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): February 10, 2023

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 10, 2023, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three months ended December 31, 2022 (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 10, 2023.

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 10, 2023

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

Edesa Biotech Reports Fiscal 1st Quarter 2023 Results

TORONTO, ON / ACCESSWIRE / February 10, 2023 / 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, 2022 and provided an update on its business.

During the fiscal first quarter, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for Edesa's drug candidate, EB05, which the company is developing for Acute Respiratory Distress Syndrome (ARDS), a severe form of respiratory failure. Approval of the company's application follows favorable Phase 2 results and provides increased access to agency staff as well as potential pathways for accelerated regulatory approval. Last month, the company also reported preliminary, topline results from a Phase 2b clinical study evaluating multiple concentrations of its drug candidate, EB01, as a monotherapy for chronic moderate-to-severe Allergic Contact Dermatitis (ACD). Among the results, 1.0% EB01 cream demonstrated statistically significant improvement over placebo for both the primary efficacy endpoint and a key secondary endpoint. Most recently, the company announced that Canadian regulators authorized a Phase 2 clinical study of Edesa's EB06 monoclonal antibody candidate as a treatment for vitiligo, an autoimmune disease that causes loss of skin color in patches.

"We are pleased to start off the year with three major pieces of good news," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. "Overall, this was a strong quarter across our operations, and we look forward to building on this momentum, including making use of our expanded access under Fast Track and advancing our strategic discussions with potential commercialization and licensing partners. We see significant opportunities for our late-stage ARDS, ACD and vitiligo assets, and look forward to sharing our clinical and operational progress, including important upcoming regulatory milestones."

Edesa's Chief Financial Officer Kathi Niffenegger reported that fiscal first quarter operating expenditures declined by more than 50% compared the same period last year, and that the company continued to demonstrate its ability to effectively manage working capital and operational priorities.

"Fiscal first quarter results reflect the flexibility of Edesa's business model and the continued execution of management's plans to focus on core value-creation opportunities," said Ms. Niffenegger. She noted that during the quarter, the company bolstered its working capital through a private placement of securities. The financing was led by a healthcare-focused institution and Edesa's Chief Executive Officer.

Edesa reported that near-term operational objectives include, among others, completing the FDA review of the company's Phase 3 protocol design for EB05, fully enrolling the Phase 3 study of EB05, and completing a Phase 2 investigational new drug application in the U.S. for systemic sclerosis.

Financial Results for the Three Months Ended December 31, 2022

Total operating expenses decreased by $2.78 million to $2.38 million for the three months ended December 31, 2022 compared to $5.16 million for the same period last year:

- Research and development expenses decreased by $2.59 million to $1.36 million for the three months ended December 31, 2022 compared to $3.95 million for the same period last year primarily due to decreased external research expenses related to the company's ongoing clinical studies and manufacturing of the company's investigational drugs.

- General and administrative expenses decreased by $0.19 million to $1.02 million for the three months ended December 31, 2022 compared to $1.21 million for the same period last year primarily due to a decrease in noncash share-based compensation.

Total other income decreased by $0.74 million to $0.04 million for the three months ended December 31, 2022 compared to $0.78 million for the same period last year primarily due to a decrease in grant income associated with the completion of clinical study activities under Edesa's federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the quarter ended December 31, 2022, Edesa reported a net loss of $2.33 million, or $0.13 per common share, compared to a net loss of $4.38 million, or $0.33 per common share, for the quarter ended December 31, 2021.

Working Capital

At December 31, 2022, Edesa had cash and cash equivalents of $8.27 million and working capital of $7.81 million. Subsequent to the end of quarter, the company has received gross proceeds of approximately $0.77 million upon the exercise of common share purchase warrants.

Calendar

Edesa management plans to participate in the American Academy of Dermatology Annual Meeting from March 17-21, 2023 and BIO Europe Spring 2023 from March 20-22, 2023. Attendees interested in meeting with management can request meetings through the conference organizers or by contacting Edesa directly 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 late-stage clinical studies. Sign up for news alerts. Connect with us on Twitter and LinkedIn.

