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 13, 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)	(I.R.S. Employer Identification No.)

100 Spy Court
Markham, Ontario 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:

☐ 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 each 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 13, 2024, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended September 30, 2024 (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 13, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 13, 2024

By: /s/ Stephen Lemieux
Stephen Lemieux
Chief Financial Officer

Edesa Biotech Reports Fiscal Year 2024 Results

TORONTO, Dec. 13, 2024 (GLOBE NEWSWIRE) -- 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, 2024 and provided an update on its business.

During the fiscal year, the company pivoted the in-house development of its anti-TLR4 drug candidate, EB05 (paridiprubart), to a U.S. government-funded study investigating novel threat-agnostic host-directed therapeutics in patients with Acute Respiratory Distress Syndrome (ARDS). Given this opportunity, Edesa is also amending a development and drug manufacturing project for the same asset that is supported by the Government of Canada. The company said that the goal is to maximize synergies between the two government-funded projects. For its anti-CXCL10 program, Edesa intends to manufacture EB06 and submit related data to the U.S. Food and Drug Administration as part of an investigational new drug (IND) application. The manufacturing of clinical-grade drug batches and initiation of the patient enrollment is subject to funding. Edesa anticipates topline results for this Phase 2 study could be available within as few as 12 to 18 months following regulatory clearance in the U.S. The study is currently approved in Canada.

“This year, Edesa maintained its momentum despite the headwinds in the drug development sector, and we once again validated our TLR4 technology with a third competitive government award,” said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. “I have maintained my strategic support financially and I believe that our team can continue to advance and expand our development pipeline and partnerships.”

Edesa's Chief Financial Officer Stephen Lemieux reported that financial results for the fiscal year benefited from prudent use of working capital and effective financial management, including a more than 20% decrease in operating expenses. “Following the end of the fiscal year, we strengthened our balance sheet, and with two governments now funding the advancement of our anti-TLR4 technology, we have improved our position for future financing, potential strategic arrangements as well as other opportunities to advance our pipeline.”

Financial Results for the Fiscal Year Ended September 30, 2024

Total operating expenses decreased by $2.2 million to $7.0 million for the year ended September 30, 2024 compared to $9.2 million for the prior year:

- Research and development expenses decreased by $1.9 million to $2.9 million for the year ended September 30, 2024 compared to $4.8 million for the prior year primarily due to decreased external research expenses related to the company’s completed dermatitis study and a reduction in labor costs and noncash share-based compensation, which were partially offset by an increase in expenses related to manufacturing of paridiprubart.

- General and administrative expenses decreased by $0.3 million to $4.1 million for year ended September 30, 2024 compared to $4.4 million for the prior year primarily due to a decrease in noncash share-based compensation, which was partially offset by an increase salaries and related costs.

Total other income was unchanged at $0.8 million for the years ended September 30, 2024 and September 30, 2023 as a $0.1 million increase in reimbursement funding from the Canadian government's Strategic Innovation Fund was offset by a $0.1 million decrease in interest income.

For the year ended September 30, 2024, Edesa reported a net loss of $6.2 million, or $1.93 per common share, compared to a net loss of $8.4 million, or $2.93 per common share, for the year ended September 30, 2023.

Working Capital

At September 30, 2024, Edesa had cash and cash equivalents of $1.0 million and negative working capital of $0.2 million. Subsequent to the fiscal year end, the company received $1.5 million in gross proceeds under a securities purchase agreement with an entity affiliated with Edesa’s Chief Executive Officer and Founder, and $0.6 million in net proceeds, after deducting sales agent commissions, from common shares sold under an at-the-market offering program.

