible to receive a target annual bonus of 40% of his base salary based on performance in the prior calendar year, subject to achieving corporate and personal targets determined by the Company and the Board. Mr. Weiler will also receive an automobile allowance of $2,000 per month and is eligible to participate in the Company's group insured benefits program, as may be in effect from time-to-time for the Company's employees generally, and executive employees specifically. Mr. Weiler is eligible for future equity-based awards, as determined by the Board, commensurate with Mr. Weiler's position and any business milestones which may be established by the Company.

If Mr. Weiler's employment with the Company is terminated for "Cause" (as such term is defined in the Weiler Employment Agreement), subject to applicable law, the Company's only obligation shall be to provide Mr. Weiler with his base salary and vacation pay earned through the date of termination and all of Mr. Weiler's non-vested equity-based awards as of the date of termination will be automatically extinguished. All vested equity-based awards will be subject to the terms of the applicable equity incentive compensation plan. If Mr. Weiler is terminated by the Company without "Cause", subject to Mr. Weiler executing a general release of claims in a form reasonably required by the Company, the Company's obligation shall be to provide Mr. Weiler with (i) a lump sum payment equal to Mr. Weiler's then current base salary for twelve months plus one additional month for every completed year of service since May 1, 2025, not to exceed an aggregate of twenty-four months (the "Weiler Severance Period"), (ii) a lump sum payment of the annual bonus to which Mr. Weiler is entitled for the calendar year immediately preceding the date of termination, if such bonus has not already been paid, (iii) a lump sum payment equal to Mr. Weiler's annual bonus entitlement, prorated over Mr. Weiler's length of service in the calendar year in which his employment is terminated, calculated in accordance with the terms of the Weiler Employment Agreement, (iv) payment of Mr. Weiler's annual bonus entitlement during the full Weiler Severance Period, calculated in accordance with the terms of the Weiler Employment Agreement, (v) continuation of Mr. Weiler's benefits and car allowance and any other benefit required to be maintained by law in accordance with the terms of the Weiler Employment Agreement and (vi) subject to applicable law, any and all vested equity-based awards shall be exercisable in accordance with the terms of the applicable equity incentive compensation plan. If Mr. Weiler's employment is terminated or "constructively terminated" (as such term is defined in the Weiler Employment Agreement) by the Company without "Cause" upon or within a twelve month period following a Change of Control (as such term is defined in the Weiler Employment Agreement), Mr. Weiler 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 his then current base salary. Mr. Weiler may resign from his employment at any time by providing the Company with a minimum of sixty days advance notice, in writing. Mr. Weiler's notice may be waived by the Company, subject only to providing Mr. Weiler with payment of his base salary and continuation of benefits until the end of the notice period. If Mr. Weiler resigns from his employment, subject to applicable law, (i) all non-vested equity-based awards held by Mr. Weiler as of the date of termination shall be automatically extinguished and all vested equity-based awards will be subject to the terms of the applicable equity incentive compensation plan and (ii) Mr. Weiler shall not be entitled to any bonus or pro rata bonus payment not already awarded on or before the date of termination.

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

Consulting Agreement with Stephen Lemieux, dated May 12, 2025

On May 12, 2025, Edesa Biotech Research entered into a Consulting Agreement with Stephen Lemieux, the Company's former Chief Financial Officer (the "Consulting Agreement"), pursuant to which Mr. Lemieux agreed to provide the Company with financial and accounting consulting services for a period of two years, which period may be extended by mutual agreement of Mr. Lemieux and the Company. In consideration for his services, the Company has agreed to pay Mr. Lemieux an hourly rate of CAD $250.00 per hour. In addition, pursuant to the Consulting Agreement, Mr. Lemieux will be entitled to his fiscal year 2025 bonus, prorated for the seven (7) months in 2025 in which he was employed by the Company as Chief Financial Officer. Mr. Lemieux will also be entitled to restricted stock units under the 2019 Plan at the discretion of the Board. The Consulting Agreement is terminable by either party upon thirty days' prior written notice.

Employment Agreement with Stephen Lemieux effective as of July 15, 2023, terminated effective May 1, 2025

On June 26, 2023 but effective as of July 15, 2023, we entered into an employment agreement with Stephen Lemieux (the "Lemieux Employment Agreement"). Pursuant to the Lemieux Employment Agreement, Mr. Lemieux served as our Chief Financial Officer for an indefinite term until Mr. Lemieux's employment is terminated in accordance with the agreement. As compensation for his services to us, Mr. Lemieux received a base salary of $330,000 per year and was eligible to receive a target annual bonus of 40% of his base salary, subject to achieving corporate and personal targets determined by us. Mr. Lemieux also received an automobile allowance of $2,000 per month and was 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. Mr. Lemieux was eligible for future equity-based awards, as determined by our Compensation Committee, commensurate with Mr. Lemieux'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 Mr. Lemieux's employment with the Company was terminated for "Cause" (as such term is defined in the Lemieux Employment Agreement), subject to applicable law, the Company's only obligation was to provide Mr. Lemieux with his base salary and vacation pay earned through the date of termination and all of Mr. Lemieux's non-vested equity-based awards as of the date of termination will be automatically extinguished. All vested equity-based awards would have been subject to the terms of the applicable equity incentive compensation plan. If Mr. Lemieux was terminated by the Company without "Cause", subject to Mr. Lemieux executing a general release of claims in a form reasonably required by the Company, the Company's obligation would have been to provide Mr. Lemieux with (i) a lump sum payment equal to Mr. Lemieux's then current base salary for twelve months plus one additional month for every completed year of service since July 15, 2023, not to exceed an aggregate of twenty- four months (the "Lemieux Severance Period"), (ii) a lump sum payment of the annual bonus to which Mr. Lemieux was entitled for the calendar year immediately preceding the date of termination, if such bonus has not already been paid, (iii) a lump sum payment equal to Mr. Lemieux's annual bonus entitlement, prorated over Mr. Lemieux's length of service in the calendar year in which his employment is terminated, calculated in accordance with the terms of the Lemieux Employment Agreement, (iv) payment of Mr. Lemieux's annual bonus entitlement during the full Lemieux Severance Period, calculated in accordance with the terms of the Lemieux Employment Agreement, (v) continuation of Mr. Lemieux's benefits and car allowance and any other benefit required to be maintained by law in accordance with the terms of the Lemieux Employment Agreement and (vi) subject to applicable law, any and all vested equity-based awards would be exercisable in accordance with the terms of the applicable equity incentive compensation plan. If Mr. Lemieux's employment was terminated or "constructively terminated" (as such term is defined in the Lemieux Employment Agreement) by the Company without "Cause" upon or within a twelve month period following a Change of Control (as such term is defined in the Lemieux Employment Agreement), Mr. Lemieux would have

been entitled to the payments and benefits provided as described in clauses (ii) to (v) above, plus a change of control payment equal to twenty-four months of his then current base salary. Mr. Lemieux was able to resign from his employment at any time by providing the Company with a minimum of sixty days advance notice, in writing. Mr. Lemieux's notice was waivable by the Company, subject only to providing Mr. Lemieux with payment of his base salary and continuation of benefits until the end of the notice period. If Mr. Lemieux resigned from his employment, subject to applicable law, (i) all non-vested equity-based awards held by Mr. Lemieux as of the date of termination would be automatically extinguished and all vested equity-based awards will be subject to the terms of the applicable equity incentive compensation plan and (ii) Mr. Lemieux would not have been entitled to any bonus or pro rata bonus payment not already awarded on or before the date of termination.

During the term of Mr. Lemieux's employment with us and for twelve months following the cessation of Mr. Lemieux's employment with us, Mr. Lemieux is prohibited from competing with our business in North America. In addition, for twenty- four months following the cessation of Mr. Lemieux's employment with us, Mr. Lemieux 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.

Outstanding Equity Awards at September 30, 2025

	Option Awards					Stock 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	Number of shares or units of stock that have not vested (1)	Market value of shares or units of stock that have not vested ($) (5)
Pardeep Nijhawan, MD	9/26/17	6,785	-	C$ 15.12	9/26/27		
	12/28/18	232	-	C$ 15.12	12/28/28		
	10/13/20	8,572	-	$ 52.08	10/13/30		
	4/22/21	17,143	-	$ 38.15	4/22/31		
	2/28/22	7,000		$ 25.97	2/28/32		
	7/20/23	12,859	4,284(2)	$ 5.79	7/20/33		
	5/29/25					110,856(3)	$ 273,814
	5/29/25					86,144(2)	$ 212,776
Stephen Lemieux, CPA	7/20/23	8,033	2,682(2)	$ 5.79	7/20/33		
	5/29/25					46,920(4)	$ 115,892
Michael Brooks, PhD	8/28/17	19,488	-	C$ 15.12	8/28/27		
	9/26/17	3,472	-	C$ 15.12	9/26/27		
	12/28/18	232	-	C$ 15.12	12/28/28		
	2/12/20	9,856	-	$ 22.12	2/12/30		
	10/13/20	7,143	-	$ 52.08	10/13/30		
	4/22/21	11,429	-	$ 38.18	4/22/31		
	2/28/22	6,215		$ 25.97	2/28/32		
	7/20/23	8,576	2,853(2)	$ 5.79	7/20/33		
	5/29/25					110,908(3)	$ 273,943
	5/29/25					57,440(2)	$ 141,877
Peter Weiler.....	5/29/25					57,792(2)	$ 142,746

(1) Our options and RSU vesting policy is described in the Outstanding Equity Awards Narrative Disclosure section.
(2) The option and RSUs vest over a period of three years, with monthly vesting on a pro-rata basis beginning on the date of grant.
(3) The RSUs vest over a period of 18 months, with monthly vesting on a pro-rate basis beginning on the date of grant.
(4) The RSUs vest over a period of 24 months, with monthly vesting on a pro-rate basis beginning on the date of grant.
(5) Represents the product of (i) $2.47 (which was the closing price of the common shares on September 30, 2025, the last trading day of fiscal 2025) and (ii) the number of common shares underlying the RSUs.

Outstanding Equity Awards Narrative Disclosure

Equity Incentive Compensation Plan

We adopted an Equity Incentive Compensation Plan in 2019 (as amended, the "2019 Plan") which amended and restated prior plans. 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 2,367,737. 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, 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 378,039 common shares at prices ranging from C$15.12 and $4.10 to $52.08 are outstanding at September 30, 2025. RSUs eligible for conversion to 333,319 common shares are outstanding at September 30, 2025.

