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): December 15, 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)	(Zip Code)

(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 December 15, 2023, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended September 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 December 15, 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: December 15, 2023

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

Edesa Biotech Reports Fiscal Year 2023 Results

TORONTO, ON / ACCESSWIRE / December 15, 2023 / Edesa Biotech, Inc. (Nasdaq:EDSA), a clinical-stage biopharmaceutical company focused on developing host-directed therapeutics for immuno-inflammatory diseases, today reported financial results for the fiscal year ended September 30, 2023 and provided an update on its business.

During the year, Edesa reported favorable results from two clinical studies and achieved multiple regulatory and operational milestones for its current and upcoming drug development programs. In October, the company secured funding of up to C$23 million from the Canadian government toward a Phase 3 clinical study and the manufacturing scale-up of Edesa's ARDS drug candidate, EB05 (paridiprubart), a portion of which is conditionally repayable. Earlier in the year, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for this same study. For its EB06 drug candidate, Edesa reported that it received regulatory authorization to initiate a Phase 2 study in vitiligo patients.

"2023 was a successful year that validated both our technology as well as the market potential of our first-in-class, host-directed therapeutic platforms. We have a Phase 3 drug candidate in the clinic, a Phase-3-ready asset ready for partnering and continued development, and two projects ready for Phase 2," said Dr. Par Nijhawan, MD, Chief Executive Officer of Edesa. "We believe that we are well positioned to achieve additional clinical and regulatory catalysts, and believe that 2024 could be another transformative year for the company."

Edesa's Chief Financial Officer Stephen Lemieux stated that "in fiscal year 2023 the company continued to demonstrate its ability to deliver clinical results in a cost-effective manner, raise funds under difficult market conditions and obtain non-dilutive funding and support. The significant funding from the Canadian government and a recently established $10 million revolving credit facility are expected to provide greater operating flexibility and extend working capital. Having partnered our Phase 3 EB05 program with the federal government, we are turning our attention now to the advancement of our vitiligo and fibrosis drug development projects."

In the coming quarters, Edesa plans to both initiate clinical and regulatory activities to study its TLR4 modulator (paridiprubart) in a wider ARDS population as well as file an investigational new drug application in fibrotic diseases like systemic sclerosis. The company is also planning for a Phase 2 study of its anti-CXCL10 monoclonal antibody in moderate-to-severe nonsegmental vitiligo patients. Edesa also reported that it is evaluating potential partnerships and funding opportunities to complete a future international Phase 3 of its dermatitis drug candidate, EB01 (1.0% daniluromer cream) following favorable Phase 2b results reported last month.

Financial Results for the Fiscal Year Ended September 30, 2023

Total operating expenses decreased by $9.2 million to $9.2 million for the year ended September 30, 2023 compared to $18.4 million for the prior year.

Research and development expenses decreased by $8.5 million to $4.8 million for the year ended September 30, 2023 compared to $13.3 million for the prior year primarily due to lower external research and development expenses related to Edesa's ongoing clinical studies and manufacturing of its investigational drugs, which included the purchase of $2.5 million in bulk drug product in the prior period.

General and administrative expenses decreased by $0.6 million to $4.4 million for the year ended September 30, 2023 compared to $5.0 million for the prior year primarily due to a decrease in noncash share-based compensation.

Total other income was unchanged at $0.8 million for the years ended September 30, 2023 and September 30, 2022.

For the year ended September 30, 2023, Edesa reported a net loss of $8.4 million, or $2.93 per common share, compared to a net loss of $17.6 million, or $8.37 per common share, for the year ended September 30, 2022.

Working Capital

At September 30, 2023, Edesa had cash and cash equivalents of $5.4 million and working capital of $4.6 million. Subsequent to the end of the fiscal year, the company raised gross proceeds to date of $0.3 million under its equity distribution agreement with Canaccord Genuity LLC.

