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 9, 2024

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 NasdaqStock 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 9, 2024, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three months ended December 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, 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 February 9, 2024.
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: February 9, 2024

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

Edesa Biotech Reports Fiscal 1st Quarter 2024 Results

TORONTO, ON / ACCESSWIRE / February 9, 2024 / 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 three months ended December 31, 2023 and provided an update on its business.

During the first fiscal quarter, the company secured funding of up to C$23 million from the Canadian government toward the development of Edesa's ARDS (Acute Respiratory Distress Syndrome) drug candidate, EB05 (paridiprubart), a portion of which is conditionally repayable. Canadian regulators also approved the company's proposal to harmonize clinical trial designs in the U.S. and Canada for the current Phase 3 trial of EB05. Edesa intends to evaluate paridiprubart in a broader ARDS population as well as file an investigational new drug application (IND) for a Phase 2 study in pulmonary fibrosis. The company is planning for a Phase 2 study of its anti-CXCL10 monoclonal antibody in moderate-to-severe nonsegmental vitiligo patients.

"We believe that the positive momentum that Edesa demonstrated at the beginning of the year puts us on a solid path to advance our respiratory and dermatology assets, including strategic discussions with potential commercialization and licensing partners," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. "Engagements with regulatory agencies have also been productive, and Edesa is on track with key regulatory submissions, including clearance of INDs for our vitiligo and fibrosis projects."

Edesa's Chief Financial Officer Stephen Lemieux reported that the company continues to benefit from the flexibility of its business model as it advances its clinical programs. "With our government funding and access to capital, we have extended our cash runway, with the option to ramp up our development activities in vitiligo and pulmonary fibrosis through potential partnerships, non-dilutive programs, direct investments in projects and other financings," he said.

Mr. Lemieux reported that Edesa is evaluating potential partnerships and funding opportunities to complete a future Phase 3 study of its dermatitis drug candidate, EB01 (1.0% daniluromer cream), following favorable Phase 2b results reported during the first fiscal quarter. "We believe that Allergic Contact Dermatitis represents a large untapped growth market for the dermatology sector. We believe our first-in-class drug candidate offers a potential new treatment paradigm for this market and we are looking forward to advancing program one step closer to commercialization."

Financial Results for the Three Months Ended December 31, 2023

Total operating expenses decreased by $0.5 million to $1.9 million for the three months ended December 31, 2023 compared to $2.4 million for the same period last year.

Research and development expenses decreased by $0.7 million to $0.7 million for the three months ended December 31, 2023 compared to $1.4 million for the same period last year primarily due to decreased external research expenses related to the company's EB01 study, which was completed during the current period, while expenses for the company's ongoing EB05 clinical study remained relatively unchanged from the prior period.

General and administrative expenses increased by $0.1 million to $1.1 million for the three months ended December 31, 2023 compared to $1.0 million for the same period last year primarily due to increased fees for professional services and noncash share-based compensation.

Total other income increased by $136,000 to $179,000 for the three months ended December 31, 2023 compared to $43,000 for the same period last year primarily due to an increase in reimbursement funding from the Canadian government's Strategic Innovation Fund.

For the quarter ended December 31, 2023, Edesa reported a net loss of $1.7 million, or $0.54 per common share, compared to a net loss of $2.3 million, or $0.89 per common share, for the quarter ended December 31, 2022.

Working Capital

At December 31, 2023, Edesa had cash and cash equivalents of $4.3 million and working capital of $3.4 million.

Calendar

Edesa management plans to participate in the American Contact Dermatitis Society Annual Meeting on March 7, 2024, the American Academy of Dermatology Annual Meeting from March 8-12, 2024 and BIO Europe Spring 2024 from March 18-20, 2024. 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 (1.0% daniluromer cream), as a topical treatment for chronic Allergic Contact Dermatitis (ACD), a common occupational skin condition. 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 plans to evaluate paridiprubart in a broader ARDS population as well as file an IND for a Phase 2 study in pulmonary fibrosis; the company's plans for a Phase 2 study of its anti-CXCL10 monoclonal antibody in moderate-to-severe nonsegmental vitiligo patients; the company's belief that the positive momentum that Edesa demonstrated at the beginning of the year puts it on a solid path to advance its respiratory and dermatology assets, including strategic discussions with potential commercialization and licensing partners; the company's belief that engagements with regulatory agencies have been productive, and the Edesa is on track with key regulatory submissions, including clearance of INDs for our vitiligo and fibrosis projects; the company belief that it has continued access to capital and government funding, it has extended its cash runway, and has the option to ramp up its development activities in vitiligo and pulmonary fibrosis through potential partnerships, non-dilutive programs, direct investments in projects and other financings; the company's ongoing plans to evaluate potential partnerships and funding opportunities to complete a future Phase 3 study of EB01; the company's belief that ACD represents a large untapped growth market for the dermatology sector; the company's belief that EB01 is a first-in-class drug candidate that offers a potential new treatment paradigm for the dermatology market, and its plans to advance its EB01 development program one step closer to commercialization; 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.

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Condensed Interim Consolidated Statements of Operations
(Unaudited)

	Three Months Ended	
	December 31, 2023	December 31, 2022
Expenses:		
Research and development	**$ 704,458**	$ 1,357,338
General and administrative	**1,152,971**	1,020,967
Loss from operations	**(1,857,429)**	(2,378,305)
Other Income (Loss):		
Reimbursement grant income	**120,834**	**-**
Other income (loss)	**58,144**	43,488
Net loss	**(1,678,451)**	(2,334,817)
Exchange differences on translation	**(572)**	(25,067)
Net comprehensive loss	**$ (1,679,023)**	$ (2,359,884)
Weighted average number of common shares	**3,128,024**	2,626,847
Loss per common share - basic and diluted	**$ (0.54)**	$ (0.89)

Condensed Interim Consolidated Balance Sheets

(Unaudited)

	December 31, 2023	September 30, 2023
Assets:		
Cash and cash equivalents	**$ 4,267,787**	$ 5,361,397
Other current assets	**1,148,472**	1,075,455
Non-current assets	**2,415,531**	2,453,585
Total Assets	**$ 7,831,790**	$ 8,890,437
Liabilities and shareholders' equity:		
Current liabilities	**$ 1,986,912**	$ 1,821,864
Non-current liabilities	**-**	19,773
Shareholders' equity	**5,844,878**	7,048,800
Total liabilities and shareholders' equity	**$ 7,831,790**	$ 8,890,437

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended	
	December 31, 2023	December 31, 2022
Cash flows from operating activities:		
Net loss	**$ (1,678,451)**	$ (2,334,817)
Adjustments for non-cash items	**229,388**	360,872
Change in working capital items	**42,535**	182,850
Net cash used in operating activities	**(1,406,528)**	(1,791,095)
Net cash used in investing activities	**-**	-
Net cash provided by financing activities	**305,742**	2,911,775
Effect of exchange rate changes on cash and cash equivalents	**7,176**	58,608
Net change in cash and cash equivalents	**(1,093,610)**	1,179,288
Cash and cash equivalents, beginning of period	**5,361,397**	7,090,919
Cash and cash equivalents, end of period	**$ 4,267,787**	$ 8,270,207