During the year ended September 30, 2025, we did not grant any stock options under the 2019 Plan. During the year ended September 30, 2024, we granted 500 employee options to purchase common shares at an exercise price of $4.10. During the year ended September 30, 2025, we granted 1,227,807 RSUs with varying vesting schedules—certain awards vested immediately upon grant, while others vest in monthly installments over 12 to 36 months. Outstanding RSUs may be converted into common shares by the holder any time after vesting and before the stated expiry. During the year ended September 30, 2024, we granted 30,159 RSUs, which vested immediately upon grant and were issued in lieu of cash compensation for salary, bonuses and consulting fees to certain members of the executive team.

Policies and Practices Related to Grants of Share Options or Similar Awards

We did not grant options, share appreciation rights, or other similar option-like instruments in the fiscal year ended September 30, 2025; however, it is our policy not to time any grants of equity awards in relation to the release of material non-public information.

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.

Other than the funds contributed under our 401(k) plan to our U.S. employees, no other funds were set aside or accrued by us during the years ended September 30, 2025 and 2024 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, 2025.

Name	Fees Earned or Paid in Cash ($) (1)	RSU Awards ($) (2) (3) (4)	Total ($)
Joan Chypyha	$ 51,500	$ 21,855	$ 73,355
David Liu	25,041	10,930	35,971
Sean MacDonald	35,000	39,738	74,738
Patrick Marshall	48,536	21,855	70,391
Charles Olson, DSc	44,000	21,855	65,855
Carlo Sistilli, CPA, CMA	65,000	39,738	104,738
Frank R. Oakes (5)	31,942	34,372	66,314

(1) The compensation paid to each of Ms. Chypyha, Mr. MacDonald, Mr. Marshall and Mr. Sistilli was paid in Canadian dollars and was converted from US dollars using the average foreign exchange rate for each month of the year from oanda.com.

(2) The amounts shown in this column represent the aggregate grant date fair value of the restricted share units 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 7 to our audited consolidated financial statements for the year ended September 30, 2025 included in this Annual Report.
(3) As of September 30, 2025, (i) Ms. Chypyha and Mr. Marshall each held 11,000 RSUs, (ii) Mr. Liu held 3,669 RSUs, (iii) Mr. MacDonald and Mr. Sistilli each held 20,001 RSUs, (iv) Mr. Olson held 7,332 RSUs and Mr. Oakes held 11,532 RSUs.
(4) There were no share options grants in the year ended September 30, 2025. As of September 30, 2025, (i) Ms. Chypyha, Mr. Marshall and Dr. Olson each held 2,858 share options, (ii) Mr. MacDonald and Mr. Sistilli each held 11,773 share options, (iii) Mr. Oakes held 11,773 share options and (iv) Dr. Liu held no share options.
(5) Mr. Oakes was not nominated for re-election at our Annual Meeting that was held on May 28, 2025.

Narrative to Director Compensation Table

Non-Employee Director Compensation Policy

The Board adopted a compensation policy effective June 7, 2019 and amended it effective March 24, 2022. As compensation for their services on the Board, each non-executive Board member received annual remuneration as noted below and prorated during the effective periods. The Chief Executive Officer does not receive any additional compensation for his services on the Board.

From March 24, 2022 through September 30, 2024, each non-executive director received annual base remuneration of $35,000 and the Board Chair received annual remuneration of $65,000, inclusive of compensation for his services on committees of the Board. Each member of the Company's Audit Committee received annual remuneration of $7,500, and the Chair of the Audit Committee received $15,000 annually for his services. Each member of the Company's Compensation Committee and Nominating and Corporate Governance Committee received annual remuneration of $4,500 for each committee on which they serve, and the Chairs of each of the Compensation Committee and Nominating and Corporate Governance Committee received $9,000 annually for their services.

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, 2025 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, 2025:

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights	Weighted-average exercise price of outstanding options 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.....	1,621,692(1)	$ 24.70(2)	693,515
Equity compensation plans not approved by security holders.....	N/A	N/A	N/A
Total	1,621,692	$ 24.70	693,515

(1) Includes 378,039 common shares issuable upon the exercise of outstanding options and 1,243,653 common shares issuable upon the conversion of outstanding RSUs.
(2) The weighted-average exercise price does not consider shares issuable upon the conversion of outstanding RSUs, which have no exercise price.

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 12, 2025, 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 preferred shares, options, warrants or restricted share units currently exercisable or convertible or exercisable or convertible within 60 days of December 12, 2025 are deemed outstanding for computing the share ownership and percentage of the person holding such preferred shares, options, warrants and restricted share units, 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 8,333,823common shares outstanding as of December 12, 2025.

Directors and Officers

Name and Address of Beneficial Owner (1)	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Joan Chypyha	10,223 (2)	*
Sean MacDonald	27,162 (3)	*
Patrick Marshall	52,325 (4)	*
Pardeep Nijhawan, MD	1,946,138 (5)	19.99%
David Liu	3,664 (6)	*
Charles Olson, DSc	10,194 (7)	*
Carlo Sistilli, CPA, CMA	36,047 (8)	*
Michael Brooks, PhD	163,370 (9)	1.9%
Peter Weiler	14,448(10)	*
Stephen Lemieux	30,492(11)	*
All current directors and executive officers as a group (9 persons)	**2,263,571**(12)	**23.6**%

* 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) 29 common shares, (ii) 2,858 common shares issuable upon exercise of options exercisable within sixty days of December 12, 2025 and (iii) 7,336 common shares issuable upon the conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025.

(3) Consists of (i) 2,053 common shares, (ii) 11,773 common shares issuable upon exercise of options exercisable within sixty days December 12, 2025 and (iii) 13,336 common shares issuable upon the conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025.

(4) Consists of (A) (i) 41,666 common shares, (ii) 2,858 common shares issuable upon exercise of options exercisable within sixty days December 12, 2025 and (iii) 7,336 common shares issuable upon the conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025 held by Patrick Marshall and (B) 465 common shares held by Quidnet Inc. for which Patrick Marshall has sole voting and dispositive power over all such shares.

(5) Consists of (A) (i) 84,973 common shares, (ii) 54,488 common shares issuable upon exercise of options exercisable within sixty days of December 12, 2025, (iii) 275,579 common shares issuable upon the conversion of restricted share units and (iv) 277,086 common shares issuable upon conversion of Series B-1 Preferred Shares within sixty days of December 12, 2025 held by Pardeep Nijhawan; (B)(i) 341,702 common shares, (ii) 342,865 common shares issuable upon exercise of warrants exercisable within sixty days of December 12, 2025 and (iii) 435,414 common shares issuable upon conversion of Series A-1 Preferred Shares within sixty days of December 12, 2025 held by Pardeep Nijhawan Medicine Professional Corporation for which Pardeep Nijhawan has sole voting and dispositive power over all such shares; (C) 32,013 common shares held by The Digestive Health Clinic

Inc. for which Pardeep Nijhawan has sole voting and dispositive power over all such shares; (D) 53,104 common shares held by 1968160 Ontario Inc. for which Pardeep Nijhawan has sole voting and dispositive power over all such shares and (E)(i) 32,609 common shares and (ii) 16,305 common shares issuable upon exercise of warrants exercisable within sixty days of December 12, 2025 held by The New Nijhawan Family Trust 2015 for which each of Pardeep Nijhawan and Nidhi Nijhawan, as trustees, have voting and dispositive power over all such shares. Excludes 243,747 common shares underlying Series B-1 Preferred Shares held by Pardeep Nijhawan Medicine Professional Corporation which are subject to a 19.99% beneficial ownership blocker.

(6) Consists of (i) 2,748 common shares and (ii) 916 common shares issuable upon the conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025 .

(7) Consists of (i) 5,502 common shares, (ii) 2,858 common shares issuable upon exercise of options exercisable within sixty days of December 12, 2025 and (iii) 1,834 common shares issuable upon the conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025.

(8) Consists of (A)(i) 11,773 common shares issuable upon exercise of options exercisable within sixty days of December 12, 2025, (ii) 10,416 common shares held by Carlo Sistilli and (iii) 13,336 common shares issuable upon the conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025 and (B) 522 common shares held by York-Cav Enterprises Inc. for which Carlo Sistilli, as President and Director, has sole voting and dispositive power over all such shares.

(9) Consists of (i) 4,354 common shares, (ii) 67,662 common shares issuable upon exercise of options exercisable within sixty days of December 12, 2025, (iii) 303 common shares issuable upon exercise of warrants exercisable within sixty days of December 12, 2025 and (iv) 91,051 common shares issuable upon conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025.

(10) Consists of 14,448 common shares issuable upon conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025.

(11) Consists of (i) 2,486 common shares, (ii) 9,238 common shares issuable upon exercise of options exercisable within sixty days of December 12, 2025 and (iii) 18,768 common shares issuable upon the conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025.

(12) Consists of (i) 612,156 common shares, (ii) 154,270 common shares issuable upon exercise of options exercisable within sixty days of December 12, 2025, (iii) 359,473 common shares issuable upon exercise of warrants exercisable within sixty days of December 12, 2025, (iv) 425,172 common shares issuable upon conversion of restricted share units that have vested or will vest within sixty days of December 12, 2025, and (v) 712,500 common shares issuable upon conversion of preferred shares within sixty days of December 12, 2025.

