UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): September 28, 2020

Edesa Biotech, Inc.

(Exact Name of Registrant as Specified in its Charter)

British Columbia, Canada	**001-37619**	**N/A**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Spy Court
Markham, Ontario, Canada L3R 5H6
(Address of Principal Executive Offices)

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Shares	EDSA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). 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. ☒

Item 8.01. Other Events

Edesa Biotech, Inc. (the "Company", "we") is filing this Current Report on Form 8-K to update our common shares issued and outstanding and beneficial ownership and to provide additional information pertaining to our expanded intellectual property portfolio. We are also filing this Current Report on Form 8-K to supplement the risk factors set forth under "Item 1A. Risk Factors" in our Annual Report on Form 10-KT for the nine-month period ended September 30, 2019 filed with the Securities and Exchange Commission on December 12, 2019 (the "Annual Report"), as supplemented by the additional risk factor in Item 8.01 in our Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2020. The risk factors set forth below relate to the expansion of our drug development pipeline and the greater priority we have placed on our EB05 development program. These supplemental risk factors should be read in conjunction with the risk factors set forth in the Annual Report and our Current Report on Form 8-K filed on March 27, 2020.

Shares Outstanding

As of September 24, 2020 we had 9,608,869 common shares issued and outstanding, which reflects an aggregate of 194,591 common shares issued upon exercise of warrants and options since the filing of our interim financial results on Form 10-Q on August 12, 2020.

Security Ownership of Certain Beneficial Owners and Management

The following tables sets forth certain information as of September 24, 2020, with respect to the beneficial ownership of our common shares by: (1) all of our directors; (2) our named executive officers; (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 theinformation furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common shares that they beneficially own, subject to applicable community property laws.

Common shares subject to options or warrants currently exercisable or exercisable within 60 days of September 24, 2020 are deemed outstanding for computing the share ownership and percentage of the person holding such options and warrants, but are not deemed outstanding for computing the percentage of any other person. The percentage ownership of our common shares of each person or entity named in thefollowing table is based on 9,608,869 common shares outstanding as of September 24, 2020.

Directors and Officers

Name and Address of Beneficial Owner (1)	Amount and Nature of Beneficial Ownership		Percent of Shares Beneficially Owned
Lorin Johnson, PhD	24,845	(2)	*
Sean MacDonald	20,035	(3)	*
Pardeep Nijhawan, MD	3,317,207	(4)	34.3%
Frank Oakes	15,524	(5)	*
Paul Pay	43,546	(6)	*
Carlo Sistilli, CPA, CMA	11,147	(7)	*
Peter van der Velden	2,184,018	(8)	22.3
Michael Brooks, PhD	202,639	(9)	2.1
Kathi Niffenegger, CPA	48,846	(10)	*
All directors and executive officers as a group (9 persons)	**5,867,807**	**(11)**	**60.4%**

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

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

(2) Consists of (i) 8,524 Common Shares, (ii) 6,393 Common Shares issuable upon exercise of Class A Warrants, (iii) 4,262 Common Shares issuable upon exercise of Class B Warrants and (iv) 5,666 Common Shares issuable upon exercise of options that are exercisable within sixty days of September 24, 2020.

(3) Consists of (i) 14,369 Common Shares and (ii) 5,666 Common Shares issuable upon exercise of options exercisable within sixty days of September 24, 2020.

(4) Consists of (A)(i) 537,312 Common Shares and (ii) 48,480 Common Shares issuable upon exercise of options exercisable within sixty days of September 24, 2020 held by Pardeep Nijhawan; (B)(i) 2,124,024 Common Shares, (ii) 6,942 Common Shares issuable upon exercise of Class A Warrants and (iii) 4,628 Common Shares issuable upon exercise of Class B Warrants held by Pardeep Nijhawan Medicine Professional Corporation for which Pardeep Nijhawan has sole voting and dispositive power over all such shares; (C)(i) 224,094 Common Shares held by The Digestive Health Clinic Inc. for which Pardeep Nijhawan has sole voting and dispositive power over all such shares and (D)(i) 371,727 Common Shares held by 1968160 Ontario Inc. for which Pardeep Nijhawan has sole voting and dispositive power over all such shares.

