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 9, 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 August 9, 2023, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended June 30, 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, as amended (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 August 9, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 9, 2023

By: */s/ Stephen Lemieux*
Name: Stephen Lemieux
Title: Chief Financial Officer

EXHIBIT 99.1

Edesa Biotech Reports Fiscal Third Quarter 2023 Results

TORONTO, ON / ACCESSWIRE / August 9, 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 nine months ended June 30, 2023 and provided an update on its business.

During the fiscal third quarter, the company reported positive results from a university study of its monoclonal antibody, paridiprubart, against a panel of respiratory pathogens. The study, which ran in parallel to the company's ongoing Phase 3 clinical study of EB05 (paridiprubart), provided further evidence that Edesa's drug candidate could potentially treat acute lung injury caused by multiple infectious diseases. Earlier this year, the company achieved regulatory milestones for this asset as well as another biologic drug candidate that Edesa plans to evaluate as a treatment for vitiligo. The company also completed a Phase 2b study of its dermatitis drug candidate, and is preparing a final clinical study report (CSR) for regulators following favorable preliminary topline data.

"The milestones that we have achieved this year, including the latest third-party confirmatory data, are creating new opportunities for the company. Host-directed therapeutics like paridiprubart could become standard countermeasures against both seasonal and unexpected outbreaks of disease, and we are prioritizing the evaluation of this first-in-class biologic beyond our current study in Covid-19-induced Acute Respiratory Distress Syndrome," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech.

"Looking across our pipeline, we are evaluating opportunities – including via third-party arrangements – to initiate a clinical study of our Phase 2-ready vitiligo asset and to complete regulatory filings for a Phase 2 study of paridiprubart in systemic sclerosis. Validating and expediting these programs are key to our development and growth strategy," said Dr. Nijhawan.

Edesa's Chief Financial Officer Stephen Lemieux said that the company continued its trend of discipline when managing its capital resources. For the fiscal year to date, operational costs declined significantly and the company raised $4.63 million in gross proceeds from the sale of common shares and the exercise of warrants. "We operate in a dynamic environment and management continued to demonstrate its ability to closely manage working capital, prioritize core development programs and align the timing of future expenditures with value-creation activities," he said.

Financial Results for the Three Months Ended June 30, 2023

Total operating expenses decreased by $3.74 million to $2.06 million for the three months ended June 30, 2023 compared to $5.80 million for the same period last year:

- Research and development expenses decreased by $3.52 million to $1.03 million for the three months ended June 30, 2023 compared to $4.55 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. In the comparative period, the company purchased bulk drug product of EB05 for its clinical study for $2.54 million.

- General and administrative expenses decreased by $0.21 million to $1.04 million for the three months ended June 30, 2023 compared to $1.25 million for the same period last year primarily due to decreased non-cash share-based compensation.

Total other income increased by $0.07 million to $0.08 million for the three months ended June 30, 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 June 30, 2023, Edesa reported a net loss of $1.98 million, or $0.10 per common share, compared to a net loss of $5.79 million, or $0.37 per common share, for the quarter ended June 30, 2022.

Financial Results for the Nine Months Ended June 30, 2023

Total operating expenses decreased by $8.68 million to $6.85 million for the nine months ended June 30, 2023 compared to $15.53 million for the same period last year:

- Research and development expenses decreased by $7.70 million to $3.84 million for the nine months ended June 30, 2023 compared to $11.54 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, and a decrease in noncash share-based compensation.

- General and administrative expenses decreased by $0.98 million to $3.01 million for the nine months ended June 30, 2023 compared to $3.99 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 $0.60 million to $0.20 million for the nine months ended June 30, 2023 compared to $0.80 million for the same period last year primarily due to a decrease in grant income associated with the completion of EB05 clinical study activities under Edesa's federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the nine months ended June 30, 2023, Edesa reported a net loss of $6.65 million, or $0.34 per common share, compared to a net loss of $14.74 million, or $1.04 per common share, for the nine months ended June 30, 2022.