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

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Velan Capital Management LLC(1)	848,647(1)	9.99%
Stonepine Capital Management, LLC(2)	781,250(2)	9.3%
Nantahala Capital Management, LLC (3)	855,584(3)	9.99%
Rubric Capital Management LP(4)	848,647(4)	9.99%

(1) Consists of (A)(i) 421,875 common shares, (ii) 63,492 common shares issuable upon exercise of warrants within sixty days of December 12, 2025 and (iii) 97,655 common shares issuable upon conversion of Series B-1 Preferred Shares within sixty days of December 12, 2025 that are beneficially owned and deemed outstanding with respect to Velan Capital Master Fund LP ("Velan Master"), (B) 15,625 common shares held by Velan Horizon Fund LP ("Velan Horizon") and (C) 250,000 common shares held by Velan Capital Opportunity Fund II LLC ("Velan Opportunity II"). Excludes common shares underlying Series B-1 Preferred Shares held by Velan Master, Velan Horizon and Velan Opportunity which are subject to a 9.99% beneficial ownership blocker. Velan Horizon GP LLC ("Velan Horizon GP"), as the general partner of Velan Horizon, may be deemed to beneficially own securities beneficially owned by Velan Horizon. Velan Capital Holdings LLC ("Velan GP"), as the general partner of Velan Master and managing member of Velan Opportunity II, may be deemed to beneficially own securities beneficially owned in the aggregate by Velan Master and Velan Opportunity II. Velan Capital Investment Management LP ("Velan Capital"), as the investment manager of each of Velan Master, Velan Horizon and Velan Opportunity II, may be deemed to beneficially own the securities beneficially owned in the aggregate by Velan Master, Velan Horizon and Velan Opportunity II. Velan Capital Management LLC ("Velan IM GP"), as the general partner of Velan Capital, may be deemed to beneficially own the securities beneficially owned in the aggregate by Velan Master, Velan Horizon and Velan Opportunity II. Balaji Venkataraman, as a Managing Member of each of Velan Horizon GP, Velan GP and Velan IM

GP, may be deemed to beneficially own the common shares beneficially owned in the aggregate by Velan Master, Velan Horizon and Velan Opportunity II. Adam Morgan, as the Chief Investment Officer of Velan Capital and a Managing Member of each of Velan Horizon GP, Velan GP and Velan IM GP, may be deemed to beneficially own the common shares beneficially owned in the aggregate by Velan Master, Velan Horizon and Velan Opportunity II. The address of the principal office of Velan Master is 89 Nexus Way, Camana Bay, Grand Cayman KY1-9009, Cayman Islands. The address of the principal office of each of Velan Horizon, Velan Opportunity II, Velan Horizon GP, Velan GP, Velan Capital, Velan IM GP and Messrs. Morgan and Venkataraman is 100 North Main Street, Suite 301, Alpharetta, Georgia 30009. We relied in part on the SEC Schedule 13D filed with the SEC on February 18, 2025 for this information.

(2) Consists of (i) 687,500 common shares and (ii) 93,750 common shares issuable upon conversion of Series B-1 Preferred Shares within sixty days of December 12, 2025 that are beneficially owned and deemed outstanding with respect to Stonepine Capital Management, LLC ("Stonepine"). Stonepine and Stonepine GP, LLC ("Stonepine GP") are the investment adviser and general partner, respectively, of Stonepine Capital, LP. ("Stonepine Partnership"). Jon Plexico is the control person of Stonepine and Stonepine GP. The principal place of business of Stonepine Capital, LP is 919 NW Bond Street, Suite 204, Bend, OR 97703. We relied in part on the SEC Schedule 13G filed with the SEC on February 25, 2025 for this information.

(3) Consists of (A)(i) 178,167 common shares and (ii) 1,417 common shares issuable upon conversion of Series B-1 Preferred Shares within sixty days of December 12, 2025 that are beneficially owned and deemed outstanding with respect to Nantahala Capital Partners Limited Partnership ("Nantahala"), (B)(i) 100,613 common shares that are beneficially owned and deemed outstanding with respect to NCP RFM LP ("NCP RFM") and (C)(i) 346,220 common shares and (ii) 229,167 common shares issuable upon conversion of Series B-1 Preferred Shares within sixty days of December 12, 2025 that are beneficially owned and deemed outstanding with respect to Blackwell Partners LLC – Series A ("Blackwell Partners"). Excludes common shares underlying Series B-1 Preferred Shares held by Nantahala and NCP RFM which are subject to a 9.99% beneficial ownership blocker. Nantahala Capital Management, LLC ("Nantahala Capital Management") is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of the common shares beneficially owned in the aggregate by Nantahala, NCP RFM and Blackwell Partners, as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management and may be deemed to have voting and dispositive power over the common shares beneficially owned in the aggregate by Nantahala, NCP RFM and Blackwell Partners. The principal place of business of Nantahala Capital Management is 130 Main St. 2nd Floor, New Canaan, CT 06840. We relied in part on the SEC Schedule 13G filed with the SEC on May 15, 2025 for this information.

(4) Consists of (i) 687,500 common shares and (ii) 161,147 common shares issuable upon conversion of Series B-1 Preferred Shares within sixty days of March 31, 2025 that are beneficially owned and deemed outstanding with respect to Rubric Capital Management LP ("Rubric"). Excludes common shares underlying Series B-1 Preferred Shares held by Rubric which are subject to a 9.99% beneficial ownership blocker. The principal place of business of Rubric is 155 East 44th Street, Suite 1630, New York, NY 10017. We relied in part on information provided by Rubric for this information.

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

Related Party Transactions

The following is a description of transactions since October 1, 2023 to which we have been a participant in which the amount involved exceeded or will exceed the lesser of (i) $120,000 and (ii) one percent of the average of our total assets at year end for the last two completed fiscal years in which any of our directors, executive officers or holders of more than 5% of our voting securities, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements.

Right-of-Use Lease Agreement

In January 2017, Edesa Biotech Research entered into a right-of-use lease agreement with 1968160 Ontario Inc., a company related to Dr. Nijhawan, our Chief Executive Officer, for office space that serves as our principal executive office. The original lease expired on December 31, 2022 and we executed a two-year term extension through December 31, 2024. Monthly rents during the term ranged from C$8,320 to C$9,020 plus HST. Rents of approximately $76,000 and $78,000 were incurred during the years ended September 30, 2025 and 2024, respectively. No rent payable was outstanding at September 30, 2025, and rent payable was approximately $30,000 at September 30, 2024.

Credit Agreement

On October 20, 2023, the Company entered into the Credit Agreement with PN MPC, an entity controlled by Dr. Nijhawan, our Chief Executive Officer, providing for the Line of Credit in the principal amount of up to $10 million, with the Credit Limit of $3.5 million, which was available immediately upon the execution of the Credit Agreement.

The Line of Credit bore interest at the Canadian Imperial Bank of Commerce US Base-Interest Rate plus 3% per annum and had a maturity date of March 31, 2026, unless terminated earlier by either party with 90 days' notice. The Company had the right at any time, and from time to time, to prepay all or any portion of each advance without premium or penalty.

Additionally, the Company agreed to pay a monthly standby fee for the term of the Credit Agreement, calculated as of the last business day of each month, on the difference between the Credit Limit at such time and the principal amount of outstanding advances, based on an annual interest rate of 1.5%.

The Credit Agreement was terminated in October 2024. Prior to the termination of the Credit Agreement, we had not borrowed any funds thereunder. We incurred no termination penalties in connection with the termination of the Credit Agreement.

Series A-1 Offering

Series A-1 Preferred Shares Offering

On October 30, 2024, we entered into a Securities Purchase Agreement (the "Series A-1 Purchase Agreement") with Pardeep Nijhawan Medicine Professional Corporation (the "Series A-1 Purchaser"), an entity controlled by Pardeep Nijhawan, our Chief Executive Officer, Secretary and member of our Board, pursuant to which we agreed to issue and sell to the Series A-1 Purchaser in a private placement, up to $5,000,000 of the Series A-1 Preferred Shares, each of which is initially convertible into approximately 2,903 common shares (the "Series A-1 Conversion Shares") at a conversion price of $3.445 per Series A-1 Conversion Share, and warrants (the "Warrants") to purchase 326,560 common shares (the "Warrant Shares") at an exercise price of $3.445 per Warrant Share. The Series A-1 Preferred Shares and the Warrants are being sold together in a fixed combination of one Series A-1 Preferred Share and a Warrant to purchase a number of common shares equal to 75% of the underlying Series A-1 Conversion Shares at a combined purchase price of $10,272.13 per Series A-1 Preferred Share and related Warrant. Under the Series A-1 Purchase Agreement, the Series A-1 Purchaser has purchased 150 Series A-1 Preferred Shares initially convertible into an aggregate of 435,414 Series A-1 Conversion Shares and Warrants to purchase up to an aggregate of 326,560 Warrant Shares for an aggregate purchase price of $1,540,819. The offering of the Series A-1 Preferred Shares and Warrants was structured as an at-market offering under the rules of The Nasdaq Stock Market. The Series A-1 Purchaser will not have the right to convert any portion of its Series A-1 Preferred Shares, or exercise any portion of the Warrants, if, together with its affiliates, it would beneficially own in excess of 19.99% of the number of common shares outstanding immediately after giving effect to such conversion or exercise. We have the right to require the Series A-1 Purchaser to purchase additional Series A-1 Preferred Shares and Warrants (up to an aggregate investment of $5.0 million); provided however, no more than an aggregate of $2.0 million of Series A-1 Preferred Shares and Warrants may be issued and sold pursuant to the Series A-1 Purchase Agreement without shareholder approval in accordance with applicable Canadian securities laws.

Series B-1 Preferred Shares Offering

On February 12, 2025, we entered into a Securities Purchase Agreement (the "Series B-1 Purchase Agreement") with a lead investor and several additional investors signatory thereto (the "Series B-1 Investors"), including, among others, (i) Pardeep Nijahawan, our Chief Executive Officer, Secretary and member of our Board and Patrick Marshall and Carlo Sistilli, members of our Board and (ii) entities affiliated with Velan IM GP, Stonepine, entities affiliated with Nantahala Capital Management and Rubric, each of which are beneficial owners of more than 5% of our common shares. Pursuant to the Series B-1 Purchase Agreement, we sold to the Series B-1 Investors in a private placement, an aggregate of (i) 834 Series B-1 Preferred Shares, each of which is initially convertible into approximately 5,208 common shares (the "Series B-1 Conversion Shares") at a conversion price of $1.92 per Series B-1 Conversion Share, and (ii) 3,468,746 common shares (the "Shares") (the "Private Placement"). The purchase price per Series B-1 Preferred Share was $10,000 and the purchase price per common share was $1.92. Pardeep Nijhawan purchased 100 Series B-1 Preferred Shares for an aggregate purchase price of $1.0 million. Patrick Marshall purchased 41,666 common shares for an aggregate purchase price of approximately $80,000. Carlo Sistilli purchased 10,416 common shares for an aggregate purchase price of approximately $20,000. The entities affiliated with Velan IM GP purchased, in the aggregate, 687,500 common shares and 568 Series B-1 Preferred Shares, for an aggregate purchase price of approximately $7.0 million. Stonepine purchased 687,500 common shares and 18 Series B-1 Preferred Shares, for an aggregate purchase price of approximately $1.5 million. The entities affiliated with Nantahala Capital Management purchased, in the aggregate, 625,000 common shares and 80 Series B-1 Preferred Shares, for an aggregate purchase price of approximately $2.0 million. Rubric purchased 687,500 common shares and 68 Series B-1 Preferred Shares, for an aggregate purchase price of approximately $2.0 million. A holder of Series B-1 Preferred Shares will not have the right to convert any portion of its Series B-1 Preferred Shares, if, together with its affiliates, it would beneficially own in excess of 4.99% (or, at the option of the holder, 9.99%) of the number of common shares outstanding immediately after giving effect to such conversion, provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 19.99%. The Private Placement closed on February 12, 2025 (the "Closing Date").

