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): February 16, 2021

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 2.02 Results of Operations and Financial Condition.

On February 16, 2021, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three-month period ended December 31, 2020 (the "Earnings Release"). The full text of the Earnings Release is attached hereto as Exhibit 99.1. The information furnished herein and therein shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Edesa Biotech, Inc. dated February 16, 2021.

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: February 16, 2021

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

Exhibit 99.1

Edesa Biotech Reports Fiscal First Quarter 2021 Results

TORONTO, ON / ACCESSWIRE / February 16, 2021 / Edesa Biotech, Inc. (Nasdaq: EDSA), a clinical-stage biopharmaceutical company focused on inflammatory and immune-related diseases, today reported financial results for the three months ended December 31, 2020 and provided an update on its business.

Earlier this month, the company announced that it has been awarded a C$14 million reimbursement grant from the Canadian government. The funds will support the Phase 2 portion of an ongoing Phase 2/Phase 3 clinical study of Edesa's investigational drug, EB05, as a treatment for Acute Respiratory Distress Syndrome (ARDS). ARDS is a life-threatening form of respiratory failure, and the leading cause of death among COVID-19 patients. Should the antibody treatment demonstrate promising results at the Phase 2 readout, the company plans to continue with a pivotal Phase 3 study and enter negotiations for additional government funding. Last month, the company announced that it received approval from the U.S. Food and Drug Administration and Health Canada to add a sub-study to the ARDS trial. The sub-study will evaluate the drug as a potential rescue therapy for critically severe COVID-19 cases.

"We initiated our ARDS study in the midst of an unprecedented resurgence of SARS-CoV-2 infections and are working closely with our hospital partners to help meet the urgent medical needs of COVID-19 patients. The federal funding will allow us to move ahead much more quickly than we could do otherwise," said Dr. Par Nijhawan, Chief Executive Officer of Edesa. "Based on current enrollment trends, we are looking forward to the first interim analysis in the near term and moving another step closer to providing a new, effective treatment option for COVID-19 patients."

In addition to its ARDS clinical program, during the first fiscal quarter, the company also reported ongoing progress in a Phase 2b study of its non-steroidal anti-inflammatory drug candidate in chronic allergic contact dermatitis. More than 50% of the patients planned for the first cohort had been randomized and dosed.

Edesa's Chief Financial Officer Kathi Niffenegger reported that the company's expenditures during the first fiscal quarter were in line with management's expectations and reflected the company's plans to advance both its ARDS and dermatitis studies concurrently. "The change in our research and development expenses over the comparable period reflect the priority we have placed in rapidly getting our monoclonal antibody candidate in the hands of frontline physicians, and expanding our international Phase 2/3 study to multiple jurisdictions," said Ms. Niffenegger.

Financial Results for the Three Months Ended December 31, 2020

There were no revenues for the three months ended December 31, 2020 compared to $0.11 million for the three months ended December 31, 2019, reflecting the winddown and discontinuation of sales of product inventory obtained in the reverse acquisition.

Total operating expenses increased by $1.40 million to $2.61 million for the three months ended December 31, 2020 compared to $1.21 million for the same period last year:

- There were no cost of sales for the three months ended December 31, 2020 as a result of the winddown and discontinuation of sales of product inventory obtained in the reverse acquisition. For the same period last year, cost of sales was less than $0.01 million.

- Research and development expenses increased by $0.85 million to $1.38 million for the three months ended December 31, 2020 compared to $0.53 million for the same period last year primarily due to increased external research expenses related to the company's ongoing clinical studies and an increase in non-cash share-based compensation. Higher salary and related personnel expenses and patent fees also contributed to the increase.

- General and administrative expenses increased by $0.55 million to $1.23 million for the three months ended December 31, 2020 compared to $0.68 million for the same period last year primarily as a result of an increase in non-cash share-based compensation. Higher salary and related personnel expenses, and legal and other professional services also contributed to the increase.

For the three months ended December 31, 2020, Edesa reported a net loss of $2.64 million, or $0.26 per common share, compared to a net loss of $1.09 million, or $0.15 per common share, for the three months ended December 31, 2019.

Working Capital

At December 31, 2020, Edesa had working capital of $6.76 million. Cash and cash equivalents totaled $6.31 million. From January 1 to February 12, 2021, the company received combined net proceeds of $3.13 million from the issuance of common shares under an equity distribution agreement with RBC Capital Markets and exercises of common share purchase warrants and share options.

Calendar

Edesa management plans to participate in the H.C. Wainwright Annual Global Life Sciences Conference scheduled for March 9-10, 2021. Investors interested in meetings with management can schedule one-on-one teleconference and video meetings through the conference website or by contacting Edesa at investors@edesabiotech.com.

About Edesa Biotech, Inc.