Working Capital

At June 30, 2023, Edesa had cash and cash equivalents of $6.46 million and working capital of $5.39 million. During the nine months ended June 30, 2023, the company has raised gross proceeds of $4.63 million from the issuance of common shares including $1.0 million from its equity distribution agreement with Canaccord Genuity LLC.

Calendar

Edesa management plans to participate in the H.C. Wainwright 25th Annual Global Investment Conference being held September 11-13 2023 in New York, NY. 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 (daniluromer), 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 positive results from a university study provide further evidence that paridiprubart could potentially treat acute lung injury caused by multiple infectious diseases; the company's plans to evaluate EB06 as a treatment for vitiligo; the company's plans to prepare a final Phase 2b clinical study report of EB01 (daniluromer) for regulators; the company's belief that the milestones it achieved this year, including the latest third-party confirmatory data, are creating new opportunities for the company and its shareholders; the company's belief that host directed therapeutics like paridiprubart could become standard countermeasures against both seasonal and unexpected outbreaks of disease; the company's plans to prioritize the evaluation of EB05 beyond its current study in Covid-19-induced ARDS; the company's plans to evaluate opportunities, including via third-party arrangements, to initiate a Phase 2 study of its vitiligo drug candidate and to complete regulatory filings for a Phase 2 study of paridiprubart in systemic sclerosis; the company's belief that validating and expediting these programs is an important part of its development and growth strategy; the company's plans to closely manage working capital, prioritize core development programs and align the timing of future expenditures with value-creation activities; 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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Condensed Interim Consolidated Statements of Operations
(Unaudited)

	Three Months Ended		Nine Months Ended	
	June 30, 2023	**June 30, 2022**	**June 30, 2023**	**June 30, 2022**
Expenses:				
Research and development	**1,025,622**	4,547,543	**3,841,150**	11,541,404
General and administrative	**1,038,587**	1,249,982	**3,011,945**	3,993,075
Loss from operations	**(2,064,209)**	(5,797,525)	**(6,853,095)**	(15,534,479)
Other Income (Loss):				
Reimbursement grant income	**-**	-	**-**	780,257
Other income (loss)	**79,303**	10,505	**199,823**	20,009
Income tax expense	**-**	-	**800**	800
Net loss	**(1,984,906)**	(5,787,020)	**(6,654,072)**	(14,735,013)
Exchange differences on translation	**39,839**	34,559	**23,415**	79,474
Net comprehensive loss	**$ (1,945,067)**	$ (5,752,461)	**$ (6,630,657)**	$ (14,655,539)
Weighted average number of common shares	**20,514,766**	15,462,287	**19,619,548**	14,227,538
Loss per common share - basic and diluted	**$ (0.10)**	$ (0.37)	**$ (0.34)**	$ (1.04)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	June 30, 2023	September 30, 2022
Assets:		
Cash and cash equivalents	**$ 6,457,170**	$ 7,090,919
Other current assets	**456,911**	2,000,994
Non-current assets	**2,505,443**	2,483,815
Total Assets	**$ 9,419,524**	$ 11,575,728
Liabilities and shareholders' equity:		
Current liabilities	**$ 1,528,966**	$ 2,140,777
Non-current liabilities	**40,075**	43,662
Shareholders' equity	**7,850,483**	9,391,289
Total liabilities and shareholders' equity	**$ 9,419,524**	$ 11,575,728

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended	
	June 30, 2023	June 30, 2022
Cash flows from operating activities:		
Net loss	**$ (6,654,072)**	$ (14,735,013)
Adjustments for non-cash items	**866,881**	1,893,898
Change in working capital items	**618,730**	6,190,020
Net cash used in operating activities	**(5,168,461)**	(6,651,095)
Net cash used in investing activities	**-**	(5,697)
Net cash provided by financing activities	**4,417,646**	11,629,914
Effect of exchange rate changes on cash and cash equivalents	**117,066**	(3,669)
Net change in cash and cash equivalents	**(633,749)**	4,969,453
Cash and cash equivalents, beginning of period	**7,090,919**	7,839,259
Cash and cash equivalents, end of period	**$ 6,457,170**	$ 12,808,712