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 11, 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 May 11, 2023, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three and six months ended March 31, 2023 (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 May 11, 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: May 11, 2023

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

Edesa Biotech Reports Fiscal 2nd Quarter 2023 Results

TORONTO, ON / ACCESSWIRE / May 11, 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 and six months ended March 31, 2023 and provided an update on its business.

During the fiscal second quarter, the company achieved two regulatory milestones, including an agreement with the U.S. Food and Drug Administration on the primary endpoint of a pivotal Phase 3 study of Edesa's ARDS (acute respiratory distress syndrome) drug candidate EB05 (paridiprubart) in critical-care patients hospitalized with SARS-CoV2 infections, and an authorization by Canadian regulators for a Phase 2 clinical study of Edesa's EB06 monoclonal antibody candidate as a treatment for vitiligo. In addition, the company reported favorable preliminary, topline results from a Phase 2b clinical study of Edesa's drug candidate EB01 as a monotherapy for moderate-to-severe chronic allergic contact dermatitis (ACD).

"These regulatory and clinical milestones represent a key part of our growth strategy, and we are excited about the opportunities we have to expand our business development discussions for these innovative assets," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. "As part of our development and go-to-market planning, we are also exploring broader potential use of our lead biologic, paridiprubart, as treatment for general ARDS and other conditions that involve dysregulated innate immune responses, such as systemic sclerosis."

Dr. Nijhawan reported that the company plans to file an investigational new drug application (IND) in the U.S. for a future Phase 2 study of EB07 (paridiprubart) in systemic sclerosis (scleroderma), a chronic fibrotic disease of the skin and internal organs that primarily impacts women. Additional objectives include the completion of the company's ongoing Phase 2/3 study of EB05 (paridiprubart), and completing the full analysis of the results from the company's ACD study.

Edesa's Chief Financial Officer Kathi Niffenegger reported that operating expenditures for the three and six month periods ended March 31, 2023 declined by 47% and 51%, respectively. "Second quarter and first half expenditures were in line with our expectations and reflected, in part, a disciplined approach toward working capital, including close management of research expenditures and greater use of internal staff resources," she said.

Financial Results for the Three Months Ended March 31, 2023

Total operating expenses decreased by $2.17 million to $2.41 million for the three months ended March 31, 2023 compared to $4.58 million for the same period last year:

- Research and development expenses decreased by $1.58 million to $1.46 million for the three months ended March 31, 2023 compared to $3.04 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 its investigational drugs.

- General and administrative expenses decreased by $0.58 million to $0.95 million for the three months ended March 31, 2023 compared to $1.53 million for the same period last year primarily due to a decrease in personnel expenses and noncash share-based compensation.

Total other income increased by $0.07 million to $0.08 million for the three months ended March 31, 2023 compared to $0.01 million for the same period last year primarily due to an increase in interest earned on cash balances.

For the quarter ended March 31, 2023, Edesa reported a net loss of $2.33 million, or $0.12 per common share, compared to a net loss of $4.57 million, or $0.33 per common share, for the quarter ended March 31, 2022.

Financial Results for the Six Months Ended March 31, 2023

Total operating expenses decreased by $4.95 million to $4.79 million for the six months ended March 31, 2023 compared to $9.74 million for the same period last year:

- Research and development expenses decreased by $4.17 million to $2.82 million for the six months ended March 31, 2023 compared to $6.99 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 its investigational drugs.

- General and administrative expenses decreased by $0.77 million to $1.97 million for the six months ended March 31, 2023 compared to $2.74 million for the same period last year primarily due to a decrease in personnel expenses and noncash share-based compensation.

Total other income decreased by $0.67 million to $0.12 million for the six months ended March 31, 2023 compared to $0.79 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 six months ended March 31, 2023, Edesa reported a net loss of $4.67 million, or $0.24 per common share, compared to a net loss of $8.95 million, or $0.66 per common share, for the six months ended March 31, 2022.

Working Capital

At March 31, 2023, Edesa had cash and cash equivalents of $7.47 million and working capital of $6.56 million. Subsequent to the end of quarter, equity sales under the company's at-the-market offering program provided net cash proceeds of $0.60 million after deducting sales agent commissions.