Calendar

Edesa management plans to participate in the 2024 Dermatology Summit on January 7, 2024 as well as in one-on-one meetings during JP Morgan week from January 8-12, 2024, in San Francisco, California. 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. The company has also received regulatory approval to conduct a Phase 2 trial its EB06 (anti-CXCL10) monoclonal antibody as a treatment for vitiligo, a life-altering autoimmune disease that causes skin to lose its color in patches. 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. Edesa is also planning to file an investigational new drug application for a future Phase 2 study of paridiprubart for fibrotic diseases such as systemic sclerosis. Sign up for news alerts. Connect with us on X (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 it achieved multiple regulatory and operational milestones for its current and upcoming drug development programs; the company's exploration of partnering/funding opportunities to complete a future international Phase 3 of its dermatitis drug candidate; the company's belief that 2023 was a successful year that validated both its technology as well as the market potential of its first-in-class, host-directed therapeutic platforms; the company's belief that it is well positioned to achieve multiple clinical and regulatory catalysts, and that 2024 could be another transformative year; the company's plans in coming quarters to initiate clinical and regulatory activities to study its TLR4 modulator (paridiprubart) in both a wider ARDS population as well as fibrotic diseases like systemic sclerosis; the company's plans for a Phase 2 study of its anti-CXCL10 monoclonal antibody in moderate-to-severe nonsegmental vitiligo patients; the company' belief that significant funding from the Canadian government and a recently established $10 million revolving credit facility could provide greater operating flexibility and extend working capital; the company's plans to turn its attention to the advancement of its vitiligo and fibrosis drug development projects; 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. 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.
(289) 800-9600
investors@edesabiotech.com

Consolidated Statements of Operations

	Years Ended		
	September 30, 2023		**September 30, 2022**
Expenses:			
Research and development	**$ 4,794,549**		$ 13,335,334
General and administrative	**4,428,209**		5,035,456
Loss from operations	**(9,222,758)**	-	(18,370,790)
Other Income (Loss):			
Reimbursement grant income	**581,039**		780,257
Other income (loss)	**268,104**		42,409
Income tax expense	**800**		800
Net loss	**(8,374,415)**	-	(17,548,924)
Exchange differences on translation	**(1,046)**		(8,340)
		#	
Net comprehensive loss	**$ (8,375,461)**		$ (17,557,264)
Weighted average number of common shares	**2,858,929**		2,096,446
Loss per common share - basic and diluted	**$ (2.93)**		$ (8.37)

Consolidated Balance Sheets

	September 30, 2023	September 30, 2022
Assets:		
Cash and cash equivalents	**$ 5,361,397**	$ 7,090,919
Other current assets	**1,075,455**	2,000,994
Non-current assets	**2,453,585**	2,483,815
Total Assets	**$ 8,890,437**	$ 11,575,728
Liabilities and shareholders' equity:		
Current liabilities	**$ 1,821,864**	$ 2,140,777
Non-current liabilities	**19,773**	43,662
Shareholders' equity	**7,048,800**	9,391,289
Total liabilities and shareholders' equity	**$ 8,890,437**	$ 11,575,728

Consolidated Statements of Cash Flows

	Years Ended	
	September 30, 2023	September 30, 2022
Cash flows from operating activities:		
Net loss	**$ (8,374,415)**	$ (17,548,924)
Adjustments for non-cash items	**1,429,928**	2,378,822
Change in working capital items	**308,004**	2,890,800
Net cash used in operating activities	**(6,636,483)**	(12,279,302)
Net cash used in investing activities	**-**	(5,656)
Net cash provided by financing activities	**4,830,111**	11,629,628
Effect of exchange rate changes on cash and cash equivalents	**76,850**	(93,010)
Net change in cash and cash equivalents	**(1,729,522)**	(748,340)
Cash and cash equivalents, beginning of year	**7,090,919**	7,839,259
Cash and cash equivalents, end of year	**$ 5,361,397**	$ 7,090,919