

**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 13, 2021**

**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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of exchange on which registered</b>
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 August 13, 2021, Edesa Biotech, Inc. (the “Company”) issued a press release announcing its financial results for the three-month and nine-month periods ended June 30, 2021 (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**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	Press release issued by Edesa Biotech, Inc. dated August 13, 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: August 13, 2021

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

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## Edesa Biotech Reports Fiscal 3rd Quarter 2021 Financial Results

TORONTO, ON / ACCESSWIRE / August 13, 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 and nine months ended June 30, 2021 and provided an update on its business.

During the quarter, the company achieved key interim milestones for both of its lead product candidates, EB05 and EB01. Independent monitoring boards assessed blinded interim treatment data and based on their positive findings recommended that the two development programs advance to the final stages of enrollment. Edesa expects the end of Phase 2 (interim) analysis of a Phase 2/3 study of EB05 as a single-dose treatment for hospitalized COVID-19 patients will be completed as early as the current quarter. The company plans to provide more detailed clinical updates as they become available. In parallel, the company has begun patient randomizations for the final part of a Phase 2b clinical study evaluating EB01 as a monotherapy for chronic Allergic Contact Dermatitis. Edesa recently added new investigational sites and expanded recruitment beyond the U.S. to Canada.

"We are pleased to have these two key programs advancing side by side toward data readouts and value inflection opportunities. EB05 and EB01 each represent novel anti-inflammatory technologies with the potential to provide transformational therapies for a broad range of inflammatory and autoimmune conditions," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. "We look forward to maintaining the momentum we achieved year to date, and announcing our end of Phase 2 results of our EB05 program as soon as available."

Edesa's Chief Financial Officer Kathi Niffenegger reported that expenditures for the fiscal third quarter were in line with management's expectations and driven primarily by incremental clinical study expenses related to patient enrollment, expanded operations and drug product-related costs. "Our R&D expenditures for the three-month and nine-month periods have largely tracked the accelerated progress of our clinical studies as well as preparations related to commercial-scale manufacturing of our product candidates," she said.

For the nine-month period ended June 30, 2021, Ms. Niffenegger reported that the company recorded reimbursements of approximately \$8.5 million under a C\$14 million reimbursement grant from the Canadian Government, including \$1.3 million for the fiscal third quarter. At June 30, 2021, Edesa had working capital of \$13.35 million, including cash and cash equivalents of \$8.05 million.

### Financial Results for the Three Months Ended June 30, 2021

There were no revenues for the three months ended June 30, 2021 compared to \$0.11 million for the three months ended June 30, 2020, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

Total operating expenses increased by \$4.19 million to \$6.07 million for the three months ended June 30, 2021 compared to \$1.88 million for the same period last year:

- Research and development expenses increased by \$3.32 million to \$4.46 million for the three months ended June 30, 2021 compared to \$1.14 million for the same period last year primarily due to increased external research expenses related to recruitment and enrollment in the company's ongoing clinical studies, increased investigational drug product expenses and an increase in noncash share-based compensation. Higher salary and related personnel expenses and patent fees also contributed to the increase.
- General and administrative expenses increased by \$0.88 million to \$1.61 million for the three months ended June 30, 2021 compared to \$0.73 million for the same period last year primarily as a result of higher salary and related personnel expenses, noncash share-based compensation and increased headcount. Higher legal and other professional services also contributed to the increase.

Total other income increased by \$1.31 million to \$1.31 million for the three months ended June 30, 2021 compared to less than \$0.01 million for the same period last year primarily due to increased grant income under the company's federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the three months ended June 30, 2021, Edesa reported a net loss of \$4.76 million, or \$0.36 per common share, compared to a net loss of \$1.77 million, or \$0.20 per common share, for the three months ended June 30, 2020.

### Financial Results for the Nine Months Ended June 30, 2021

There were no revenues for the nine months ended June 30, 2021 compared to \$0.33 million for the nine months ended June 30, 2020, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

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Total operating expenses increased by \$13.48 million to \$18.20 million for the nine months ended June 30, 2021 compared to \$4.72 million for the same period last year:

- Research and development expenses increased by \$11.65 million to \$13.82 million for the nine months ended June 30, 2021 compared to \$2.17 million for the same period last year primarily due to milestone payments related to advancement of the company's EB05 clinical program, increased external research expenses related to accelerated activity in the company's ongoing clinical studies, increased investigational drug product expenses and an increase in noncash share-based compensation. Higher salary and related personnel expenses and patent fees also contributed to the increase.
- General and administrative expenses increased by \$1.85 million to \$4.38 million for the nine months ended June 30, 2021 compared to \$2.53 million for the same period last year primarily as a result of higher salary and related personnel expenses, noncash share-based compensation and increased headcount. Higher legal and other professional services also contributed to the increase.

Total other income increased by \$8.50 million to \$8.54 million for the nine months ended June 30, 2021 compared to \$0.04 million for the same period last year primarily due to increased grant income under the company's federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the nine months ended June 30, 2021, Edesa reported a net loss of \$9.66 million, or \$0.83 per common share, compared to a net loss of \$4.35 million, or \$0.52 per common share, for the nine months ended June 30, 2020.

