

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): May 15, 2020

Edesa Biotech, Inc.
(Exact Name of Registrant as Specified in its Charter)

British Columbia, Canada
(State or Other Jurisdiction of Incorporation)

001-37619
(Commission File Number)

N/A
(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 May 15, 2020, Edesa Biotech, Inc. (the “company”) issued a press release announcing its financial results for the three-month and six-month periods ended March 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 May 15, 2020.

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: May 15, 2020

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



Edesa Biotech Reports Fiscal 2nd Quarter 2020 Results

TORONTO, ON / ACCESSWIRE / May 15, 2020 / Edesa Biotech, Inc. (Nasdaq: EDSA), a clinical-stage biopharmaceutical company, today reported financial results for the three and six months ended March 31, 2020 and provided an update on its business.

Edesa reported that two new biologic drug candidates acquired last month are rapidly being integrated into the company's development pipeline. Known as EB05 and EB06, these TLR4 and CXCL10 antagonists are believed to have application in a broad range of therapeutic areas, including potential treatments for COVID-19 pneumonia and acute respiratory distress syndrome (ARDS). Since the lead drug has already been manufactured, the company believes that with government support it could quickly begin clinical studies in COVID-19 patients.

Dr. Par Nijhawan, Chief Executive Officer of Edesa, said that the company is applying its expertise in immune modulation and inflammation therapies toward finding solutions for hospitalized COVID-19 patients. "We believe there is compelling data to prioritize this project, and we are optimistic that modulating these well understood TLR4 and CXCL10 signaling pathways could reduce the number of ICU patients and intubation/ventilation procedures, and save lives," he said.

Dr. Nijhawan noted that ARDS, a respiratory condition which stops oxygen from reaching the bloodstream, remains a serious unmet medical need. "Even excluding COVID-19 patients, there are approximately 3 million cases of ARDS each year globally despite the widespread use of prophylactic vaccines and herd immunity," he said.

During the quarter, Edesa also reported that the company took steps to simplify enrollment and patient care for its ongoing Phase 2b clinical study of EB01 for the treatment of allergic contact dermatitis. To support current social distancing requirements, the trial protocol now allows for fewer in-person office visits and provides guidelines for remote telehealth appointments, among other procedural updates. The company is closely monitoring the impacts of governmental directives related to COVID-19 on its investigation centers and patient enrollment.

Edesa's Chief Financial Officer, Kathi Niffenegger, reported that there have been no significant changes to the company's internal operations related to the pandemic, and that Edesa staff have been working remotely since early March. "Expenditures have continued to track in line with management's plans and our clinical activities. We strengthened our balance sheet in January and plan to continue to evaluate our options for non-dilutive grant funding to accelerate the advancement of our newly acquired drug candidates."

Financial Results for the Three Months Ended March 31, 2020*

Total revenues for the three months ended March 31, 2020 were \$0.11 million, reflecting sale of product inventory obtained in the reverse acquisition completed in June 2019. There were no revenues for the three months ended March 31, 2019.

Total operating expenses increased by \$1.09 million to \$1.63 million for the three months ended March 31, 2020 compared to \$0.54 million for the same period last year:

- Cost of sales and services was \$0.01 million for the three months ended March 31, 2020, reflecting the sales of product inventory obtained in the reverse acquisition. There were no product sales in the same period last year.
- Research and development expenses increased by \$0.39 million to \$0.50 million for the three months ended March 31, 2020 compared to \$0.11 million for the same period last year. The increase was primarily due to increased external research expenses related to the initiation of clinical studies for the company's EB01 drug product candidate as well as increased salary and related personnel expenses.
- General and administrative expenses increased by \$0.68 million to \$1.11 million for the three months ended March 31, 2020 compared to \$0.43 million for the same period last year. The increase was primarily due to increased salary and related personnel expenses, increased legal and professional fees, and public company expenses.

For the three months ended March 31, 2020, Edesa reported a net loss of \$1.49 million, or \$0.17 per basic share, compared to a net loss of \$0.53 million, or \$0.16 per basic share, for the three months ended March 31, 2019.

Financial Results for the Six Months Ended March 31, 2020*

Total revenues for the six months ended March 31, 2020 were \$0.22 million, reflecting sale of product inventory obtained in the reverse acquisition completed in June 2019. There were no revenues for the six months ended March 31, 2019.