(5) Consists of (A)(i) 6,165 Common Shares and (ii) 6,618 Common Shares issuable upon exercise of options that are exercisable within sixty days of September 24, 2020 held by Frank Oakes and(B)(i) 1,218 Common Shares, (ii) 914 Common Shares issuable upon exercise of Class A Warrants and (iii) 609Common Shares issuable upon exercise of Class B Warrants held by Frank and Dorothy Oakes Family Trust for which each of Frank Oakes and Dorothy Oakes, as trustees, have voting and dispositive power over all such shares.

(6) Consists of (i) 2,436 Common Shares, (ii) 1,827 Common Shares issuable upon exercise of Class A Warrants, (iii) 1,218 Common Shares issuable upon exercise of Class B Warrants and (iv) 38,065 Common Shares issuable upon exercise of options exercisable within sixty days of September 24, 2020.

(7) Consists of (A) 5,666 Common Shares issuable upon exercise of options exercisable within sixty days of September 24, 2020 held by Carlo Sistilli and (B)(i) 2,436 Common Shares, (ii) 1,827 Common Shares issuable upon exercise of Class A Warrants and (iii) 1,218 Common Shares issuable upon exercise of Class B Warrants held byYork-Cav Enterprises Inc for which Carlo Sistilli, as President and Director, has sole voting and dispositive power over all such shares.

(8) Consists of (A) 5,666 Common Shares issuable upon exercise of options exercisable within sixty days of September 24, 2020 held by Peter van der Velden; (B)(i) 1,833,066 Common Shares, (ii) 96,542 Common Shares issuable upon exercise of Class A Warrants and (iii) 64,362 Common Shares issuable upon exercise of Class B Warrants held by Lumira Capital II,L.P. and (C)(i) 169,502 Common Shares, (ii) 8,928 Common Shares issuable upon exercise of Class A Warrants and (iii) 5,952 Common Shares issuable upon exercise of Class B Warrants held by Lumira Capital II (International), L.P., an affiliate of Lumira Capital II, L.P. Lumira Capital GP, L.P., the general partners of which are Lumira GP Inc. and Lumira GP Holdings Co., is the general partner of each of Lumira Capital II, L.P. and Lumira Capital II (International), L.P. Each of Lumira Capital II, L.P. and Lumira Capital II (International), L.P. is managed by Lumira Capital Investment Management Inc. Each of Lumira Capital GP, L.P., Lumira GP Inc., Lumira GP Holdings Co. and Lumira Capital Investment Management Inc. may be deemed to beneficially own the shares held by Lumira Capital II, L.P. and Lumira Capital II (International), L.P. and such entities control voting and investment power over such shares through an investment committee of the Lumira group. Peter van der Velden is an executive officer of Lumira GP Inc., Lumira GP Holdings Co. and Lumira Capital Investment Management Inc.

(9) Consists of (i) 4,327 Common Shares, (ii) 1,371 Common Shares issuable upon exercise of Class A Warrants, (iii) 914 Common Shares issuable upon exercise of Class B Warrants and(iv) 196,027 Common Shares issuable upon exercise of options exercisable within sixty days of September 24, 2020.

(10) Consists of (A) 46,105 Common Shares issuable upon exercise of options that areexercisable within sixty days of September 24, 2020 held by Kathi Niffenegger and (B) (i) 1,218 Common Shares, (ii) 914 Common Shares issuable upon exercise of Class A Warrants and (iii) 609 Common Shares issuable upon exercise of Class B Warrants held by the Kathi Niffenegger Trust for which Kathi Niffenegger, as trustee, has sole voting anddispositive power over all such shares.

(11) Consists of (i) 5,300,418 Common Shares, (ii) 125,658 Common Shares issuable upon exercise of Class A Warrants, (iii) 83,772 Common Shares issuable upon exercise of Class B Warrants and (i) 357,959 Common Shares issuable upon exercise of options that are exercisable within sixty days of September 24, 2020.

