

**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): August 14, 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))

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.

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 Capital Market

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2019, Edesa Biotech, Inc. (the “Company”) issued a press release announcing its financial results for its fiscal quarter ended June 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Edesa Biotech, Inc. dated August 14, 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: August 14, 2019

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



Edesa Biotech Reports Quarterly Financial Results

TORONTO, ON / ACCESSWIRE / August 14, 2019 / Edesa Biotech, Inc. (Nasdaq: EDSA), a clinical-stage biopharmaceutical company, today reported financial results for the three and six months ended June 30, 2019 and provided an update on its business.

During the quarter, Edesa completed its reverse acquisition and Nasdaq listing, and announced plans to proceed with its clinical investigation of EB01, a novel sPLA2 inhibitor, which the company is developing as a potential treatment for chronic allergic contact dermatitis (ACD). Edesa is currently performing site initiation visits at investigational centers in the U.S. and expects to proceed with enrolling the first patient into its Phase 2b clinical trial in the current quarter.

“Our first quarter as a public company has been very productive and I am pleased to report that our team has maintained a rapid pace toward the initiation of our Phase 2b clinical study of EB01,” said Dr. Par Nijhawan, Chief Executive Officer of Edesa. “The next few quarters will be an exciting time for Edesa as we expect to enroll our first EB01 patient, expand the utility of our sPLA2 anti-inflammatory technology into additional indications and evaluate additional assets that can provide new value creation opportunities.”

Edesa's Chief Financial Officer, Kathi Niffenegger, reported that the combined company's working capital at the end of the fiscal quarter was higher than projected. “Our working capital benefited from lower than expected acquisition-related costs as well as steps taken by management to conserve cash during the transaction. As a result, we are well positioned to support our current clinical plans and activities,” she said.

Financial Results

Three months ended June 30, 2019

Total revenues were not material for the three months ended June 30, 2019 and June 30, 2018 as the company continued to focus on developing and obtaining regulatory approval for its product candidates.

Total operating expenses increased by \$0.90 million to \$1.32 million for the three months ended June 30, 2019 compared to \$0.42 million for the same period last year:

- Research and development expenses increased by \$0.20 million to \$0.50 million for the three months ended June 30, 2019 compared to \$0.30 million for the same period last year primarily due to an increase in clinical research expenses associated with the Phase 2B clinical study of Edesa's EB01 product candidate as well as higher personnel expenses.
 - General and administrative expenses increased by \$0.70 million to \$0.82 million for the three months ended June 30, 2019 compared to \$0.12 million for the same period last year primarily due to increased legal and professional fees related to the company's reverse acquisition, increased personnel expenses and the initiation of public company expenses, which Edesa did not incur as a privately held company.
-

Net loss for the three months ended June 30, 2019 was \$1.29 million, or \$0.30 per basic share, compared to a net loss of \$0.41 million, or \$0.13 per basic share, for the three months ended June 30, 2018.

Six months ended June 30, 2019

Total revenues were not material for the six months ended June 30, 2019 and June 30, 2018.

Total operating expenses increased by \$1.01 million to \$1.86 million for the six months ended June 30, 2019 compared to \$0.85 million for the same period last year:

- Research and development expenses increased by \$0.03 million to \$0.61 million for the six months ended June 30, 2019 compared to \$0.58 million for the same period last year primarily due to an increase in clinical research expenses associated with the Phase 2B clinical study of Edesa's EB01 product candidate as well as higher patent fees and personnel expenses.
- General and administrative expenses increased by \$0.97 million to \$1.25 million for the six months ended June 30, 2019 compared to \$0.28 million for the same period last year primarily due to increased legal and professional fees related to the company's reverse acquisition, increased personnel expenses and the initiation of public company expenses, which Edesa did not incur as a privately held company.

Net loss for the six months ended June 30, 2019 was \$1.82 million, or \$0.48 per basic share, compared to a net loss of \$0.83 million, or \$0.26 per basic share, for the six months ended June 30, 2018.

Edesa changed its year end from December 31 to September 30 resulting in six months activity during this transitional period through June 30, 2019.