In connection with the Purchase Agreement, on February 12, 2025, we also entered into the Investor Rights Agreement with the Series B-1 Investors, whereby we agreed to provide the Series B-1 Investors with certain registration and other rights. Pursuant to the terms of the Investor Rights Agreement, we agreed to (i) use reasonable best efforts to file a registration statement for the resale of the Shares and Series B-1 Conversion Shares (together, the "Registrable Securities") within 30 days after the Closing Date and cause such registration statement to become effective no later than 75 days after the Closing Date (or 120 days in the event of a full review by the SEC) and (ii) use reasonable best efforts to keep any such registration statement continuously effective until the date that all of the Registrable Securities (X) have been sold under such registration statement, (Y) have been sold pursuant to Rule 144, or (Z) may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144.

The Investor Rights Agreement provides that the Board, following the Annual Meeting held in 2025, shall consist of 7 members, one of which shall be a director nominated by the Velan (the "Lead Investor Nominee"), who shall serve on the Board effective as of the Closing Date, until the earlier of such time as (i) Velan no longer holds at least 51% of the common shares (calculated on an as-converted-to-common shares basis), subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common shares, issued to Velan in the Private Placement and (ii) Velan beneficially owns less than 5% of the outstanding common shares as a result of a disposition of shares by Velan (such period, the "Lead Investor Rights Period"). We also agreed to use our reasonable best efforts to solicit shareholder approval of the Lead Investor Nominee at each general or special meeting of shareholders of the Company at which an election of directors is held during the Lead Investor Rights Period.

Additionally, the Investor Rights Agreement includes certain protective provisions that restrict our ability to, among other things, (i) amend, modify, alter or repeal any provision of our governing documents in a manner adverse to the holders of Series B-1 Preferred Shares, (ii) alter or change the special rights and restrictions of the Series B-1 Preferred Shares and (iii) increase or decrease the authorized number of Series B-1 Preferred Shares, in each case, without the written consent of Velan Series B-1 Investors.

Pursuant to the Investor Rights Agreement, during the Lead Investor Rights Period, Velan is entitled to designate one (1) non-voting observer to the Board to attend all meetings of the Board and committees and subcommittees thereof, subject to the terms of the Investor Rights Agreement.

Director Independence

In evaluating the independence of our Board members and the composition of the committees of our Board, the Board utilizes the definition of "independence" as that term is defined by the Exchange Act and the Nasdaq Listing Rules. Using this standard, the Board has determined that Joan Chypyha, Sean MacDonald, Patrick Marshall, David Liu, Charles Olson and Carlo Sistilli are "independent directors." Accordingly, our Board is composed of a majority of independent directors as required by the rules of Nasdaq. Mr. Oakes, who was not nominated for re-election at our Annual Meeting that took place on May 28, 2025, was also determined to be an "independent director" when he served on the Board. Pardeep Nijhawan is not an independent director due to his position as our Chief Executive Officer. We have established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, each of which are composed of independent directors.

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, 2025 and 2024 rendered by MNP LLP.

Principal Accountant Fees and Services

Type of Service	Year Ended 2025	Year Ended 2024
Audit Fees	$ 115,140	$ 138,434
Audit - related fees	72,632	102,882
Tax Fees	14,311	2,360
Total	$ 202,083	$ 243,676

Audit Fees

Audit fees consisted of fees incurred for professional services rendered for audits and interim reviews of the years ended September 30, 2025 and 2024. Audit-related fees include assurance and related services that were incurred for 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, 2025 and 2024.

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, 2025 and 2024.

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 Articles of Edesa Biotech, Inc. (included as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on February 13, 2025, and incorporated herein by reference).
3.7	Notice of Articles of Edesa Biotech, Inc. (included as Exhibit 3.7 to the Company's Registration Statement on Form S-3 filed on March 4, 2025, 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 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).

4.3 Form of Private Placement Warrant (included as Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 23, 2022, and incorporated herein by reference).

4.4 Form of Placement Agent Warrant (included as Exhibit 4.3 to the Company's Current Report on Form 8-K filed on March 23, 2022, and incorporated herein by reference).

4.5 Form of Class A Warrant (included as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 3, 2022, and incorporated herein by reference).

4.6 Description of Securities (filed herewith).

4.7 Form of Warrant (included as Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on October 31, 2024, 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 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).

10.3@ 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).

10.4@ 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).

10.5@ 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).

10.6@ 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).

10.7 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).

10.8+ 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).

10.9 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).

10.10 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).

10.11+ Third Amendment to Exclusive License Agreement, dated October 26, 2022, by and between the Registrant and Yissum Research Development Company (included as Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on December 16, 2022 and incorporated herein by reference).

10.12+ 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).

10.13+ 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).

10.14+ 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).

10.15+ 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).

10.16+ Exclusive License Agreement, dated as of March 16, 2021, by and between 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).

10.17@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).

10.18@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).

10.19 Form of Securities Purchase Agreement, dated March 21, 2022, by and between the Company and the Purchaser (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 23, 2022, and incorporated herein by reference).

10.20@Amendment to Employment Agreement, entered into on April 12, 2022, by and between Par Nijhawan and Edesa Biotech, Inc. (included as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 13, 2022, and incorporated herein by reference).

10.21@Amendment to Employment Agreement, entered into on April 12, 2022, by and between Michael Brooks and Edesa Biotech USA, Inc. (included as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 13, 2022, and incorporated herein by reference).

10.22 Form of Non-U.S. Subscription Agreement (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 3, 2022, and incorporated herein by reference).

10.23 Form of U.S. Subscription Agreement (included as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 3, 2022, and incorporated herein by reference).

10.24 Lease Extending and Amending Agreement dated as of December 31, 2022 by and between Edesa Biotech Research, Inc. and 1968160 Ontario, Inc. (included as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on February 10, 2023 and incorporated herein by reference).

10.25 Equity Distribution Agreement, dated as of March 27, 2023, by and between Edesa Biotech, Inc. and Canaccord Genuity LLC (included as Exhibit 1.1 to the Company's Current Report on Form 8-K filed on March 27, 2023, and incorporated herein by reference).

10.26@ Amendment No. 2 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 May 24, 2023, and incorporated herein by reference).

10.27@ Employment Agreement by and between the Company and Stephen Lemieux, dated June 26, 2023 (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 27, 2023, and incorporated herein by reference).

10.28@ Amended and Restated Employment Agreement, by and between the Company and Pardeep Nijhawan, dated August 4, 2023 (included as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023, and incorporated herein by reference).

10.29@ Amended and Restated Employment Agreement, by and between the Company and Michael Brooks, dated August 4, 2023 (included as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2023, and incorporated herein by reference).

10.30+ Strategic Innovation Fund Agreement, dated October 12, 2023, by and among Edesa Biotech Research, Inc., Edesa Biotech, Inc., and his Majesty the King in right of Canada as represented by the Minister of Industry (included as Exhibit 10.33 to the Company's Annual Report on Form 10-K filed on December 15, 2023, and incorporated herein by reference).

10.31 Credit Agreement, effective as of October 20, 2023, by and between the Company and Pardeep Nijhawan Medicine Professional Corporation (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 23, 2023, and incorporated herein by reference).

10.32+ First Amendment to Exclusive License Agreement, dated as of September 21, 2023, by and between Edesa Biotech Research, Inc. and Dr. Saul Yedgar (included as Exhibit 10.35 to the Company's Annual Report on Form 10-K filed on December 15, 2023, and incorporated herein by reference).

10.33@ First Amendment to Amended and Restated Employment Agreement, by and between the Company and Pardeep Nijhawan, dated December 7, 2023 (included as Exhibit 10.36 to the Company's Annual Report on Form 10-K filed on December 15, 2023, and incorporated herein by reference).

10.34@ Amendment No. 3 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 May 30, 2024, and incorporated herein by reference).

10.35 At The Market Offering Agreement, dated October 4, 2024, by and between Edesa Biotech, Inc. and H.C. Wainwright & Co., LLC (included as Exhibit 1.1 to the Company's Current Report on Form 8-K filed on October 4, 2024, and incorporated herein by reference).

10.36 Securities Purchase Agreement, dated October 30, 2024, by and between Edesa Biotech, Inc. and Pardeep Nijhawan Medicine Professional Corporation (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 31, 2024, and incorporated herein by reference).

10.37 Form of Securities Purchase Agreement, dated February 12, 2025, between Edesa Biotech, Inc. and the investors signatory thereto (included as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on February 13, 2025, and incorporated herein by reference).

10.38 Form of Investor Rights Agreement, dated February 12, 2025, between Edesa Biotech, Inc. and the investors signatory thereto (included as Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on February 13, 2025, and incorporated herein by reference).

10.39@ Employment Agreement, dated April 3, 2025, by and between the Company and Peter Weiler (included as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on April 4, 2025, and incorporated herein by reference).

10.40 Consulting Agreement, dated May 12, 2025, between Edesa Biotech Research, Inc. and Stephen Lemieux (included as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 14, 2025, and incorporated herein by reference).

10.41 Amendment No. 4 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 May 28, 2025, and incorporated herein by reference).

10.42+ Amendment Agreement No. 1 to Strategic Innovation Fund Agreement, dated September 30, 2025, by and among Edesa Biotech Research, Inc., Edesa Biotech, Inc., and his Majesty the King in right of Canada as represented by the Minister of Industry (filed herewith).

19.1 Insider Trading Policy (included as Exhibit 19.1 to the Company's Annual Report on Form 10-K filed on December 13, 2024, 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.

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.
97.1	Incentive Compensation Repayment (Clawback) Policy (included as Exhibit 97.1 to the Company's Annual Report on Form 10-K filed on December 15, 2023, and incorporated herein by reference).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* 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.