Calendar

Edesa management plans to participate in one-on-one meetings during JP Morgan week, which begins on January 13, 2025, 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. Its clinical pipeline is focused on two therapeutic areas: Medical Dermatology and Respiratory. In Medical Dermatology, Edesa is developing EB06, an anti-CXCL10 monoclonal antibody candidate, as therapy for vitiligo, a common autoimmune disorder that causes skin to lose its color in patches. Its medical dermatology assets also include

EB01 (1.0% daniluromer cream), a Phase 3-ready asset developed for use as a potential therapy for moderate-to-severe chronic Allergic Contact Dermatitis (ACD), a common occupational skin condition. The company's most advanced Respiratory drug candidate is EB05 (paridiprubart), which is being evaluated in a U.S. government-funded platform study as a treatment for Acute Respiratory Distress Syndrome (ARDS), a life-threatening form of respiratory failure. The EB05 program has been the recipient of two funding awards from the Government of Canada to support the further development of this asset. In addition to EB05, Edesa is preparing an investigational new drug application (IND) in the United States for EB07 (paridiprubart) to conduct a future Phase 2 study in patients with pulmonary fibrosis. Sign up for news alerts. Connect with us on X 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: Edesa's ability to pivot the in-house development of its anti-TLR4 drug candidate; the company's plans to amend its contribution agreement with the Government of Canada; the company's goal to maximize synergies between two government-funded projects; Edesa plans to manufacture EB06 and submit related data to the FDA as part of an IND application; the company's plans to manufacture clinical-grade drug and initiate patient enrollment; the company's plans to finance clinical and manufacturing activities; the company's estimate that topline results for its Phase 2 vitiligo study could be available within as few as 12 to 18 months following regulatory clearance; the company's belief that in 2024 it maintained its momentum despite the headwinds in the drug development sector and once again validated its TLR4 technology with a third competitive government award; the company's belief that its team can continue to advance and expand its development pipeline and partnerships; the company's belief that its fiscal year financial results benefited from prudent use of working capital and effective financial management; the company's belief that with two governments funding the advancement of its anti-TLR4 technology, it has improved its position for future financing, potential strategic arrangements and alternatives as well as other opportunities to advance its pipeline; 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.

Consolidated Statements of Operations

	Years Ended	
	September 30, 2024	**September 30, 2023**
Expenses:		
Research and development	**$ 2,881,967**	$ 4,794,549
General and administrative	**4,132,777**	4,428,209
Loss from operations	**(7,014,744)**	(9,222,758)
Other Income (Loss):		
Reimbursement grant income	**698,277**	581,039
Other income (loss)	**147,222**	268,104
Income tax expense	**800**	800
Net loss	**(6,170,045)**	(8,374,415)
Exchange differences on translation	**(27,965)**	(1,046)
Net comprehensive loss	**$ (6,198,010)**	$ (8,375,461)

Weighted average number of common shares	**3,197,423**	2,858,929
Loss per common share - basic and diluted	**$ (1.93)**	$ (2.93)

Consolidated Balance Sheets

	September 30, 2024	September 30, 2023
Assets:		
Cash and cash equivalents	**$ 1,037,320**	$ 5,361,397
Other current assets	**638,302**	1,075,455
Non-current assets	**2,138,360**	2,453,585
Total Assets	**$ 3,813,982**	$ 8,890,437
Liabilities and shareholders' equity:		
Current liabilities	**$ 1,832,827**	$ 1,821,864
Non-current liabilities	**-**	19,773
Shareholders' equity	**1,981,155**	7,048,800
Total liabilities and shareholders' equity	**$ 3,813,982**	$ 8,890,437

Consolidated Statements of Cash Flows

	Years Ended	
	September 30, 2024	September 30, 2023
Cash flows from operating activities:		
Net loss	**$ (6,170,045)**	$ (8,374,415)
Adjustments for non-cash items	**708,775**	1,429,928
Change in working capital items	**571,065**	308,004
Net cash used in operating activities	**(4,890,205)**	(6,636,483)
Net cash provided by financing activities	**592,031**	4,830,111
Effect of exchange rate changes on cash and cash equivalents	**(25,903)**	76,850
Net change in cash and cash equivalents	**(4,324,077)**	(1,729,522)
Cash and cash equivalents, beginning of year	**5,361,397**	7,090,919
Cash and cash equivalents, end of year	**$ 1,037,320**	$ 5,361,397

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