

**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 14, 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 May 14, 2021, Edesa Biotech, Inc. (the “Company”) issued a press release announcing its financial results for the three-month and six-month periods ended March 31, 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 May 14, 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: May 14, 2021

By: /s/ Kathi Niffenegger

Name: Kathi Niffenegger

Title: Chief Financial Officer

---



### Edesa Biotech Reports Fiscal 2nd Quarter 2021 Results

TORONTO, ON / ACCESSWIRE / May 14, 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 six months ended March 31, 2021 and provided an update on its business.

The company reported that it has enrolled more than 285 patients in an ongoing Phase 2/3 clinical study of its investigational drug, EB05, as a single-dose treatment for hospitalized COVID-19 patients with or at risk of developing Acute Respiratory Distress Syndrome (ARDS). ARDS is the leading cause of death in COVID-19 patients. The study is being funded in part by a C\$14 million reimbursement grant from the Canadian Government. In addition, Edesa completed enrollment of the first cohort of a Phase 2b clinical study evaluating another drug candidate, EB01, as a monotherapy for chronic Allergic Contact Dermatitis. The company is currently performing a blinded interim analysis on EB01. Edesa recently expanded its global rights to the technology that forms the basis of EB01 for all fields of use in humans and animals. During the second fiscal quarter, Edesa raised net cash proceeds of approximately \$12.1 million from equity financings and warrant/option exercises.

"We achieved another quarter of positive momentum, highlighted by key enrollment milestones in two separate clinical programs, the award of a C\$14 million competitive grant announced by the Prime Minister of Canada, and the completion of an over-subscribed equity offering. While the results of our clinical studies will be data-driven, and are subject to regulatory review, we are already preparing to be in position to rapidly advance these studies should the interim results be positive and get these promising treatments in the hands of physicians. With these projects and initiatives in mind, we believe 2021 could be a transformative year for the company," said Dr. Par Nijhawan, Chief Executive Officer of Edesa Biotech.

Edesa's Chief Financial Officer Kathi Niffenegger reported that working capital was significantly bolstered by the federal reimbursement grant and equity financings. At March 31, 2021, Edesa had working capital of \$16.80 million. Cash and cash equivalents totaled \$10.97 million. Research and development expenditures have largely tracked the company's accelerated clinical progress.

"We have recorded cash reimbursements of approximately \$7.2 million under our federal grant. This has allowed us to advance our ARDS project more quickly and significantly offset development costs," said Ms. Niffenegger.

She added, "In the second fiscal quarter, research and development expenditures have been driven by the achievement of development milestones and drug product costs, and have generally shifted earlier than originally estimated due to the rapid pace of enrollment and related activities in our two ongoing clinical trials. Overall project expenditures have been in line with management's expectations."

#### Financial Results for the Three Months Ended March 31, 2021

There were no revenues for the three months ended March 31, 2021 compared to \$0.11 million for the three months ended March 31, 2020, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

---

Total operating expenses increased by \$7.88 million to \$9.51 million for the three months ended March 31, 2021 compared to \$1.63 million for the same period last year:

- Research and development expenses increased by \$7.48 million to \$7.98 million for the three months ended March 31, 2021 compared to \$0.50 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 ongoing clinical studies, increased investigational drug product expenses and an increase in non-cash share-based compensation. Higher salary and related personnel expenses, increased employee headcount and patent fees also contributed to the increase.
- General and administrative expenses increased by \$0.43 million to \$1.54 million for the three months ended March 31, 2021 compared to \$1.11 million for the same period last year primarily as a result of higher salary and related personnel expenses. Higher legal and other professional services also contributed to the increase.

Total other income increased by \$7.22 million to \$7.25 million for the three months ended March 31, 2021 compared to \$0.03 million for the same period last year primarily due to increased grant income related to the initiation of reimbursements under the company's federal grant with the Canadian government's Strategic Innovation Fund.

For the three months ended March 31, 2021, Edesa reported a net loss of \$2.26 million, or \$0.19 per common share, compared to a net loss of \$1.49 million, or \$0.17 per common share, for the three months ended March 31, 2020.

#### **Financial Results for the Six Months Ended March 31, 2021**

There were no revenues for the six months ended March 31, 2021 compared to \$0.22 million for the six months ended March 31, 2020, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

Total operating expenses increased by \$9.28 million to \$12.12 million for the six months ended March 31, 2021 compared to \$2.84 million for the same period last year:

- Research and development expenses increased by \$8.32 million to \$9.35 million for the six months ended March 31, 2021 compared to \$1.03 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 ongoing clinical studies, increased investigational drug product expenses and an increase in non-cash share-based compensation. Higher salary and related personnel expenses, increased employee headcount and patent fees also contributed to the increase.
  - General and administrative expenses increased by \$0.97 million to \$2.77 million for the six months ended March 31, 2021 compared to \$1.80 million for the same period last year primarily as a result of higher salary and related personnel expenses, and non-cash share-based compensation. Higher legal and other professional services also contributed to the increase.
-

Total other income increased by \$7.19 million to \$7.23 million for the six months ended March 31, 2021 compared to \$0.04 million for the same period last year primarily due to increased grant income related to the initiation of reimbursements under the company's federal grant with the Canadian government's Strategic Innovation Fund.