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 12, 2025

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

Date: December 12, 2025

/s/ Peter Weiler
Peter Weiler
Chief Financial Officer
(Principal Financial Officer)

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Pardeep Nijhawan **Pardeep Nijhawan**	Director, Chief Executive Officer, and Corporate Secretary (Principal Executive Officer)	December 12, 2025
/s/ Peter Weiler **Peter Weiler**	Chief Financial Officer (Principal Financial and Accounting Officer)	December 12, 2025
/s/ Joan Chypyha **Joan Chypyha**	Director	December 12, 2025
/s/ David Liu **David Liu**	Director	December 12, 2025
/s/ Sean MacDonald **Sean MacDonald**	Director	December 12, 2025
/s/ Patrick Marshall **Patrick Marshall**	Director	December 12, 2025
/s/ Charles Olson **Charles Olson**	Director	December 12, 2025
/s/ Carlo Sistilli **Carlo Sistilli**	Chairman of the Board of Directors	December 12, 2025

EDESA BIOTECH, INC.
INDEX TO FINANCIAL STATEMENTS

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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, 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, 2025, in conformity with accounting principles generally accepted in the United States of America.

Material Uncertainty Related to Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has incurred a net comprehensive loss and negative cash flows from operations and has accumulated deficit, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. This matter is also described in the "Critical Audit Matters" section of our report.

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.

MNP LLP
1 Adelaide Street East, Suite 1900, Toronto ON, M5C 2V9 1.877.251.2922 T: 416.596.1711 F: 416.596.7894

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Going Concern

Critical Audit Matter Description

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has incurred a net comprehensive loss, negative cash flows from operations and has accumulated deficit as at September 30, 2025 that raise substantial doubt about its ability to continue as a going concern. The ability of the Company to continue as a going concern is ultimately dependent on obtaining additional funding through financing, grants and other strategic alternatives. Management intends to continue to fund its business by way of equity financing. However, the Company has not concluded that these plans alleviate the substantial doubt related to its ability to continue as a going concern. This matter is also described in the "Material Uncertainty Related to Going Concern" section of our report.

We identified the Company's ability to continue as a going concern as a critical audit matter because auditing the Company's going concern assessment is complex and involves a high degree of auditor judgment to assess the reasonableness of the cash flow forecasts.

Audit Response

We responded to this matter by performing procedures over management's assessment of the Company's ability to continue as a going concern. Our audit work in relation to this included, but was not restricted to, the following:

- We evaluated the cash flow forecasts prepared by management and evaluated the integrity and arithmetical accuracy of the model.
- We evaluated the key assumptions used in management's model to estimate future cash flows by comparing assumptions used by management against historical performance and budgets.
- We assessed the adequacy of the going concern disclosures included in Note 1 of the consolidated financial statements.

MNP LLP

Chartered Professional Accountants
Licensed Public Accountants

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

Toronto, Canada
December 12, 2025

EDESA BIOTECH, INC.
Consolidated Balance Sheets

	September 30, 2025	September 30, 2024
Assets:		
Current assets:		
Cash and cash equivalents	**$ 10,792,172**	$ 1,037,320
Accounts and other receivable	**642,866**	270,908
Prepaid expenses and other current assets	**77,838**	367,394
Total current assets	**11,512,876**	1,675,622
Non-current assets:		
Long-term deposits	**39,966**	41,151
Intangible asset, net	**1,977,676**	2,078,848
Right-of-use assets	**-**	18,361
Total assets	**$ 13,530,518**	$ 3,813,982
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable and accrued liabilities	**$ 1,078,536**	$ 1,812,960
Short-term right-of-use lease liabilities	**-**	19,867
Total current liabilities	**1,078,536**	1,832,827
Shareholders' equity:		
Capital shares		
Authorized unlimited common shares without par value		
Issued and outstanding:		
7,141,783 common shares (September 30, 2024 - 3,247,389)	**54,515,421**	47,236,024
Authorized preferred shares issued and outstanding		
150 Series A-1 preferred shares (September 30, 2024 - 0)	**1,092,133**	-
834 Series B-1 preferred shares (September 30, 2024 - 0)	**8,168,063**	-
Additional paid-in capital	**14,753,110**	13,576,757
Accumulated other comprehensive loss	**(165,771)**	(242,613)
Accumulated deficit	**(65,910,974)**	(58,589,013)
Total shareholders' equity	**12,451,982**	1,981,155
Total liabilities and shareholders' equity	**$ 13,530,518**	$ 3,813,982

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

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

	Fiscal Year End	
	September 30, 2025	**September 30, 2024**
Expenses:		
Research and development	**$ 3,668,738**	$ 2,881,967
General and administrative	**4,242,828**	4,132,777
Loss from operations	**(7,911,566)**	(7,014,744)
Other income:		
Reimbursement grant income	**783,894**	698,277
Interest income	**2,558**	153,498
Misc other income	**-**	14,766
Foreign exchange (loss)	**(59,609)**	(21,042)
	726,843	845,499
Loss before income taxes	**(7,184,723)**	(6,169,245)
Income tax expense	**800**	800
Net loss	**(7,185,523)**	(6,170,045)
Exchange differences on translation	**76,842**	(27,965)
Net comprehensive loss	**$ (7,108,681)**	$ (6,198,010)
Weighted average number of common shares	**5,676,708**	3,197,423
Loss per common share - basic and diluted	**$ (1.27)**	$ (1.93)

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

EDESA BIOTECH, INC.
Consolidated Statements of Cash Flows

	Fiscal Year End	
	September 30, 2025	**September 30, 2024**
Cash flows from operating activities:		
Net loss	**$ (7,185,523)**	$ (6,170,045)
Adjustments for:		
Depreciation and amortization	**119,273**	186,049
Share-based compensation	**729,642**	537,492
Gain on loan forgiveness	**-**	(14,766)
Changes in working capital items:		
Accounts and other receivable	**(377,987)**	356,339
Prepaid expenses and other current assets	**107,832**	197,136
Accounts payable and accrued liabilities	**(715,499)**	17,590
Net cash used in operating activities	**(7,322,262)**	(4,890,205)
Cash flows from financing activities:		
Proceeds from issuance of common shares and warrants	**7,717,634**	729,387
Proceeds from issuance of Series A-1 preferred shares and warrants	**1,540,820**	-
Proceeds from issuance of Series B-1 preferred shares	**8,340,000**	-
Payments for issuance costs of common shares and warrants	**(328,953)**	(107,824)
Payment for issuance costs of preferred shares	**(215,157)**	-
Payment for issuance costs of warrants	**(23,446)**	-
Repayment of debt	-	(29,532)
Net cash provided by financing activities	**17,030,898**	592,031
Effect of exchange rate changes on cash and cash equivalents	**46,216**	(25,903)
Net change in cash and cash equivalents	**9,754,852**	(4,324,077)
Cash and cash equivalents, beginning of year	**1,037,320**	5,361,397
Cash and cash equivalents, end of year	**$ 10,792,172**	$ 1,037,320

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

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

	Shares #	Common Shares	Series A-1 Preferred Shares	Series B-1 Preferred Shares	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
Balance - September 30, 2023	**3,075,473**	**$ 46,643,151**	**$ -**	**$ -**	**$ 13,039,265**	**$ (214,648)**	**$ (52,418,968)**	**$ 7,048,800**
Issuance of common shares upon exercise of warrants	171,916	729,387	-	-	-	-	-	729,387
Issuance costs	-	(136,514)	-	-	-	-	-	(136,514)
Share-based compensation	-	-	-	-	537,492	-	-	537,492
Net loss and comprehensive loss	-	-	-	-	-	(27,965)	(6,170,045)	(6,198,010)
Balance - September 30, 2024	**3,247,389**	**$ 47,236,024**	**$ -**	**$ -**	**$ 13,576,757**	**$ (242,613)**	**$ (58,589,013)**	**$ 1,981,155**
Issuance of common shares	3,862,803	7,717,634	-	-	-	-	-	7,717,634
Issuance of Series A-1 preferred shares and warrants	-	-	998,915	-	541,905	-	-	1,540,820
Issuance of Series B-1 preferred shares	-	-	-	8,340,000	-	-	-	8,340,000
Issuance of common shares upon exercise of restricted share units	31,591	71,748	-	-	(71,748)	-	-	-
Issuance costs	-	(509,985)	(43,220)	(171,937)	(23,446)	-	-	(748,588)
Preferred return on Series A-1 preferred shares	-	-	136,438	-	-	-	(136,438)	-
Share-based compensation	-	-	-	-	729,642			729,642
Net loss and comprehensive loss						76,842	(7,185,523)	(7,108,681)
Balance - September 30, 2025	**7,141,783**	**$ 54,515,421**	**$ 1,092,133**	**$ 8,168,063**	**$ 14,753,110**	**$ (165,771)**	**$ (65,910,974)**	**$ 12,451,982**

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

1. Nature of operations

Edesa Biotech, Inc. (the "Company" or "Edesa") is a biopharmaceutical company focused on acquiring, developing and commercializing clinical stage drugs for 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., a California, USA corporation.

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

Going Concern

These consolidated financial statements have been prepared on a going concern basis which presumes the realization of assets and the discharge of liabilities in the normal course of operations for at least the next twelve months.

For the year ended September 30, 2025, the Company incurred a comprehensive loss of $7.1 million resulting in an accumulated deficit of $65.9 million. For the year ended September 30, 2025, the Company had a net cash outflow from operating activities of $7.3 million and ended the year with $10.8 million in cash and cash equivalents and a net working capital surplus of $10.4 million. During the year ended September 30, 2025, the Company received net proceeds of $17.0 million from equity financings, including the issuance of common shares and preferred shares in multiple transactions. Subsequent to year end, the Company received additional net proceeds of approximately $3.4 million from the issuance of equity securities sold pursuant to the Company's ATM with H.C. Wainwright & Co., LLC. The Company's ability to continue as a going concern is dependent on obtaining additional funding through financings, other strategic activities as well as via grants, to fund the development of its drug candidates. There can be no assurance that the Company will be successful in raising the necessary financing. These conditions indicate the existence of a material uncertainty that may cast substantial doubt about the Company's ability to continue as a going concern.

These consolidated financial statements do not give effect to any adjustments which would be necessary should the Company be unable to continue as a going concern and, therefore, be required to realize its assets and discharge its liabilities in other than the normal course of business and at amounts different from those reflected in the accompanying consolidated financial statements. These adjustments could be material.

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.

