

**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): December 12, 2019

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)

(905) 475-1234
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 December 12, 2019, Edesa Biotech, Inc. (the “Company”) issued a press release announcing its financial results for the nine-month period ended September 30, 2019 (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 December 12, 2019.

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: December 12, 2019

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



Edesa Biotech Reports Financial Results for Short Period Fiscal Year

TORONTO, ON / ACCESSWIRE / December 12, 2019 / Edesa Biotech, Inc. (Nasdaq: EDSA), a clinical-stage biopharmaceutical company, today reported financial results for the nine-month period ended September 30, 2019 and provided an update on its business.

Edesa recently enrolled the first patient in a Phase 2b clinical study of its lead product candidate, EB01. The company is developing EB01 as a monotherapy for patients with chronic allergic contact dermatitis (ACD), a debilitating disease that is frequently caused by allergens present in the workplace. In December, the company reported that based on positive safety data in healthy volunteers, the company would expand the study to include ACD patients with symptoms on the face, a commonly effected area. The experimental drug previously demonstrated positive results in two previous studies in ACD patients.

In 2019, Edesa also advanced plans to expand the utility of its anti-inflammatory technology, which forms the basis of EB01, into additional indications. This included an approval by Health Canada to conduct a proof-of-concept study of the company's product candidate, EB02, as a treatment for hemorrhoids disease (HD).

"We have maintained a rapid pace this year and I'm pleased to report that our team has delivered on our key clinical and corporate milestones. In addition to the transition we made to the public equity markets, we laid the foundation for a number of value creation opportunities in the coming year," said Dr. Par Nijhawan, Chief Executive Officer of Edesa. "We are looking forward to the interim data readout for our Phase 2b study in ACD as well as initiating a clinical study of our anti-inflammatory technology in HD."

Edesa's Chief Financial Officer, Kathi Niffenegger, CPA reported that operating expenses, including expenditures related to increased activities for the EB01 clinical program, were largely in line with management's expectations for the fiscal year. "We remain committed to the capital efficient product development model that Edesa adopted as a private company and plan to continue to focus our working capital on the advancement of our clinical pipeline."

Financial Results for the Nine-Month Period Ended September 30, 2019*

The company's year-end financial results reflect a nine-month period as a result of a change in fiscal year following the company's reverse acquisition completed in June 2019.

Total revenues for the nine-month period ended September 30, 2019 were \$0.41 million, reflecting the initiation of sales of product inventory obtained in the reverse acquisition completed in June 2019. There were no revenues for the year ended December 31, 2018.

Total operating expenses increased by \$1.62 million to \$3.24 million for the nine-month period ended September 30, 2019 compared to \$1.62 million for the prior year ended December 31, 2018:

- Cost of sales and services was \$0.10 million for the nine-month period ended September 30, 2019, reflecting the initiation of sales of product inventory obtained in the reverse acquisition. There were no revenues in the prior year ended December 31, 2018.
- Research and development expenses were \$1.10 million for the nine-month period ended September 30, 2019, reflecting greater clinical research activities related to the initiation of the company's Phase 2B clinical study of its EB01 product candidate as well as higher personnel expenses. Research and development expenses were \$1.08 million for the prior year.
- General and administrative expenses were \$2.05 million for the nine-month period ended September 30, 2019, reflecting increased legal and professional fees related to the company's reverse acquisition, increased personnel expenses and public company expenses, which Edesa did not incur as a privately held company. General and administrative expenses were \$0.54 million for the prior year.

For the nine-month period ended September 30, 2019, Edesa reported a net loss of \$2.78 million, or \$0.55 per basic share, compared to a net loss of \$1.54 million, or \$0.47 per basic share, for the prior year ended December 31, 2018.

Working Capital

At September 30, 2019, the company had working capital of \$5.18 million. Cash and cash equivalents totaled \$5.03 million.

Calendar

Management will be attending the Dermatology Summit on January 12, 2020 and the Biotech Showcase from January 13-15, 2020. Both events are being held in San Francisco, California. Members of the investment or biopharma communities interested in meetings with management can schedule one-on-ones through the conference online systems or by contacting Edesa at investors@edesabiotech.com.

**As a result of the acquisition accounting for the business combination completed on June 7, 2019, and the subsequent change in year end of the company's subsidiary Edesa Biotech Research, Inc., the comparative year-end data represent the nine months period ended September 30, 2019 and the twelve months ended December 31, 2018, which should be taken into account when reviewing comparative results. Financial results for any periods ended prior to June 7, 2019 reflect the financials of Edesa Biotech Research, Inc. on a standalone basis.*

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.

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 expand the utility of its sPLA2 anti-inflammatory technology into additional indications, including HD. 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 and the timing and success of submission, acceptance and approval of regulatory filings. 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

Gary Koppenjan
Edesa Biotech, Inc.
(805) 488-2800
investors@edesabiotech.com

Edesa Biotech, Inc.
Consolidated Statements of Operations

	Nine-Month Period Ended September 30, 2019	Year Ended December 31, 2018
Total Revenues	\$ 410,870	\$ -
Expenses:		
Cost of sales	101,286	-
Research and development	1,096,426	1,075,491
General and administrative	2,045,296	543,155
Total Expenses	3,243,008	1,618,646
Loss from Operations	(2,832,138)	(1,618,646)
Other Income (Loss)	55,404	82,090
Net Loss	(2,776,734)	(1,536,556)
Exchange differences on translation	87,899	(328,838)
Net Loss and Comprehensive Loss	\$ (2,688,835)	\$ (1,865,394)
Weighted average number of common shares	5,036,331	3,239,902
Loss per common share - basic and diluted	\$ (0.55)	\$ (0.47)

Edesa Biotech, Inc.
Consolidated Balance Sheets

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets:		
Cash and cash equivalents	\$ 5,030,583	\$ 3,367,098
Other current assets	614,123	23,826
Noncurrent assets	<u>73,058</u>	<u>7,386</u>
Total assets	<u>\$ 5,717,764</u>	<u>\$ 3,398,310</u>
Liabilities and shareholders' equity:		
Accounts payable and accrued liabilities	\$ 461,634	\$ 183,820
Shareholders' equity	<u>5,256,130</u>	<u>3,214,490</u>
Total liabilities and shareholders' equity	<u>\$ 5,717,764</u>	<u>\$ 3,398,310</u>

Edesa Biotech, Inc.
Consolidated Statements of Cash Flows

	Nine-Month Period Ended September 30, 2019	Year Ended December 31, 2018
Cash Flows From Operating Activities:		
Net loss	\$ (2,776,734)	\$ (1,536,556)
Items not affecting cash	37,681	82,999
Changes in working capital items	<u>(2,106,734)</u>	<u>164,727</u>
Net cash used in operating activities	<u>(4,845,787)</u>	<u>(1,288,830)</u>
Cash Flows From Investing Activities:		
Cash acquired from reverse acquisition	6,389,322	-
Net (purchases) proceeds of property and equipment	<u>28,646</u>	<u>(6,869)</u>
Net cash provided by (used in) investing activities	<u>6,417,968</u>	<u>(6,869)</u>
Effect of exchange rate changes on cash and cash equivalents	<u>91,304</u>	<u>(337,325)</u>
Net change in cash and cash equivalents	<u>1,663,485</u>	<u>(1,633,024)</u>
Cash and cash equivalents, beginning of period and year	<u>3,367,098</u>	<u>5,000,122</u>
Cash and cash equivalents, end of period and year	<u>\$ 5,030,583</u>	<u>\$ 3,367,098</u>