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

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Shares Beneficially Owned
Inveready (1)	531,986	5.5%
Lumira Capital II, L.P. (2)	2,178,352	22.3%

(1) Consists of 531,986 Common Shares. Voting and investment power over the shares held by Inveready Innvierte Biotech II, S.C.R. S.A is exercised by its board of directors. The address of the shareholder is c/o Inveready Technology Investment Group, C/dels Cavaliers, 50, Barcelona, 08034, Spain.

(2) Consists of (A)(i) 1,833,066 Common Shares, (ii) 96,542 Common Shares issuable upon exercise of Class A Warrants and (iii) 64,362 Common Shares issuable upon exercise of Class B Warrants heldby Lumira Capital II, L.P. and (B)(i) 169,502 Common Shares, (ii) 8,928 Common Shares issuable upon exercise of Class A Warrants and (iii) 5,952 Common Shares issuable upon exercise of Class B Warrants held by Lumira Capital II (International), L.P., an affiliate of Lumira Capital II, L.P. Lumira Capital GP, L.P., the general partners of which are Lumira GP Inc. and Lumira GP Holdings Co., is the general partner of each of Lumira Capital II, L.P. and Lumira Capital II (International), L.P. Each of Lumira Capital II, L.P. and Lumira Capital II (International), L.P. is managed by Lumira Capital Investment Management Inc. Each of Lumira Capital GP, L.P., Lumira GP Inc., Lumira GP Holdings Co. and Lumira Capital Investment Management Inc. may be deemed to beneficially own the shares held by Lumira Capital II, L.P. and Lumira Capital II (International), L.P and such entities control voting and investment power over such shares through an investment committee of the Lumira group. The address of each entity listed in this note is 141 Adelaide Street West, Suite 770, Toronto, Ontario, Canada M5H 3L5.

Intellectual Property

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

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

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

We expect patents and other proprietary intellectual property rights to be an essential element of our business. We intend to protect our proprietary positions by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements. We also rely on trade secrets, know-how, continuing technological innovation and other in-licensing opportunities to develop and maintain our proprietary position. Our success will depend, in part, on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights.

Supplemental Risk Factors

Risks Related to Our Business

We depend heavily on the success of our lead product candidates, EB01 and EB05, which we are developing for the treatment of chronic ACD and ARDS, respectively. If we are unable to obtain regulatory approval or commercialize EB01 or EB05, or experience significant delays in doing so, our business will be materially harmed.

Our ability to generate product revenues, which may not occur for multiple years, if at all, will depend heavily on the successful development and commercialization of EB01 as a treatment for chronic ACD or EB05 as a treatment for ARDS. The success of our product candidates, including EB01 and EB05, will depend on a number of factors, including the following:

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

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize EB01, EB05 or any of our other product candidates, which would materially harm our business. Many of these factors are beyond our control. Accordingly, we may never be able to generate revenues through the license or sale of any of our product candidates.

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

Public health threats could adversely affect our ongoing or planned research and development activities. In particular, a novel strain of coronavirus, SARS-CoV-2 (which causes the disease now called COVID-19), was reported to have surfaced in Wuhan, China in December 2019, and has since spread globally, including to every state in the United States. On January 31, 2020, the Secretary of Health and Human Services (HHS) issued a Public Health Emergency determination in response to the spread of COVID-19. A Public Health Emergency determination remains in effect for 90 days and can be renewed for additional 90 day periods. The Secretary of HHS renewed his Public Health Emergency determination on April 21, 2020, and again on July 23, 2020. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to COVID-19. The outbreak of COVID-19 has severely impacted global economic activity and caused significant volatility and negative pressure in financial markets. The global impact of the outbreak has been rapidly evolving and many countries, including the United States, have reacted by instituting quarantines, mandating business and school closures and restricting travel. As a result, the COVID-19 pandemic is negatively impacting almost every industry directly or indirectly. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. Global epidemics, such as the coronavirus, could also negatively affect site activation, as well as recruitment and retention, at sites in a region or city whose health care system becomes overwhelmed due to the illness, which could have a material adverse effect on our business and our results of operation and financial condition.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

The clinical trial designs, endpoints and outcomes that will be required to obtain marketing approval of a drug to treat chronic ACD, ARDS or any other indication are uncertain. We may never receive marketing approval for our drug candidates, including EB01 as a treatment for chronic ACD and EB05 as a treatment for ARDS.