In August 2022 the Company filed a $150.0 million shelf registration statement that expired in August 2025, under which the Company entered into an equity distribution agreement with Canaccord for $20.0 million in gross proceeds, subject to certain offering limitations that allowed the Company to offer and sell common shares having an aggregate gross sales price of up to $8.4 million ("Canaccord ATM"). For the fiscal year ended September 30, 2024, the Company sold a total of 171,916 common shares pursuant to the agreement for net proceeds of $0.6 million after deducting commissions and costs of $0.1 million. The Canaccord ATM was terminated in October 2024.

In October 2024, the Company entered into an At The Market Offering Agreement with H.C. Wainwright & Co., LLC as a sales agent ("HCW ATM") 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 $4.0 million in gross proceeds. For the fiscal year ended September 30, 2025, the Company sold a total of 394,057 common shares pursuant to the agreement for net proceeds of approximately $1.0 million after deducting sales agent commissions.

A new shelf registration statement on Form S-3, allowing for the offer and sale of up to $4.0 million of securities, was filed and declared effective by the SEC on September 9, 2025. Subsequent to September 30, 2025, the Company sold an additional 1,177,568 common shares under the HCW ATM for net proceeds of approximately $3.4 million after deducting sales agent commissions.

The Company's primary use of cash and cash equivalents is to fund operating expenses, which consist of research and development ("R&D") and general and administrative ("G&A") expenditures. Cash used to fund operating expenses is impacted by the timing of when the Company pays these expenses, as reflected in the change in accounts payable and accrued expenses. Net cash used in operating activities was $7.3 million and $4.9 million for the years ended September 30, 2025 and 2024, respectively. The Company incurred net losses of $7.2 million and $6.2 million for the years ended September 30, 2025 and 2024. As of September 30, 2025, the Company had a working capital surplus of $10.4 million. The Company has historically funded its operations through equity financings and government grants.

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.

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. Significant areas of judgment and estimation include, but are not limited to, the valuation of accounts and other receivables; the valuation and useful lives of intangible assets; the measurement of right-of-use assets and lease liabilities; deferred income taxes; the determination of the fair value of share-based compensation; the determination of the fair value of warrants and the allocation of proceeds from equity issuances; and forecasting future cash flows in assessing our 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 held in checking, savings and money market mutual funds 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.

Accounts and other receivables

The Company assesses the collectability of its accounts receivables through a review of its current aging and payment terms, as well as an analysis of its historical collection rate, general economic conditions and credit status of the government agencies. Accounts and other receivables include reimbursement grant income for the Company's federal grant with the Canadian government's SIF and Harmonized Sales Tax ("HST") refunds receivables. As of September 30, 2025, all outstanding accounts, grants and HST refunds receivables 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. 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 year.

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.

Right-of-Use assets and liabilities

The Company recognizes right-of-use ("ROU") assets and liabilities on the balance sheet for operating leases with terms longer than 12 months. The Company follows the ongoing practical expedient not to recognize ROU assets and liabilities for short- term leases. The ROU assets are initially measured at cost and amortized using the straight-line method through the end of the lease term. The ROU liabilities are initially 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.

Fair value measurement

The Company uses the fair value measurement framework for valuing financial assets and liabilities. See Note 10.

Reimbursement Grant Income

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 has equity incentive plans under which various types of equity-based awards including share options, restricted shares and restricted share unit awards may be granted to employees, non-employee directors and non-employee consultants and warrants that may be granted as compensation to non-employees.

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.

The Company recognizes compensation expense for all share-based awards based on the estimated grant-date fair values. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

The fair value of share options is determined using the Black-Scholes option pricing model. The Company utilizes a dividend yield of zero based on the fact that the Company has never paid cash dividends and has no current intention of paying cash dividends. The Company elected an accounting policy to record forfeitures as they occur. See Note 7 for a discussion of the assumptions used by the Company in determining the grant date fair value of options granted under the Black-Scholes option pricing model, as well as a summary of the share option activity under the Company's share-based compensation plan for all years presented.

The provisions of the Company's share-based compensation plans do not require the Company to settle any options or restricted share units by transferring cash or other assets, and therefore the Company classifies the awards as equity.

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 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 year.

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 share 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 share options and warrants would have an antidilutive effect on loss per share for the years ended September 30, 2025 and 2024 and are therefore excluded from the computation of diluted loss per share. See Note 7 for additional information on outstanding equity instruments at September 30, 2025 and 2024.

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.

Future accounting pronouncements

In November 2023, the FASB issued Accounting Standards Update ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires disclosure of incremental segment information on an interim and annual basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal periods beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. The Company does not expect that this standard will have a material impact on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. The standard will require more detailed information in the rate reconciliation table and for income taxes paid, among other enhancements. The standard is effective for years beginning after December 15, 2024 and early adoption is permitted. The Company is currently evaluating the impact of the guidance on the consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"), which requires public entities to disclose additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. This guidance is effective for annual reporting periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

4. 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, which have been fully converted to common shares. The value of the license includes acquisition legal costs. See Note 6 for license commitments.

Intangible assets, net consisted of the following:

	September 30, 2025	September 30, 2024
The Constructs	$ 2,529,483	$ 2,529,483
Less: accumulated amortization	(551,807)	(450,635)
Total intangible assets, net	$ 1,977,676	$ 2,078,848

Amortization expense amounted to $101,172 for each of the years ended September 30, 2025, and 2024, respectively.

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

Year Ending	
September 30, 2026	101,172
September 30, 2027	101,172
September 30, 2028	101,172
September 30, 2029	101,172
September 30, 2030	101,172
Thereafter	1,471,816
	$ 1,977,676

5. Right-of-Use Asset and Liabilities

Related party ROU asset and liability

The Company leases a facility used for executive offices from a related company. The original lease expired in December 2022 and the Company executed a two-year term extension through December 31, 2024.

The components of lease cost were as follows:

	Fiscal Year End	
	September 30, 2025	**September 30, 2024**
Right-of-use lease cost, included in general and administrative on the Statements of Operations	**$ 17,893**	$ 78,073

Lease terms and discount rates were as follows:

	September 30, 2025	**September 30, 2024**
Remaining lease term (months):	**0**	3
Estimated incremental borrowing rate:	**9.2%**	9.2%

Cash flow information was as follows:

	Fiscal Year End	
	September 30, 2025	**September 30, 2024**
Cash paid for amounts included in the measurement of right-of-use lease liabilities, included in accounts payable and accrued liabilities on the Statements of Cash Flow.	**$ 17,893**	$ 77,954

6. Commitments

Research and other commitments

The Company has commitments for contract manufacturing and other service providers for chemistry, manufacturing and controls and related development activities associated with its product candidates. Aggregate future contractual payments at September 30, 2025 are as follows:

Year Ending	
September 30, 2026	$ 770,000
September 30, 2027	88,000
September 30, 2028	-
September 30, 2029	-
September 30, 2030	-
	$ 858,000

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 4 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 milestone, royalty or sublicensing payments were made to the third party during the years ended September 30, 2025 and 2024. 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. No expense was recorded during the years ended September 30, 2025 and September 30, 2024.

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 $18.4 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, 2025 and 2024, 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 years ended September 30, 2025 and 2024, the Company recorded expenses of $100,000 in each year 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 $68.9 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 quarterly as long as the requirement to file an IND remains unfulfilled.

Retirement savings plan 401(k) contributions

Executive officers and employees of the 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 $13,750 and $17,870 during the years ended September 30, 2025 and 2024, respectively.

7. Capital shares

Series B-1 Preferred Shares Offering

On February 12, 2025, the Company entered into a Securities Purchase Agreement ("Series B-1 Purchase Agreement") with certain investors, including members of the Company's board of directors and executive officers (the "Series B-1 Investors"), pursuant to which the Company issued and sold to the Series B-1 Investors in a private placement (the "Private Placement"), an aggregate of (i) 834 shares (the "Series B-1 Preferred Shares") of the Company's newly designated Series B-1 Convertible Preferred Shares, stated value $10,000 per share, each of which is initially convertible into approximately 5,208 common shares (the "Series B-1 Conversion Shares"), without par value, of the Company (the "Common Shares") at a conversion price of $1.92 per Series B-1 Conversion Share, and (ii) 3,468,746 Common Shares. The purchase price per Series B-1 Preferred Share was $10,000 and the purchase price per Common Share was $1.92. The gross proceeds to the Company were approximately $15.0 million, prior to deducting offering expenses payable by the Company which were allocated between the Series B-1 Preferred Shares and Common Shares based on the market price of the Company's Common Shares on the issuance date. A Series B-1 Investor will not have the right to convert any portion of its Series B-1 Preferred Shares if, together with its affiliates, it would beneficially own in excess of 4.99%, 9.99% or 19.99% of the number of Common Shares outstanding immediately after giving effect to such conversion.

The Series B-1 Purchase Agreement contains customary representations and warranties and agreements of the Company and the Series B-1 Investors and customary indemnification rights and obligations of the parties.

The Series B-1 Preferred Shares are presented as permanent shareholders' equity.

The Series B-1 Preferred Shares did not exist in the comparative period; therefore, no prior-period disclosure is presented.

	Series B-1 Convertible Preferred Shares (#)	Series B-1 Convertible Preferred Shares
Balance - September 30, 2024	-	-
Issuance of Series B-1 Preferred Shares	834	$ 8,340,000
Series B-1 Preferred Shares issuance costs	-	(171,937)
Balance - September 30, 2025	834	$ 8,168,063

Series A-1 Preferred Shares Offering

On October 30, 2024, the Company entered into a Securities Purchase Agreement ("Series A-1 Purchase Agreement") with an entity controlled by the Company's Chief Executive Officer, Secretary and member of the board of directors of the Company ("Series A-1 Purchaser"), pursuant to which the Company agreed to issue and sell to the Series A-1 Purchaser in a private placement, up to $5,000,000 of shares of the Company's newly designated Series A-1 Convertible Preferred Shares, stated value $10,000 per share (the "Series A-1 Preferred Shares"), each of which is initially convertible into approximately 2,903 Common Shares (the "Series A-1 Conversion Shares"), at a conversion price of $3.445 per Series A-1 Conversion Share, and warrants ("Warrants") to purchase Common Shares (the "Series A-1 Warrant Shares") at an exercise price of $3.445 per Series A-1 Warrant Share. The Series A-1 Preferred Shares and the Warrants are being sold together in a fixed combination of one Series A-1 Preferred Share and a Warrant to purchase a number of Common Shares equal to 75% of the underlying Series A-1 Conversion Shares at a combined purchase price of $10,272.13 per Series A-1 Preferred Share and related Warrants. Under the Series A-1 Purchase Agreement, the Series A-1 Purchaser has purchased 150 Series A-1 Preferred Shares initially convertible into an aggregate of 435,414 Series A-1 Conversion Shares and Warrants to purchase up to an aggregate of 326,560 Warrant Shares for an aggregate purchase price of $1,540,819. The offering of the Series A-1 Preferred Shares and Warrants was structured as an at-market offering under the rules of The Nasdaq Stock Market. The Series A-1 Purchaser will not have the right to convert any portion of its Series A-1 Preferred Shares if, together with its affiliates, it would beneficially own in excess of 19.99% of the number of Common Shares outstanding immediately after giving effect to such conversion.