## Event Calendar

Edesa management is scheduled to present at the *H.C. Wainwright Global Investment Conference* being held September 13-15, 2021 in New York City. Attendees interested in meeting with management can schedule one-on-one meetings through the conference or by contacting Edesa at [investors@edesabiotech.com](mailto: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 the company is 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](#). Connect with Edesa on [Twitter](#) and [LinkedIn](#).

## 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 the timing of enrollment milestones and data readouts for its COVID-19 and dermatitis studies; the company's belief that its product candidates may provide transformational therapies for a broad range of inflammatory and autoimmune conditions; and the company's intention to maintain the momentum it has achieved during 2021 and move another step closer to providing new, effective treatment options for 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.*

## Contact

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**Condensed Interim Consolidated Statements of Operations**  
(Unaudited)

	Three Months Ended		Nine Months Ended	
	<u>June 30, 2021</u>	<u>June 30, 2020</u>	<u>June 30, 2021</u>	<u>June 30, 2020</u>
<b>Total Revenues</b>	<b>\$ -</b>	<b>\$ 109,985</b>	<b>\$ -</b>	<b>\$ 328,301</b>
<b>Expenses:</b>				
Cost of sales	-	1,472	-	15,287
Research and development	<b>4,464,347</b>	1,143,868	<b>13,819,305</b>	2,174,680
General and administrative	<b>1,608,232</b>	733,079	<b>4,377,507</b>	2,528,702
	<b>6,072,579</b>	1,878,419	<b>18,196,812</b>	4,718,669
<b>Loss from Operations</b>	<b>(6,072,579)</b>	(1,768,434)	<b>(18,196,812)</b>	(4,390,368)
<b>Other Income (Loss):</b>				
Reimbursement grant income	<b>1,306,796</b>	-	<b>8,477,261</b>	-
Other income (loss)	<b>6,273</b>	2,671	<b>63,242</b>	41,436
<b>Loss before income taxes</b>	<b>(4,759,510)</b>	(1,765,763)	<b>(9,656,309)</b>	(4,348,932)
<b>Income tax expense</b>	-	-	<b>800</b>	800
<b>Net Loss</b>	<b>(4,759,510)</b>	(1,765,763)	<b>(9,657,109)</b>	(4,349,732)
Exchange differences on translation	<b>174,128</b>	68,972	<b>267,075</b>	47,178
<b>Net Comprehensive Loss</b>	<b>\$ (4,585,382)</b>	<b>\$ (1,696,791)</b>	<b>\$ (9,390,034)</b>	<b>\$ (4,302,554)</b>
Weighted average number of common shares	<b>13,251,999</b>	8,859,520	<b>11,680,294</b>	8,364,866
<b>Loss per common share - basic and diluted</b>	<b>\$ (0.36)</b>	<b>\$ (0.20)</b>	<b>\$ (0.83)</b>	<b>\$ (0.52)</b>

**Condensed Interim Consolidated Balance Sheets**  
(Unaudited)

	<u>June 30,</u> <u>2021</u>	<u>September 30,</u> <u>2020</u>
<b>Assets:</b>		
Cash and cash equivalents	\$ 8,052,574	\$ 7,213,695
Other current assets	6,281,733	890,323
Non-current assets	<u>2,543,036</u>	<u>2,658,357</u>
<b>Total Assets</b>	<u>\$ 16,877,343</u>	<u>\$ 10,762,375</u>
<b>Liabilities, shareholders' equity and temporary equity:</b>		
Current liabilities	\$ 983,467	\$ 1,529,857
Noncurrent liabilities	90,121	124,388
Temporary equity	-	2,476,955
Shareholders' equity	<u>15,803,755</u>	<u>6,631,175</u>
<b>Total liabilities, shareholders' equity and temporary equity</b>	<u>\$ 16,877,343</u>	<u>\$ 10,762,375</u>

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**Condensed Interim Consolidated Statements of Cash Flows**  
(Unaudited)

	<u>Nine Months Ended</u>	
	<u>June 30, 2021</u>	<u>June 30, 2020</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,657,109)	\$ (4,349,732)
Adjustments for noncash items	2,380,648	540,945
Change in working capital items	<u>(6,033,149)</u>	<u>495,384</u>
<b>Net cash used in operating activities</b>	<b>(13,309,610)</b>	<b>(3,313,403)</b>
<b>Net cash provided by (used in) investing activities</b>	<b>(7,610)</b>	<b>15,532</b>
<b>Net cash provided by financing activities</b>	<b>13,953,703</b>	<b>3,864,307</b>
Effect of exchange rate changes on cash and cash equivalents	<u>202,396</u>	<u>43,676</u>
Increase in cash and cash equivalents during the period	<b>838,879</b>	<b>610,112</b>
Cash and cash equivalents, beginning of period	<u>7,213,695</u>	<u>5,030,583</u>
<b>Cash and cash equivalents, end of period</b>	<b><u>\$ 8,052,574</u></b>	<b><u>\$ 5,640,695</u></b>

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