SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Edesa Biotech, Inc.

Form: 8-K

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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): March 27, 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

Ongoing Phase 2b Clinical Study of EB01 in Allergic Contact Dermatitis

Edesa Biotech, Inc. (the "Company") reports that it will file a protocol amendment with the U.S. Food and Drug Administration for its ongoing Phase 2b clinical study in allergic contact dermatitis (the "Study"). The amendment provides for, among other changes, a reduction in the number of in-person office visits, allowances for remote telehealth appointments and other procedural updates to simplify enrollment and patient care.

The proposed changes to the protocol, which the Company expects to be implemented in the coming weeks subject to the approval of the Study's institutional review (ethics) board, are designed, in part, to respond to and mitigate the impacts of the COVID-19 pandemic on investigational centers. These impacts include governmental orders to restrict travel and practice social distancing, as well as governmental and institutional directives to devote critical healthcare resources to the COVID-19 pandemic.

As of March 27, 2020, the Company reports that five of its investigational sites have temporarily paused new patient randomization in the Study, either voluntarily, out of an abundance of caution for patient and staff safety, or at the direction of local governments or institutions. At this time, the remaining five investigational sites are continuing enrollment and/or care for subjects already enrolled. The Company is in the process of identifying and screening additional investigational sites to either replace or supplement current sites. Investigators have not experienced any interruption in clinical trial supply of drug product for the Study as a result of the COVID-19 pandemic. At this time, it is unclear if the temporary pausing of enrollment at certain investigational sites, or mitigations

being implemented by the Company to simplify enrollment and patient care, will materially impact the timeline for completing the Study.

Supplemental Risk Factor

The Company is supplementing the risk factors set forth under "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the nine-month period ended September 30, 2019 with the additional risk factor set forth below. This supplemental risk factor should be read in conjunction with the additional risk factors set forth in the Annual Report.

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 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.

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: March 27, 2020

By: /s/ Michael Brooks
Name: Michael Brooks, PhD
Title: President