The Warrants expire five years from the issuance date. The Warrants may only be exercised on a cashless basis if there is no registration statement registering, or the prospectus contained therein is not available for, the issuance or resale of the Common Shares issuable upon exercise of the Warrants to or by the holders thereof. The exercise price of the Warrants is subject to customary antidilution adjustments in the event of share splits, reclassifications, recapitalizations and similar events. The Series A-1 Purchaser will not have the right to exercise any portion of its Warrants if, together with its affiliates, it would beneficially own in excess of 19.99% of the number of Common Shares outstanding immediately after giving effect to such exercise.

The Company has the right to require the Series A-1 Purchaser to purchase additional Series A-1 Preferred Shares and Warrants (up to an aggregate investment of $5.0 million); provided however, no more than an aggregate of $2.0 million of Series A-1 Preferred Shares and Warrants may be issued and sold pursuant to the Series A-1 Purchase Agreement without shareholder approval in accordance with applicable Canadian securities laws.

The Series A-1 Purchase Agreement contains customary representations and warranties and agreements of the Company and the Series A-1 Purchaser and customary indemnification rights and obligations of the parties.

The Company has the option to redeem the Series A-1 Preferred Shares, and upon conversion or liquidation, holders are entitled to receive the stated value plus a 10% annual return on capital, payable in Common Shares at the conversion price, calculated daily until the three-year anniversary of issuance.

The Series A-1 Preferred Shares are presented as permanent shareholders' equity. The total proceeds were allocated between the Series A-1 Preferred Shares and warrants using relative fair value. The fair value of the Series A-1 Preferred Shares was determined as a reference to the fair value of Common Shares on the issuance date and the fair value of the warrants was determined using Black-Scholes option pricing model as detailed below.

The Series A-1 Convertible Preferred Shares did not exist in the comparative period; therefore, no prior-period disclosure is presented.

	Series A-1 Convertible Preferred Shares (#)	Series A-1 Convertible Preferred Shares
Balance - September 30, 2024	-	-
Issuance of Series A-1 Preferred Shares	150	$ 998,915
Series A-1 Preferred Shares issuance costs	-	(43,220)
Preferred return on Series A-1 Preferred Shares	-	136,438
Balance - September 30, 2025	150	$ 1,092,133

Equity distribution agreement

At The Market offering agreement

On October 4, 2024, the Company entered into an At The Market offering agreement with H.C. Wainwright & Co., LLC as a sales agent ("HCW ATM") 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 $3.87 million in gross proceeds. The Company has no obligation to sell any of the common shares and may at any time suspend sales or terminate the equity distribution agreement in accordance with its terms. Subsequent to the year ended September 30, 2025, the Company sold a total of 1,177,568 common shares pursuant to the agreement for net proceeds of approximately $3.4 million after deducting sales agent commissions.

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, 2023	720,909	$ 19.51
Expired	(111,192)	7.26
Balance - September 30, 2024	609,717	$ 21.74
Issued	326,560	3.45
Expired	(1,687)	22.40
Balance - September 30, 2025	934,590	$ 15.35

The weighted average contractual life remaining on the outstanding warrants at September 30, 2025 is 28 months.

The following table summarizes information about the warrants outstanding at September 30, 2025:

Number of Warrants	Exercise Prices	Expiry Dates
173,614	$ 10.50	December 2025
15,627	$ 56.00	February 2026
27,399	$ 31.94	March 2027
391,390	$ 24.64	September 2027
326,560	$ 3.45	October 2029
934,590		

The fair value of warrants issued during the year ended September 30, 2025 were estimated using the Black-Scholes option valuation model using the following assumptions:

	Year Ended September 30, 2025 Class A Pref Share
Risk free interest rate	4.14%
Expected life (years)	5
Expected share price volatility	91.24%
Expected dividend yield	0.00%

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, which amended and restated prior plans. Options, restricted shares and restricted share units are eligible for grant under the 2019 Plan. The total number of shares available for issuance under the terms of the 2019 Plan is 2,367,737. The remaining number of shares available to grant at September 30, 2025 is 693,515.

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, 2023	420,615	$ 25.60	$ 18.84
Granted	500	4.10	3.10
Forfeited	(2,401)	15.00	10.70
Expired	(35,674)	33.18	24.63
Balance - September 30, 2024	383,040	$ 24.93	$ 18.33
Forfeited	(196)	4.10	3.10
Expired	(4,805)	44.18	37.95
Balance - September 30, 2025	378,039	$ 24.70	$ 18.12

There were no options exercised during the years ended September 30, 2025 or September 30, 2024. The intrinsic value of options outstanding at September 30, 2025 was $0.00.

The weighted average contractual life remaining on the outstanding options at September 30, 2025 is 68 months.

The following table summarizes information about the options under the 2019 Plan outstanding and exercisable at September 30, 2025:

Number of Options	Exercisable at September 30, 2025 (#)	Range of Exercise Prices	Expiry Dates
37,719	37,719	C$ 15.12	August 2027 - Dec 2028
43,031	43,031	$ 22.12	Feb 2030
51,006	51,006	$ 52.08 - 56.49	September 2030 - Oct 2030
79,651	79,651	$ 36.75 - 40.18	March 2025 - Sep 2031
56,865	56,865	$ 25.97	March 2025 - Feb 2032
109,767	91,887	$ 4.10 - 10.01	March 2025 - Oct 2033
378,039	360,159		

The options exercisable at September 30, 2025 had a weighted average exercise price of $25.59 and an intrinsic value of $0.00 and a weighted average remaining life of 67 months. There were 17,880 options at September 30, 2025 that had not vested with a weighted average exercise price of $6.77 and an intrinsic value of $0.00 and a weighted average remaining life of 91 months.

The fair value of options granted during the year ended September 30, 2024 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Year Ended September 30, 2024
Risk free interest rate	4.92%
Expected life (years)	5
Expected share price volatility	97.26%
Expected dividend yield	0.00%

As of September 30, 2025, the Company had approximately $0.01 million of unrecognized share-based compensation expense, which is expected to be recognized over a period of 12 months.

Restricted share units

The Company's 2019 Plan allows restricted share units ("RSUs") to be granted to directors, officers, employees and certain external consultants and advisers. Under the 2019 Plan, the RSU term is not to exceed 10 years. The fair value of RSUs is determined based on the market price of the Company's common shares on the grant date.

The following is a summary of changes in the status of RSUs from October 1, 2024 through September 30, 2025:

	Number of RSU	Weighted Average Grant Date Fair Value
Balance - September 30, 2023	33,045	$ 5.60
Granted	30,159	4.56
Balance - September 30, 2024	63,204	$ 5.10
Granted	1,227,807	$ 2.01
Exercised	(31,591)	$ 2.27
Forfeited	(7,230)	$ 1.99
Cancelled	(8,537)	$ 1.99
Balance - September 30, 2025	1,243,653	$ 2.16

The following table summarizes information about the RSUs under the 2019 Plan outstanding and exercisable at September 30, 2025:

	Number of RSU	Exercisable at September 30, 2025 (#)	Expiry Date
Fully-vested RSUs	137,918	137,918	August 2033 - September 2035
Vesting in the next 12 months	250,822	76,086	May 2035
Vesting from 13–24 months	434,321	78,435	May 2035
Vesting in 24 months or greater	420,592	40,880	May 2035
	1,243,653	333,319	

The Company has granted RSUs with varying vesting schedules. Certain RSU's vest immediately upon the grant date, while others vest over a period ranging from 12 to 36 months. Outstanding RSUs can be converted to Common Shares by the holder at any time after vesting and before the expiry date. As of September 30, 2025, the Company had approximately $1.8 million of unrecognized restricted share unit compensation expense, which is expected to be recognized over a period of 32 months.

The Company recorded $0.7 million and $0.5 million of share-based compensation expenses for the years ended September 30, 2025 and 2024, respectively. These amounts include expenses related to both stock options and RSUs granted to employees and directors under the Company's equity compensation plans.

8. Government Contributions

SIF

The Company's wholly owned subsidiary Edesa Biotech Research is party to a multi-year contribution agreement with the Canadian government's Strategic Innovation Fund, or SIF, dated October 12, 2023, and an Amendment Agreement No. 1 to the agreement, dated September 30, 2025 (together, the "2023 SIF Agreement"). Under the 2023 SIF Agreement, the Government of Canada committed up to C$23 million in partially repayable funding toward (i) conducting and completing the Company's Phase 3 clinical study of its experimental drug EB05, (ii) submitting EB05 for governmental approvals and manufacturing scale-up, following, and subject to, completing the Phase 3 study and (iii) conducting two non-clinical safety studies to assess the potential long-term impact of EB05 exposure (the "Project"). Of the C$23 million committed by SIF, up to C$5.8 million is not repayable by the Company. The remaining C$17.2 million is conditionally repayable starting in 2032 only if and when the Company earns gross revenue. The repayable portion would be payable over fifteen (15) years based on a percentage rate of the Company's annual revenue growth. The maximum amount repayable is 1.4 times the original repayable amount. In addition, the Company is entitled to partial reimbursement of certain eligible expenses.

The Company also agreed to certain financial and non-financial covenants and other obligations in relation to the Project. Certain customary events of default, such as the Company's or Edesa Biotech Research's breach of their covenants and obligations under the Agreement, their insolvency, winding up or dissolution, and other similar events, may permit the Government of Canada to declare an event of default. Upon an event of default, subject to applicable cure, the Government of Canada may exercise a number of remedies, including suspending or terminating funding, demanding repayment of funding previously received and/or terminating the 2023 SIF Agreement.

The funding and any associated conditional repayments are not secured by any assets of Edesa Biotech Research or the Company.

The 2023 SIF Agreement will expire on the later of December 31, 2045 or the date of the last repayment, unless earlier terminated, subject to certain provisions that extend three (3) years beyond the term or early termination.