Total operating expenses increased by \$1.89 million to \$2.84 million for the six months ended March 31, 2020 compared to \$0.95 million for the same period last year:

- Cost of sales and services was \$0.01 million for the six months ended March 31, 2020, reflecting the sales of product inventory obtained in the reverse acquisition. There were no product sales in the same period last year.
- Research and development expenses increased by \$0.66 million to \$1.03 million for the six months ended March 31, 2020 compared to \$0.37 million for the same period last year. The increase was primarily due to increased external research expenses related to the initiation of clinical studies for the company's EB01 drug product candidate as well as increased salary and related personnel expenses.
- General and administrative expenses increased by \$1.22 million to \$1.80 million for the six months ended March 31, 2020 compared to \$0.58 million for the same period last year. The increase was primarily due to increased salary and related personnel expenses, increased legal and professional fees, and public company expenses.

For the six months ended March 31, 2020, Edesa reported a net loss of \$2.58 million, or \$0.32 per basic share, compared to a net loss of \$0.89 million, or \$0.28 per basic share, for the six months ended March 31, 2019.

** Financial results for any periods ended prior to June 7, 2019 reflect the financials of the company's subsidiary Edesa Biotech Research, Inc. on a standalone basis.*

Working Capital

At March 31, 2020, the company had working capital of \$6.85 million. Cash and cash equivalents totaled \$6.99 million.

About Edesa Biotech, Inc.

[Edesa Biotech, Inc.](#) (Nasdaq: EDSA) is a clinical-stage biopharmaceutical company focused on efficiently developing innovative treatments that address significant unmet medical needs. Edesa's lead product candidate, EB01, is a novel non-steroidal anti-inflammatory molecule (sPLA2 inhibitor) for the treatment of chronic allergic contact dermatitis which has demonstrated statistically significant improvements in multiple clinical studies. A Phase 2b clinical study of EB01 was initiated in October 2019. Edesa also intends to expand the utility of its sPLA2 inhibitor technology, which forms the basis for EB01, across multiple indications and expand its portfolio with assets that can drive long-term growth opportunities. The company is based in Markham, Ontario, Canada, with U.S. offices 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: the company's plans to seek non-dilutive grant funding and initiate new clinical studies for ARDS in COVID-19 patients. 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.

Contacts

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Condensed Interim Consolidated Statements of Operations
(Unaudited)

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>March 31, 2020</u>	<u>March 31, 2019</u>	<u>March 31, 2020</u>	<u>March 31, 2019</u>
Total Revenues	\$ 110,516	\$ -	\$ 218,316	\$ -
Expenses:				
Cost of sales and services	10,037	-	13,815	-
Research and development	502,814	111,702	1,030,812	369,093
General and administrative	1,113,917	429,076	1,795,623	577,426
	<u>1,626,768</u>	<u>540,778</u>	<u>2,840,250</u>	<u>946,519</u>
Loss from Operations	(1,516,252)	(540,778)	(2,621,934)	(946,519)
Other Income	26,616	11,948	38,765	52,840
Income tax expense	-	-	800	-
Net Loss	(1,489,636)	(528,830)	(2,583,969)	(893,679)
Exchange differences on translation	(39,908)	73,253	(21,794)	91,013
Net Loss and Comprehensive Loss	\$ (1,529,544)	\$ (455,577)	\$ (2,605,763)	\$ (802,666)
Weighted average number of common shares outstanding	8,740,065	3,239,902	8,118,891	3,239,902
Loss per share - basic and diluted	\$ (0.17)	\$ (0.16)	\$ (0.32)	\$ (0.28)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	<u>March 31,</u> <u>2020</u>	<u>September 30,</u> <u>2019</u>
Assets:		
Cash and cash equivalents	\$ 6,989,930	\$ 5,030,583
Other current assets	436,092	614,123
Operating lease right-of-use assets	181,492	-
Property and equipment, net	25,110	73,058
Total Assets	<u>\$ 7,632,624</u>	<u>\$ 5,717,764</u>
Liabilities and Shareholders' Equity:		
Current liabilities	\$ 578,938	\$ 461,634
Noncurrent liabilities	122,743	-
Shareholders' equity	6,930,943	5,256,130
Total Liabilities and Shareholders' Equity	<u>\$ 7,632,624</u>	<u>\$ 5,717,764</u>

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended	
	March 31, 2020	March 31, 2019
Cash flows from operating activities:		
Net loss	\$ (2,583,969)	\$ (893,679)
Adjustments for non-cash items	432,400	25,796
Change in working capital items	191,410	86,655
Net cash used in operating activities	(1,960,159)	(781,228)
Net cash provided by (used in) investing activities	42,359	(1,504)
Net cash provided by financing activities	3,891,801	-
Effect of exchange rate changes on cash and cash equivalents	(14,654)	94,643
Net change in cash and cash equivalents	1,959,347	(688,089)
Cash and cash equivalents, beginning of period	5,030,583	3,730,230
Cash and cash equivalents, end of period	\$ 6,989,930	\$ 3,042,141