Working Capital

At June 30, 2019, the company had working capital of \$6.11 million. Cash and cash equivalents totaled \$6.36 million.

Investor Calendar

The company is scheduled to present at the H.C. Wainwright & Co. 21st Annual Global Investment Conference, September 8-10, 2019 in New York, NY. Management will also be attending the BIO Investor Forum in San Francisco, October 22-23, 2019. Investors interested in meetings with management can schedule through the conference meeting systems, or by contacting Edesa investors relations at investors@edesabiotech.com

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. 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 commitment to rapidly advance its clinical plans and in the next few quarters enroll its first EB01 patient, expand the utility of its sPLA2 anti-inflammatory technology into additional indications and evaluate additional assets that can provide new value creation opportunities. 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

Condensed Interim Consolidated Statements of Operations
(Unaudited)

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>June 30, 2019</u>	<u>June 30, 2018</u>	<u>June 30, 2019</u>	<u>June 30, 2018</u>
Total Revenues	\$ 500	\$ -	\$ 500	\$ -
Expenses:				
Research and development	502,927	298,223	614,629	578,268
General and administrative	817,927	123,770	1,246,999	275,020
	<u>1,320,854</u>	<u>421,993</u>	<u>1,861,628</u>	<u>853,288</u>
Loss from operations	(1,320,354)	(421,993)	(1,861,128)	(853,288)
Other Income (Loss):				
Interest income	15,565	16,337	31,485	32,995
Foreign exchange gain (loss)	8,610	(6,184)	4,634	(6,803)
Gain on disposition of property and equipment	2,172	-	2,172	-
	<u>26,347</u>	<u>10,153</u>	<u>38,291</u>	<u>26,192</u>
Net loss	(1,294,007)	(411,840)	(1,822,837)	(827,096)
Exchange differences on translation	27,443	19,518	100,696	(362,747)
Net loss and comprehensive loss	\$ (1,266,564)	\$ (392,322)	\$ (1,722,141)	\$ (1,189,843)
Weighted average number of common shares outstanding	4,317,759	3,239,902	3,781,808	3,239,902
Loss per share - basic and diluted	\$ (0.30)	\$ (0.13)	\$ (0.48)	\$ (0.26)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	<u>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets:		
Cash and cash equivalents	\$ 6,363,096	\$ 3,367,098
Accounts and other receivable	345,014	\$ 7,339
Inventory	77,913	\$ -
Prepaid expenses and deposits	337,668	16,487
Noncurrent assets	103,929	7,386
Total Assets	<u>\$ 7,227,620</u>	<u>\$ 3,398,310</u>
Liabilities and Shareholders' Equity:		
Current liabilities	\$ 1,015,004	\$ 183,820
Shareholders' equity	6,212,616	3,214,490
Total Liabilities and Shareholders' Equity	<u>\$ 7,227,620</u>	<u>\$ 3,398,310</u>

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	<u>Six Months Ended</u>	
	<u>June 30, 2019</u>	<u>June 30, 2018</u>
Cash flows from operating activities:		
Net loss	\$ (1,822,837)	\$ (827,096)
Adjustments for:		
Depreciation	2,099	811
Gain on disposition of property and equipment	(2,172)	-
Share-based compensation	24,866	46,680
Change in working capital items:		
Accounts and other receivable	(116,991)	3,977
Prepaid expenses and other assets	(265,770)	91,863
Accounts payable and accrued liabilities	(1,338,556)	(4,209)
Net cash used in operating activities	(3,519,361)	(687,974)
Cash flows from investing activities:		
Cash acquired from reverse acquisition	6,389,322	-
Purchases of property and equipment	(2,267)	(6,869)
Proceeds on sales of property and equipment	18,152	-
Net cash provided by (used in) investing activities	6,405,207	(6,869)
Effect of exchange rate changes on cash and cash equivalents	110,152	(367,520)
Increase (decrease) in cash and cash equivalents during the period	2,995,998	(1,062,363)
Cash and cash equivalents, beginning of period	3,367,098	5,000,122
Cash and cash equivalents, end of period	\$ 6,363,096	\$ 3,937,759