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): February14, 2022

Edesa Biotech, Inc.

(Exact Name of Registrant as Specified in its Charter)

British Columbia, Canada	**001-37619**	**N/A**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 February 14, 2022, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three months ended December 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

Exhibit No.	**Description**
99.1	Press release issued by Edesa Biotech, Inc. dated February 14, 2022.

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: February 14, 2022

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

Edesa Biotech Reports Fiscal 1st Quarter 2022 Results

TORONTO, ON / ACCESSWIRE / February 14, 2022 / Edesa Biotech, Inc. (Nasdaq:EDSA), a clinical-stage biopharmaceutical company focused on inflammatory and immune-related diseases, today reported financial results for the three months ended December 31, 2021 and provided an update on its business.

During the quarter, Health Canada approved the Phase 3 design of a Phase 2/3 clinical study evaluating the company's monoclonal antibody, designated EB05, as a rescue therapy for critically ill patients with a life-threatening form of respiratory failure known as ARDS. The authorization follows Phase 2 results that demonstrated a significant reduction in mortality among critically ill Covid-19 patients treated with EB05.

Par Nijhawan, MD, Chief Executive Officer of Edesa, said that the promising EB05 results provide an opportunity for the company to play a significant role in building a lasting solution to the pandemic, as Covid becomes endemic and governments focus more on treatments for those who become hospitalized.

"Our expectation is that Covid-19 cases are going to continue to drive ARDS-related ICU admissions well beyond historical levels for the foreseeable future. There's a significant and urgent unmet medical need for critical care treatments and we believe that EB05 could become an important part of reducing mortality and improving ICU capacity. If these two challenges can be managed, it helps provide the world with a way forward to live with Covid," he said.

The company also reported that its Phase 2b clinical study in chronic Allergic Contact Dermatitis (ACD) reached an enrollment milestone during the quarter, and that enrollment in the study has returned to a pre-pandemic pace in recent months. Recruitment also continues for the EB05 study. The company plans to provide more detailed clinical updates for these development programs as they become available. "In the coming quarters we look forward to completing recruitment and presenting topline results for these lead product candidates," said Dr. Nijhawan.

Edesa's Chief Financial Officer Kathi Niffenegger said that the fiscal first quarter reflected increased development and regulatory activities for the company's ongoing clinical programs. Results continued to benefit from reimbursements under the company's government grant.

"Our fiscal first quarter results demonstrated the disciplined approach we are taking to deploying our working capital and the flexibility management has to align the timing of scale-up expenditures with clinical advancements and other important value inflection points," said Ms. Niffenegger.

Financial Results for the Three Months Ended December 31, 2021

Total operating expenses increased by $2.55 million to $5.16 million for the three months ended December 31, 2021 compared to $2.61 million for the same period last year:

- Research and development expenses increased by $2.57 million to $3.95 million for the three months ended December 31, 2021 compared to $1.38 million for the same period last year primarily due to increased external research expenses related to the company's ongoing clinical studies, increased investigational drug product expenses, higher salary and related personnel expenses due to increased headcount and higher patent fees, which were partially offset by a decrease in noncash share-based compensation.

- General and administrative expenses decreased by $0.02 million to $1.21 million for the three months ended December 31, 2021 compared to $1.23 million for the same period last year primarily as a result of decreased noncash share-based compensation, which was partially offset by higher insurance, and legal and other professional service fees.

Total other income (loss) increased by $0.80 million to an overall gain of $0.78 million for the three months ended December 31, 2021 compared to an overall loss of $0.02 million for the prior year primarily due to increased grant income under the company's federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the quarter ended December 31, 2021, Edesa reported a net loss of $4.38 million, or $0.33 per common share, compared to a net loss of $2.64 million, or $0.26 per common share, for the quarter ended December 31, 2020.

Working Capital

At December 31, 2021, Edesa had working capital of $8.14 million. Cash and cash equivalents totaled $5.88 million. Subsequent to the end of the fiscal first quarter, the company received gross proceeds of approximately $1.19 million from the issuance of common shares under an equity distribution agreement with RBC Capital Markets.

Calendar

Edesa management plans to participate in the BIO Europe Spring 2022 virtual conference scheduled for March 28-31, 2022. Members of the investment or biopharma community who are interested in meeting with management can schedule one-on-one calls through the conference website or by contacting Edesa at 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 Edesa 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. By targeting sPLA2 with enzyme inhibitors – at the inception of inflammation rather than after inflammation has occurred – Edesa believes that drugs based on this technology could provide a powerful anti-inflammatory therapeutic strategy for treating diverse inflammatory/allergic conditions. The company is based in Markham, Ontario, Canada, with a U.S. subsidiary located in Southern California. Sign up for news alerts. Connect with us 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: the company's belief that promising EB05 results provide an opportunity for it to play a significant role in building a lasting solution to the pandemic; the company's expectation that Covid-19 cases are going to continue to drive ARDS-related ICU admissions well beyond historical levels for the foreseeable future; the company's belief that there's a significant and urgent unmet medical need for critical care treatments and that EB05 could become an important part of reducing mortality and improving ICU capacity; the company's plans to provide more detailed clinical updates for these development programs as they become available; and the company's timing and plans regarding its clinical studies in general. 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

Condensed Interim Consolidated Statements of Operations

(Unaudited)

	Three Months Ended	
	December 31, 2021	**December 31, 2020**
Expenses:		
Research and development	**3,951,046**	1,379,654
General and administrative	**1,210,677**	1,234,148
Loss from operations	**(5,161,723)**	(2,613,802)
Other Income (Loss):		
Reimbursement grant income	**780,257**	-
Other income (loss)	**2,789**	(23,810)
Net loss	**(4,378,677)**	(2,637,612)
Exchange differences on translation	**31,849**	103,427
Net comprehensive loss	**$ (4,346,828)**	$ (2,534,185)
Weighted average number of common shares	**13,351,547**	10,277,750
Loss per common share - basic and diluted	**$ (0.33)**	$ (0.26)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	December 31, 2021	September 30, 2021
Assets:		
Cash and cash equivalents	**$ 5,880,749**	$ 7,839,259
Other current assets	**4,011,043**	4,251,472
Non-current asset	**2,451,564**	2,493,924
Total Assets	**$ 12,343,356**	$ 14,584,655
Liabilities and shareholders' equity:		
Current liabilities	**$ 1,746,867**	$ 1,458,650
Non-current liabilities	**47,244**	67,714
Shareholders' equity	**10,549,245**	13,058,291
Total liabilities and shareholders' equity	**$ 12,343,356**	$ 14,584,655

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended	
	December 31, 2021	December 31, 2020
Cash flows from operating activities:		
Net loss	**$ (4,378,677)**	$ (2,637,612)
Adjustments for non-cash items	**639,030**	751,752
Change in working capital items	**532,033**	(1,124,669)
Net cash used in operating activities	**(3,207,614)**	(3,010,529)
Net cash used in investing activities	**(3,140)**	(1,135)
Net cash provided by financing activities	**1,228,504**	1,994,972
Effect of exchange rate changes on cash and cash equivalents	**23,740**	108,290
Net change in cash and cash equivalents	**(1,958,510)**	(908,402)
Cash and cash equivalents, beginning of period	**7,839,259**	7,213,695
Cash and cash equivalents, end of period	**$ 5,880,749**	$ 6,305,293