ARDS CLINICAL PROGRAM

EB05, a novel monoclonal antibody targeting Toll-like Receptor 4 (TLR4) as a critical care therapy for Acute Respiratory Distress Syndrome (ARDS) - Phase 3: Enrolling

EB05 inhibits signaling through TLR4 - a key pattern recognition receptor involved in the activation of the innate immune system. Excessive TLR4 pathway activation can be pathological and has been linked to various inflammatory conditions, including viral-mediated acute lung injury. EB05 has extensive preclinical and clinical experience, including evaluations in more than 600 hospitalized Covid-19 subjects. In an international Phase 2 study, a single dose of EB05 demonstrated compelling preliminary evidence of the drug's ability to reduce mortality in target patient populations.

CONTACT DERMATITIS CLINICAL PROGRAM

EB01, a non-steroidal anti-inflammatory compound that inhibits secretory phospholipase 2 (sPLA2) as a treatment for the symptoms of chronic moderate-to-severe Allergic Contact Dermatitis (ACD) - Phase 2b

EB01 exerts its anti-inflammatory activity through the inhibition of sPLA2 pro-inflammatory enzymes. The sPLA2 enzyme family plays a key role in initiating inflammation associated with numerous diseases. 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. Edesa recently reported preliminary, topline results from a Phase 2b clinical study evaluating multiple concentrations of its drug candidate, EB01, as a monotherapy for chronic moderate-to-severe ACD. Among the results, 1.0% EB01 cream demonstrated statistically significant improvement over placebo for both the primary efficacy endpoint and a key secondary endpoint. EB01 has also demonstrated efficacy for the treatment of ACD in two previous clinical trials.

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 it will continue to building on the fiscal year-to-date operational accomplishments, including making use of its expanded access under FDA's Fast Track designation and advancing its strategic discussions with potential commercialization and licensing partners; the company's belief that there are significant opportunities for its late-stage ARDS, ACD and vitiligo assets; the company's plans to complete the FDA review process of its Phase 3 protocol design for EB05; the company's plans to fully enroll the Phase 3 study of EB05; the company's plans to complete a Phase 2 investigational new drug application in the U.S. for systemic sclerosis; 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
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Edesa Biotech, Inc.
(805) 488-2800 ext. 150

Condensed Interim Consolidated Statements of Operations
(Unaudited)

	Three Months Ended	
	December 31, 2022	**December 31, 2021**
Expenses:		
Research and development	**1,357,338**	3,951,046
General and administrative	**1,020,967**	1,210,677
Loss from operations	**(2,378,305)**	(5,161,723)

Other Income (Loss):		
Reimbursement grant income	-	780,257
Other income (loss)	**43,488**	2,789
Net loss	**(2,334,817)**	(4,378,677)
Exchange differences on translation	**(25,067)**	31,849
Net comprehensive loss	**$ (2,359,884)**	$ (4,346,828)
Weighted average number of common shares	**18,387,980**	13,351,547
Loss per common share - basic and diluted	**$ (0.13)**	$ (0.33)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	December 31, 2022	September 30, 2022
Assets:		
Cash and cash equivalents	**$ 8,270,207**	$ 7,090,919
Other current assets	**816,422**	2,000,994
Non-current assets	**2,588,133**	2,483,815
Total Assets	**$ 11,674,762**	$ 11,575,728
Liabilities and shareholders' equity:		
Current liabilities	**$ 1,280,404**	$ 2,140,777
Non-current liabilities	**120,902**	43,662
Shareholders' equity	**10,273,456**	9,391,289
Total liabilities and shareholders' equity	**$ 11,674,762**	$ 11,575,728

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended	
	December 31, 2022	December 31, 2021
Cash flows from operating activities:		
Net loss	**$ (2,334,817)**	$ (4,378,677)
Adjustments for non-cash items	**360,872**	639,030
Change in working capital items	**182,850**	532,033
Net cash used in operating activities	**(1,791,095)**	(3,207,614)
Net cash used in investing activities	-	(3,140)
Net cash provided by financing activities	**2,911,775**	1,228,504
Effect of exchange rate changes on cash and cash equivalents	**58,608**	23,740
Net change in cash and cash equivalents	**1,179,288**	(1,958,510)
Cash and cash equivalents, beginning of period	**7,090,919**	7,839,259
Cash and cash equivalents, end of period	**$ 8,270,207**	$ 5,880,749