To our knowledge, there are currently no FDA-approved treatment options specifically indicated for chronic ACD. Accordingly, there is not a well-established development path that, with positive outcomes in clinical trials, would be reasonably assured of receiving marketing approval for chronic ACD. In particular, if our Phase 2B clinical trial of EB01 in individuals with chronic ACD is successful and, similarly, if our Phase 2/Phase 3 clinical trial of EB05 in Canada, once initiated, and if our IND for EB05 is approved by the FDA, we plan, in each case, to use the applicable trial to support pivotal clinical trials designed to establish the efficacy of EB01 or EB05, as applicable, to support, together with additional long-term safety data, an application for regulatory approval as a treatment for chronic ACD or ARDS, as applicable. As of September 28, 2020, our IND for EB05 is under review by the FDA. Unless we receive comments from the FDA, we expect to be in a position to commence the U.S. portion of our EB05 study by the end of October, 2020. At this time, we are uncertain as to whether we will receive comments or whether any such comments would delay the commencement of the U.S. portion of our clinical study. The FDA, Health Canada or any other regulatory authority outside of the United States may determine that the designs or endpoints of any potentially pivotal trial that we conduct, or that the outcome shown on any particular endpoint in any potentially pivotal trial that we conduct, are not sufficient to establish a clinically meaningful benefit for EB01 in the treatment of chronic ACD, EB05 in the treatment of ARDS, or otherwise, to support approval, even if the primary endpoint or endpoints of the trial is or are met with statistical significance. If this occurs, our business could be materially harmed. Moreover, if the FDA requires us to conduct additional clinical trials beyond the ones that we currently contemplate in order to support regulatory approval in the United States of EB01 for the treatment of chronic ACD or EB05 for the treatment of ARDS, or if Health Canada requires us to conduct additional clinical studies beyond the ones that we currently contemplate in order to support regulatory approval in Canada of EB05 for the treatment of ARDS, our finances and results from operations will be adversely impacted.

Likewise, if we conduct any future clinical trials designed to support marketing approval of EB02 as a treatment for HD or clinical trials designed to support marketing approval of any other of our product candidates, such as EB06, the FDA, Health Canada or any other regulatory authority outside of the United States may determine that the designs or endpoints of the trial, or that the outcomes shown on any particular endpoint in the trial, are not sufficient to establish a clinically meaningful benefit or otherwise to support approval, even if the primary endpoint of the trial is met with statistical significance.

Even if our Phase 2/3 study of EB05 in hospitalized COVID-19 patients demonstrates efficacy, it is not certain that additional studies may not be required or the data will be sufficient to enable EB05 to gain regulatory approval as a treatment for ARDS.

If our Phase 2/3 clinical trial of EB05 in hospitalized COVID-19 patients demonstrates efficacy, we plan to seek marketing approval with the FDA and regulatory authorities outside the United States. We cannot predict whether each of these regulatory agencies will agree that the data and information from our Phase 2/3 study 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. The likelihood that the FDA or any regulatory authority outside the United States will concur with our plan is uncertain. The FDA or any other regulatory authority may instead determine that additional clinical and/or non-clinical trials are required to establish the efficacy of EB05 as a treatment for COVID-19-induced ARDS, even if the outcome of our Phase 2/3 study in individuals is favorable. If the FDA or a regulatory authority outside of the United States makes the determination that additional clinical and/or non-clinical trials are required, it would result in a more expensive and potentially longer development program for EB05 than we currently contemplate, which could delay our ability to generate product revenues with EB05, interfere with our ability to enter into any potential licensing or collaboration arrangements with respect to this program, cause the value of the company to decline, and limit our ability to obtain additional financing.

If we experience new or additional delays or difficulties in the enrollment of patients in our clinical trial of EB01, or our planned clinical trials of EB05, once initiated in Canada or approved by the FDA, as applicable, or any other product candidate, our application and or receipt of marketing approvals could be delayed or prevented.