Under the 2023 SIF Agreement the Company recorded grant income of $0.8 million and $0.7 million for the years ended September 30, 2025 and September 30, 2024, respectively.

Canada Emergency Business Account

During year ended September 30, 2024, the Company recognized a $20,000 Canadian dollar gain from loan forgiveness related to its Canada Emergency Business Account ("CEBA") loan. This forgiveness was granted upon successful repayment of $40,000 Canadian dollar of the loan balance, in accordance with CEBA program terms. The forgiven amount is recorded as other income in the consolidated statements of operations. The CEBA loan has been fully repaid and closed with CIBC.

9. Income Tax

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

	September 30, 2025	September 30, 2024
Net loss before recovery of income taxes	**$ (7,185,000)**	$ (6,169,000)
Canadian federal and provincial statutory income tax rate	**26.5%**	26.5%
Expected income tax recovery	**$ (1,910,000)**	$ (1,635,000)
Effect of foreign currency and foreign tax rate differences	**216,800**	(58,200)
Permanent differences	**200,000**	147,000
Share issuance cost booked through equity or capitalization	**(202,000)**	36,000
Non-capital losses limitation - U.S.	**0**	0
Other	**(19,000)**	(38,000)
Change in valuation allowance	**1,715,000**	1,549,000
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, 2025	September 30, 2024
Non-capital losses carried forward - Canada	**$ 17,270,000**	$ 15,547,000
Non-capital losses carried forward - U.S.	**749,000**	742,000
Research and development tax credits	**1,510,000**	1,504,000
Share issuance and financing costs	**314,000**	381,000
Right-of-use lease liabilities	**-**	5,000
Other temporary differences	**21,000**	21,000
Subtotal	**$ 19,864,000**	$ 18,200,000
Less: valuation allowance	**(19,733,000)**	(18,074,000)
Total net deferred tax assets	**$ 131,000**	$ 126,000
Property and equipment	**$ (3,000)**	$ (2,000)
Right-of-use assets	**-**	(5,000)
Grant Income receivable	**(129,000)**	(71,000)
Deferred share issuance costs	**1,000**	(48,000)
Total deferred tax liabilities	**$ (131,000)**	$ (126,000)
Net deferred taxes	**$ -**	$ -

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

Non-capital losses, capital losses, and research and development credits generated by 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 $29.3 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, 2025 expire as follows:

2026	41,000
2027	84,000
2028	172,000
2029	509,000
2030	636,000
2031	506,000
2032	498,000
2033	79,000
2034	1,420,000
2035	1,611,000
2036	1,612,000
2037	1,566,000
2038	2,573,000
2039	1,260,000
2040	5,792,000
2041	9,172,000
2042	15,827,000
2043	7,621,000
2044	6,188,000
2044	7,526,000
Total	$ 64,693,000

Share issuance and financing costs will be fully amortized in 2030.

The U.S. non-capital losses carried forward at September 30, 2025 totaled approximately $3.45 million, which do not expire for federal taxes. The U.S. state research and development tax credits carried forward at September 30, 2025 totaled approximately $0.6 million, which do not expire for state taxes. The approximate U.S. state non-capital losses carried forward at September 30, 2025 expire as follows:

2039	$ 70,000
2040	150,000
2041	68,000
2042	6,000
2044	41,000
2044	25,000
Total	$ 360,000

10. 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.

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.

(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 year end from the carrying value of its cash and cash equivalents and accounts and other receivable. The Company manages this risk by maintaining bank accounts with Canadian Chartered Banks, U.S. banks believed to be credit worthy and 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 and receivables through a review of the current aging and terms, as well as an analysis of historical collection rates, general economic conditions and credit status of government agencies. Credit risk for the reimbursement grant and HST refunds receivable are not considered significant since amounts are due from the Canadian government's 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, 2025, the Company and its Canadian subsidiary had assets denominated in Canadian dollars of approximately C$3.0 million and the U.S. dollar exchange rate at this date was equal to 1.3918 Canadian dollars. Based on the exposure at September 30, 2025, a 10% annual change in the Canadian/U.S. exchange rate would impact the Company's loss and other comprehensive loss by approximately $0.2 million.

(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.

11. Loss per Share

The Company had securities outstanding which could potentially dilute basic earnings per share in the future but were excluded from the computation of diluted loss per share in the periods presented, as their effect would have been anti-dilutive.

12. Related party transactions

On February 12, 2025 (the "Closing Date"), the Company entered into the Series B-1 Purchase Agreement with the Series B-1 Investors. Pursuant to the Series B-1 Purchase Agreement, the Company sold to the Series B-1 Investors in a private placement, an aggregate of (i) 834 Series B-1 Preferred Shares, each of which is initially convertible into approximately 5,208 Series B-1 Conversion Shares at a conversion price of $1.92 per Series B-1 Conversion Share, and (ii) 3,468,746 Common Shares. The purchase price per Series B-1 Preferred Share was $10,000 and the purchase price per common share was $1.92. The Company's Chief Executive Officer, Secretary, and a member of the board of directors purchased 100 Series B-1 Preferred Shares for an aggregate purchase price of $1.0 million. A director purchased 41,666 Common Shares for an aggregate purchase price of approximately $80,000. Another director purchased 10,416 Common Shares for an aggregate purchase price of approximately $20,000. Entities affiliated with significant beneficial owner purchased, in aggregate, 2,687,500 Common Shares and 734 Series B-1 Preferred Shares for aggregate gross proceeds of approximately $12.5 million. A holder of Series B-1 Preferred Shares will not have the right to convert any portion of its Series B-1 Preferred Shares, if, together with its affiliates, it would beneficially own in excess of 4.99% (or, at the option of the holder, 9.99%) of the number of Common Shares outstanding immediately after giving effect to such conversion, provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 61 days' notice to the Company, but not to any percentage in excess of 19.99%.

In connection with the Series B-1 Purchase Agreement, on February 12, 2025, the Company also entered into an Investor Rights Agreement ("IRA") with the Series B-1 Investors, whereby the Company agreed to provide the Series B-1 Investors with certain registration and other rights. The IRA provides that the board of directors, following the Company's annual meeting to be held on May 28, 2025, shall consist of seven members, one of whom shall be a director nominated by the lead investor (the "Lead Investor Nominee"), who shall serve on the board effective as of the Closing Date, until the earlier of such time as (i) the lead investor no longer holds at least 51% of the Common Shares (calculated on an as-converted-to-Common Shares basis), subject to appropriate adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization with respect to the Common Shares issued in the private placement, or (ii) the lead investor beneficially owns less than 5% of the outstanding Common Shares as a result of a disposition of shares (such period, the "Lead Investor Rights Period"). The Company also agreed to use its reasonable best efforts to solicit shareholder approval of the Lead Investor Nominee at each general or special meeting of shareholders of the Company at which an election of directors is held during the Lead Investor Right Period.

Additionally, the IRA includes certain protective provisions that restrict the Company's ability to, among other things, (i) amend, modify, alter or repeal any provision of the Company's governing documents in a manner adverse to the holders of Series B-1 Preferred Shares, (ii) alter or change the special rights and restrictions of the Series B-1 Preferred Shares and (iii) increase or decrease the authorized number of Series B-1 Preferred Shares, in each case, without the written consent of the lead investor.

Pursuant to the IRA, during the Lead Investor Rights Period, the lead investor is entitled to designate one (1) non-voting observer to the Board to attend all meetings of the Board and committees and subcommittees thereof, subject to the terms of the IRA.

On October 30, 2024, the Company entered into the Series A-1 Purchase Agreement with the Series A-1 Purchaser, an entity controlled by the Company's Chief Executive Officer, Secretary and member of the board of directors of the Company, pursuant to which the Company agreed to issue and sell to the Series A-1 Purchaser in a private placement, up to $5,000,000 of the Series A-1 Preferred Shares, each of which is initially convertible into the Series A-1 Conversion Shares, at a conversion price of $3.445 per Series A-1 Conversion Share, and Warrants to purchase Common Shares at an exercise price of $3.445. Under the Series A-1 Purchase Agreement, the Series A-1 Purchaser has purchased 150 Series A-1 Preferred Shares initially convertible into an aggregate of 435,414 Series A-1 Conversion Shares and Warrants to purchase up to an aggregate of 326,560 Warrant Shares for an aggregate purchase price of $1,540,819. The offering of the Series A-1 Preferred Shares and Warrants was structured as an at-market offering under the rules of The Nasdaq Stock Market. The Series A-1 Purchaser will not have the right to convert any portion of its Series A-1 Preferred Shares, or exercise any portion of the Warrants, if, together with its affiliates, it would beneficially own in excess of 19.99% of the number of Common Shares outstanding immediately after giving effect to such conversion or exercise. See Note 5 – Series A-1 Convertible Preferred Shares offering.

During each of the years ended September 30, 2025 and 2024, the Company paid cash of $76,000 and $78,000, respectively, for a ROU lease from a company controlled by the Company's CEO. 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. On December 31, 2022, the Company executed a two-year lease extension through December 31, 2024 in accordance with the terms of the original lease agreement. Rents of approximately $30,000 was payable at September 30, 2024. No rent was payable at September 30, 2025.

The Company agreed to pay a monthly standby fee for the term of the Credit Agreement, which amounted to $4,000 in the year ending September 30, 2025 and $51,000 in the year ending September 30, 2024.

At September 30, 2025, accounts and other receivable included immaterial balance due from certain executive officers related to foreign exchange payroll adjustments recorded during fiscal 2025. These amounts are being recovered through scheduled deductions and are expected to be settled by December 2025. Other than these FX-related adjustments, the Company did not have any loans or other receivables outstanding from its directors or executive officers as of September 30, 2025.

13. Subsequent events

Subsequent to September 30, 2025, the Company sold a total of 1,177,568 common shares pursuant to the HCW ATM agreement with H.C. Wainwright & Co., LLC for net proceeds of approximately $3.4 million, after deducting sales agent commissions. In addition, subsequent to September 30, 2025, the Company granted an aggregate of 21,642 restricted share units under its equity incentive plan. During the same period, 14,472 RSUs were settled in an equivalent number of common shares. Subsequent to September 30, 2025, the Company entered into certain service agreements with third-party service providers related to its research and development activities. Under the terms of these agreements, the Company may be required to make future payments of up to an aggregate of approximately $4.2 million, contingent upon the scope of services performed and terms of the underlying agreements.

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