Edesa Biotech, Inc. (Nasdaq: EDSA) is a clinical-stage biopharmaceutical company focused on developing innovative treatments for inflammatory and immune-related diseases with clear unmet medical needs. The company's two lead product candidates, EB05 and EB01, are in later stage clinical studies. EB05 is a monoclonal antibody therapy that we are developing as a treatment for Acute Respiratory Distress Syndrome (ARDS). ARDS is a life-threatening form of respiratory failure, and the leading cause of death among COVID-19 patients. Edesa is also developing an sPLA2 inhibitor, designated as EB01, as a topical treatment for chronic allergic contact dermatitis (ACD), a common, potentially debilitating condition and occupational illness. EB01 employs a novel, non-steroidal mechanism of action and in two clinical studies has demonstrated statistically significant improvement of multiple symptoms in ACD patients. The company is based in Markham, Ontario, Canada, with a U.S. subsidiary located in Southern California. Sign up for news alerts.

Edesa Forward-Looking Statements

This press release may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "plan," "estimate," "expect," "intend," "may," "will," "would," "could," "should," "might," "potential," or "continue" and variations or similar expressions, including statements related to: upcoming milestones in the company's clinical studies, including enrollment milestones and interim readouts for its COVID-19 and dermatitis studies. Readers should not unduly rely on these forward-looking statements, which are not a guarantee of future performance. There can be no assurance that forward-looking statements will prove to be accurate, as all such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results or future events to differ materially from the forward-looking statements. Such risks include: the ability of Edesa to obtain regulatory approval for or successfully commercialize any of its product candidates, the risk that access to sufficient capital to fund Edesa's operations may not be available or may be available on terms that are not commercially favorable to Edesa, the risk that Edesa's product candidates may not be effective against the diseases tested in its clinical trials, the risk that Edesa fails to comply with the terms of license agreements with third parties and as a result loses the right to use key intellectual property in its business, Edesa's ability to protect its intellectual property, the timing and success of submission, acceptance and approval of regulatory filings, and the impacts of public health crises, such as COVID-19. Many of these factors that will determine actual results are beyond the company's ability to control or predict. For a discussion of further risks and uncertainties related to Edesa's business, please refer to Edesa's public company reports filed with the U.S. Securities and Exchange Commission and the British Columbia Securities Commission. All forward-looking statements are made as of the date hereof and are subject to change. Except as required by law, Edesa assumes no obligation to update such statements.

Contact

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Condensed Interim Consolidated Statements of Operations
(Unaudited)

	Three Months Ended	
	December 31, 2020	**December 31, 2019**
Total Revenues	**$ -**	$ 107,800
Expenses:		
Cost of sales	**-**	3,778
Research and development	**1,379,654**	527,998
General and administrative	**1,234,148**	681,706
	2,613,802	1,213,482
Loss from operations	**(2,613,802)**	(1,105,682)
Other income (loss)	**(23,810)**	12,149
Income tax expense	**-**	800
Net loss	**(2,637,612)**	(1,094,333)
Exchange differences on translation	**103,427**	18,114
Net comprehensive loss	**$ (2,534,185)**	$ (1,076,219)
Weighted average number of common shares	**10,277,750**	7,504,468
Loss per common share - basic and diluted	**$ (0.26)**	$ (0.15)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	December 31, 2020	September 30, 2020
Assets:		
Cash and cash equivalents	**$ 6,305,293**	$ 7,213,695
Other current assets	**1,362,032**	890,323
Property and equipment, net	**14,788**	14,815
Intangible asset, net	**2,458,243**	2,483,536
Operating lease right-of-use assets	**150,413**	160,006
Total Assets	**$ 10,290,769**	$ 10,762,375
Liabilities, shareholders' equity and temporary equity:		
Current liabilities	**$ 906,327**	$ 1,529,857
Noncurrent liabilities	**127,005**	124,388
Temporary equity	**1,372,213**	2,476,955
Shareholders' equity	**7,885,224**	6,631,175
Total liabilities, shareholders' equity and temporary equity	**$ 10,290,769**	$ 10,762,375

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended	
	December 31, 2020	**December 31, 2019**
Cash flows from operating activities:		
Net loss	**$ (2,637,612)**	$ (1,094,333)
Adjustments for non-cash items	**751,752**	11,178
Change in working capital items	**(1,124,669)**	293,443
Net cash used in operating activities	**(3,010,529)**	(789,712)
Net cash used in investing activities	**(1,135)**	(477,293)
Net cash provided by financing activities	**1,994,972**	45,000
Effect of exchange rate changes on cash and cash equivalents	**108,290**	18,472
Increase in cash and cash equivalents during the period	**(908,402)**	(1,203,533)
Cash and cash equivalents, beginning of period	**7,213,695**	5,030,583
Cash and cash equivalents, end of period	**$ 6,305,293**	$ 3,827,050