Calendar

Edesa management plans to participate in the BIO International Convention being held June 5-8, 2023 in Boston, Mass. 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 developing innovative ways to treat inflammatory and immune-related diseases. The company's most advanced drug candidate is EB05 (paridiprubart), a monoclonal antibody developed for acute and chronic disease indications that involve dysregulated innate immune responses. Edesa is currently evaluating EB05 in a Phase 3 study as a potential treatment for Acute Respiratory Distress Syndrome (ARDS), a life-threatening form of respiratory failure. In addition, Edesa is developing an sPLA2 inhibitor, EB01, as a topical treatment for chronic Allergic Contact Dermatitis (ACD), a common occupational skin condition. The company has also received regulatory approval to conduct a Phase 2 trial its EB06 monoclonal antibody as a treatment for vitiligo, a life-altering autoimmune disease that causes skin to lose its color in patches. Edesa is also planning to file an investigational new drug application for a future Phase 2 study of paridiprubart for systemic sclerosis (scleroderma), an autoimmune rheumatic disorder that causes fibrosis, (scarring/hardening) of skin and internal organs such as the lungs, heart and kidneys. 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 the regulatory and clinical milestones described in this press release represent a key part of the company's growth strategy; the company's plans to broaden its business development discussions for its EB01, EB05, EB06 and EB07 assets; the company's plans to explore broader potential use of its lead biologic, paridiprubart, as treatment for general ARDS and other conditions that involve dysregulated innate immune responses, such as systemic sclerosis; the company's plans to file an IND in the U.S. for a future Phase 2 study of EB07 (paridiprubart) in systemic sclerosis; Edesa's plans to complete its ongoing Phase 2/3 study of EB05 (paridiprubart) in patients hospitalized with SARS-CoV2 infection; Edesa's plans to complete the full analysis of the results from the company's ACD study; 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		Six Months Ended	
	March 31, 2023	**March 31, 2022**	**March 31, 2023**	**March 31, 2022**
Expenses:				
Research and development	**1,458,190**	3,042,815	**2,815,528**	6,993,861
General and administrative	**952,391**	1,532,416	**1,973,358**	2,743,093
Loss from operations	**(2,410,581)**	(4,575,231)	**(4,788,886)**	(9,736,954)
Other Income (Loss):				
Reimbursement grant income	**-**	-	**-**	780,257
Other income (loss)	**77,032**	6,715	**120,520**	9,504
Income tax expense	**800**	800	**800**	800
Net loss	**(2,334,349)**	(4,569,316)	**(4,669,166)**	(8,947,993)
Exchange differences on translation	**8,643**	13,066	**(16,424)**	44,915
Net comprehensive loss	**$ (2,325,706)**	$ (4,556,250)	**$ (4,685,590)**	$ (8,903,078)
Weighted average number of common shares	**19,973,319**	13,867,345	**19,171,939**	13,610,164
Loss per common share - basic and diluted	**$ (0.12)**	$ (0.33)	**$ (0.24)**	$ (0.66)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	March 31, 2023	September 30, 2022
Assets:		
Cash and cash equivalents	**$ 7,471,252**	$ 7,090,919
Other current assets	**658,342**	2,000,994
Non-current assets	**2,543,891**	2,483,815
Total Assets	**$ 10,673,485**	$ 11,575,728
Liabilities and shareholders' equity:		
Current liabilities	**$ 1,564,786**	$ 2,140,777
Non-current liabilities	**108,762**	43,662
Shareholders' equity	**8,999,937**	9,391,289
Total liabilities and shareholders' equity	**$ 10,673,485**	$ 11,575,728

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended	
	March 31, 2023	March 31, 2022
Cash flows from operating activities:		
Net loss	**$ (4,669,166)**	$ (8,947,993)
Adjustments for non-cash items	**675,723**	1,298,919
Change in working capital items	**630,203**	4,024,806
Net cash used in operating activities	**(3,363,240)**	(3,624,268)
Net cash used in investing activities	**-**	(4,339)
Net cash provided by financing activities	**3,676,415**	11,629,914
Effect of exchange rate changes on cash and cash equivalents	**67,158**	46,633
Net change in cash and cash equivalents	**380,333**	8,047,940
Cash and cash equivalents, beginning of period	**7,090,919**	7,839,259
Cash and cash equivalents, end of period	**$ 7,471,252**	$ 15,887,199