With respect to enrolling patients in our clinical trial of EB01, recruiting patients with moderate to severe chronic ACD may be challenging as there have not been recent clinical studies conducted with this patient population. If we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials of our product candidates including, in particular, our ongoing trial of EB01 and our planned pivotal trials of EB01 as a treatment for ACD or our planned trials of EB05 as treatment for ARDS, we may not be able to initiate or complete the clinical trials.

Enrollment delays in our ongoing or planned clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients in our ongoing or planned clinical trials of EB01, EB05 or any other Edesa product candidate, would result in significant delays or may require us to abandon one or more clinical trials or planned clinical trials altogether.

If the commercial opportunity in chronic ACD or COVID-19-induced ARDS is smaller than we anticipate, our future revenue from EB01 or EB05, as applicable, will be adversely affected and our business will suffer.

It is critical to our ability to grow and become profitable that we successfully identify patients with chronic ACD or COVID-19-induced ARDS. Our projections of the number of people who have these conditions as well as the subset who have the potential to benefit from treatment with EB01 or EB05, are based on a variety of sources, including third-party estimates and analyses in the scientific literature, and may prove to be incorrect. Further, new information may emerge that changes our estimate of the prevalence of these diseases or the number of patient candidates for these drug candidates. The effort to identify patients for our other potential target indications is at an early stage, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for our drug candidates may be limited or may not be amenable to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the commercial opportunity for these conditions is smaller than we anticipate, our future financial performance may be adversely impacted.

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

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

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

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

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

Our ability to commercialize EB01, EB05 or any other product candidate successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of EB01, EB05 or other product candidates. Collaborations are complex and time-consuming to negotiate and document and we face significant competition in seeking appropriate collaborators. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we would likely need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

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

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, Health Canada and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market EB01, EB05 or any other Edesa product candidate from regulatory authorities in any jurisdiction.

We have only limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates and expect to rely on third-party contract research organizations to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and effectiveness. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that EB01, EB05 or any of our other product candidates is not effective, is only moderately effective or has undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval or that prevent or limit commercial use.

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

Risks Related to Our Intellectual Property

We are dependent on a license relationship with NovImmune SA for our EB05 and EB06 programs

In April 2020, we entered into an exclusive license agreement with NovImmune SA, which operates under the brand Light Chain Bioscience, or Light Chain, to obtain exclusive rights throughout the world to certain know-how, patents and data relating to the monoclonal antibodies targeting TLR4 and CXCL10. Due to the COVID-19 global health emergency, we have prioritized the development of EB05, which has previously demonstrated efficacy in blocking TLR4 signaling in two previous clinical studies, as a potential treatment for ARDS resulting from COVID-19 and other conditions. If we default or fail to perform any of the terms, covenants, provisions or our obligations under the License Agreement, Light Chain has the option to terminate the License Agreement, subject to advance notice to cure such default. Any termination of this license agreement would have a materially adverse impact on our business and results from operations.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements. When used in this report, the words "expects," "anticipates," "suggests," "believes," "intends," "estimates," "plans," "projects," "continue," "ongoing," "potential," "expect," "predict," "believe," "intend," "may," "will," "should," "could," "would" and similar expressions are intended to identify forward-looking statements. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in the forward-looking statements for many reasons, including the risks described in our Annual Transition Report on Form 10-KT for the nine-month period ended September 30, 2019 , filed with the Securities and Exchange Commission on December 12, 2019, as supplemented by the additional risk factor in Item 8.01 in our Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2020, the risk factors contained in this Current Report on Form 8-K and the risk factors contained in other reports we file with the Securities and Exchange Commission. Although we believe the expectations reflected in the forward-looking statements are reasonable, they relate only to events as of the date on which the statements are made. We do not intend to update any of the forward-looking statements after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Edesa Biotech, Inc.

Date: September 28, 2020

By: /s/ Kathi Niffenegger
Name: Kathi Niffenegger
Title: Chief Financial Officer