For the six months ended March 31, 2021, Edesa reported a net loss of \$4.90 million, or \$0.45 per common share, compared to a net loss of \$2.58 million, or \$0.32 per common share, for the six months ended March 31, 2020.

## **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](#).

## **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, the company's preparations to be in position to rapidly advance its clinical studies and the company's belief that 2021 could be a transformative year. 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**

Gary Koppenjan  
Edesa Biotech, Inc.  
(805) 488-2800 ext. 150  
[investors@edesabiotech.com](mailto:investors@edesabiotech.com)

---

**Condensed Interim Consolidated Statements of Operations**

(Unaudited)

	Three Months Ended		Six Months Ended	
	March 31, 2021	March 31, 2020	March 31, 2021	March 31, 2020
<b>Total Revenues</b>	\$ -	\$ 110,516	\$ -	\$ 218,316
<b>Expenses:</b>				
Cost of sales	-	10,037	-	13,815
Research and development	7,975,304	502,814	9,354,958	1,030,812
General and administrative	1,535,127	1,113,917	2,769,275	1,795,623
	<u>9,510,431</u>	<u>1,626,768</u>	<u>12,124,233</u>	<u>2,840,250</u>
<b>Loss from operations</b>	<b>(9,510,431)</b>	<b>(1,516,252)</b>	<b>(12,124,233)</b>	<b>(2,621,934)</b>
<b>Other Income (Loss):</b>				
Reimbursement grant income	7,170,465	-	7,170,465	-
Other income (loss)	80,779	26,616	56,969	38,765
<b>Loss before income taxes</b>	<b>(2,259,187)</b>	<b>(1,489,636)</b>	<b>(4,896,799)</b>	<b>(2,583,169)</b>
<b>Income tax expense</b>	<b>800</b>	<b>-</b>	<b>800</b>	<b>800</b>
<b>Net loss</b>	<b>(2,259,987)</b>	<b>(1,489,636)</b>	<b>(4,897,599)</b>	<b>(2,583,969)</b>
Exchange differences on translation	(10,480)	(39,908)	92,947	(21,794)
<b>Net comprehensive loss</b>	<b>\$ (2,270,467)</b>	<b>\$ (1,529,544)</b>	<b>\$ (4,804,652)</b>	<b>\$ (2,605,763)</b>
Weighted average number of common shares	11,641,201	8,740,065	10,894,441	8,118,891
<b>Loss per common share - basic and diluted</b>	<b>\$ (0.19)</b>	<b>\$ (0.17)</b>	<b>\$ (0.45)</b>	<b>\$ (0.32)</b>

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

	<u>March 31, 2021</u>	<u>September 30, 2020</u>
<b>Assets:</b>		
Cash and cash equivalents	\$ 10,966,194	\$ 7,213,695
Other current assets	10,452,165	890,323
Non-current assets	<u>2,583,331</u>	<u>2,658,357</u>
<b>Total Assets</b>	<b>\$ 24,001,690</b>	<b>\$ 10,762,375</b>
<b>Liabilities, shareholders' equity and temporary equity:</b>		
Current liabilities	\$ 4,620,135	\$ 1,529,857
Noncurrent liabilities	108,771	124,388
Temporary equity	-	2,476,955
Shareholders' equity	<u>19,272,784</u>	<u>6,631,175</u>
<b>Total liabilities, shareholders' equity and temporary equity</b>	<b>\$ 24,001,690</b>	<b>\$ 10,762,375</b>

---



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

	<b>Six Months Ended</b>	
	<b>March 31, 2021</b>	<b>March 31, 2020</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,897,599)	\$ (2,583,969)
Adjustments for non-cash items	1,248,994	393,829
Change in working capital items	<u>(6,541,452)</u>	<u>229,981</u>
<b>Net cash used in operating activities</b>	<b>(10,190,057)</b>	<b>(1,960,159)</b>
<b>Net cash provided by (used in) investing activities</b>	<b>(4,098)</b>	<b>42,359</b>
<b>Net cash provided by financing activities</b>	<b>13,937,798</b>	<b>3,891,801</b>
Effect of exchange rate changes on cash and cash equivalents	<u>8,856</u>	<u>(14,654)</u>
Increase in cash and cash equivalents during the period	<b>3,752,499</b>	<b>1,959,347</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>\$ 10,966,194</u></b>	<b><u>\$ 6,989,930</u></b>

---