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, 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 August 9, 2024, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended June 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 August 9, 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: August 9, 2024

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

EXHIBIT 99.1

Edesa Biotech Reports Fiscal 3rd Quarter 2024 Results

TORONTO, Aug. 09, 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 three and nine months ended June 30, 2024 and provided an update on its business.

During the quarter, the company's anti-TLR4 drug candidate, EB05 (paridiprubart), was selected by the U.S. Department of Health and Human Services for use in a U.S. government-funded platform study investigating novel threat-agnostic host-directed therapeutics in patients with Acute Respiratory Distress Syndrome (ARDS). Edesa is providing drug product for the trial as well as technical support at its own expense. In addition, the company reported today that it plans to continue utilizing its internal resources to advance its vitiligo and pulmonary fibrosis programs, including preparations to file an Investigational New Drug application with the U.S. Food and Drug Administration for a Phase 2 study of its anti-CXCL10 technology in moderate-to-severe vitiligo patients.

"We believe the fully funded government ARDS clinical study has the potential to open significant new value-creation opportunities for Edesa," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. "This commitment to our TLR4 technology positions us to increase investment and operational focus on our other programs."

Edesa's Chief Financial Officer Stephen Lemieux reported that financial results for the three and nine months ended June 30, 2024 were in line with management's expectations. "Our fiscal quarter and nine-month results demonstrate our commitment to prudent use of working capital and effective financial management, while we strategically advance our pipeline. We believe this steady performance enhances our position for future financing and other opportunities to support the advancement of our clinical programs," he said.

Financial Results for the Three Months Ended June 30, 2024

Total operating expenses decreased by $0.2 million to $1.9 million for the three months ended June 30, 2024 compared to $2.1 million for the same period last year.

- Research and development expenses decreased by $0.1 million to $0.9 million for the three months ended June 30, 2024 compared to $1.0 million for the same period last year primarily due to decreased external research expenses related to the company's ongoing Phase 3 ARDS study and its completed dermatitis study, which were partially offset by an increase in expenses related to manufacturing of the company's investigational drug, paridiprubart.

- General and administrative expenses were unchanged at $1.0 million for the three months ended June 30, 2024 and June 30, 2023.

Total other income increased by $185,000 to $264,000 for the three months ended June 30, 2024 compared to $79,000 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 June 30, 2024, Edesa reported a net loss of $1.7 million, or $0.52 per common share, compared to a net loss of $2.0 million, or $0.68 per common share, for the quarter ended June 30, 2023.

Financial Results for the Nine Months Ended June 30, 2024

Total operating expenses decreased by $0.9 million to $6.0 million for the nine months ended June 30, 2024 compared to $6.9 million for the same period last year:

- Research and development expenses decreased by $1.0 million to $2.8 million for the nine months ended June 30, 2024 compared to $3.8 million for the same period last year primarily due to decreased external research expenses related to the company's completed dermatitis study and a reduction in noncash share-based compensation and labor costs, which were partially offset by an increase in expenses for the company's ongoing ARDS study and expenses related to manufacturing of paridiprubart.

- General and administrative expenses increased by $0.2 million to $3.2 million for the nine months ended June 30, 2024 compared to $3.0 million for the same period last year primarily due to increased fees for professional services, which were partially offset by a decrease in non-cash share-based compensation.

Total other income increased by $0.6 million to $0.8 million for the nine months ended June 30, 2024 compared to $0.2 million for the same period last year primarily due to an increase in reimbursement funding from the Canadian government's Strategic Innovation Fund.

For the nine months ended June 30, 2024, Edesa reported a net loss of $5.2 million, or $1.64 per common share, compared to a net loss of $6.7 million, or $2.37 per common share, for the nine months ended June 30, 2023.

Working Capital

At June 30, 2024, Edesa had cash and cash equivalents of $2.0 million and working capital of $0.7 million. Subsequent to the quarter end, the company received $0.3 million in reimbursement funding from the Canadian government's Strategic Innovation Fund. To date, the company has not drawn any funds under a $10.0 million revolving credit agreement with the company's founder and chief executive officer.

Calendar

Edesa management plans to participate in the Canaccord 44th Annual Growth Conference being held August 13-15, 2024 in Boston, Mass; the H.C. Wainwright 26th Annual Global Investment Conference being held September 9-11, 2024 in New York, NY and the Dermatology Drug Development Summit being held November 12-14, 2024 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. EB05 has also been included in a U.S. government funded platform study of host directed therapeutics. In addition, the company has received Canadian 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: Edesa plans to provide drug product and technical support for a U.S. funded ARDS study; the company's plans to continue using internal resources to advance its vitiligo and pulmonary fibrosis programs, including preparations to file an Investigational New Drug application with the U.S. Food and Drug Administration for a Phase 2 study of its anti-CXCL10 technology in moderate-to-severe vitiligo patients; the company's belief that the fully funded government ARDS study opens significant new value-creation opportunities for Edesa,; the company's belief that it is now in a position to redeploy its resources for its anti-inflammatory TLR4 technology and other programs; the company's plans to potentially place increased operational focus on vitiligo and pulmonary fibrosis areas and its belief that is significant unmet medical need and increasing industry interest in these indications; the company's belief that its third fiscal quarter and nine month results demonstrate its commitment to prudent use of working capital and effective financial management; the company's belief that its steady performance enhances its position for future financing and other opportunities to support the advancement of our clinical programs; the company's plans to strategically 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.

Contact:
Gary Koppenjan
Edesa Biotech, Inc.
(289) 800-9600
investors@edesabiotech.com

Condensed Interim Consolidated Statements of Operations
(Unaudited)

	Three Months Ended		Nine Months Ended	
	June 30, 2024	**June 30, 2023**	**June 30, 2024**	**June 30, 2023**
Expenses:				
Research and development	**897,305**	1,025,622	**$ 2,778,100**	$ 3,841,150
General and administrative	**1,035,140**	1,038,587	**3,232,248**	3,011,945
Loss from operations	**(1,932,445)**	(2,064,209)	**(6,010,348)**	(6,853,095)
Other Income (Loss):				
Reimbursement grant income	**236,226**	-	**661,062**	-
Other income (loss)	**28,007**	79,303	**142,092**	199,823
Income tax expense	**-**	-	**800**	800
Net loss	**(1,668,212)**	(1,984,906)	**(5,207,994)**	(6,654,072)
Exchange differences on translation	**1,612**	39,839	**(10,143)**	23,415
Net comprehensive loss	**$ (1,666,600)**	$ (1,945,067)	**$ (5,218,137)**	$ (6,630,657)
Weighted average number of common shares	**3,221,806**	2,930,681	**3,180,647**	2,802,793
Loss per common share - basic and diluted	**$ (0.52)**	$ (0.68)	**$ (1.64)**	$ (2.37)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	June 30, 2024	**September 30, 2023**
Assets:		
Cash and cash equivalents	**$ 2,040,884**	$ 5,361,397
Other current assets	**1,005,750**	1,075,455
Non-current assets	**2,181,088**	2,453,585
Total Assets	**$ 5,227,722**	$ 8,890,437
Liabilities and shareholders' equity:		
Current liabilities	**$ 2,360,627**	$ 1,821,864
Non-current liabilities	**-**	19,773
Shareholders' equity	**2,867,095**	7,048,800
Total liabilities and shareholders' equity	**$ 5,227,722**	$ 8,890,437

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended	
	June 30, 2024	**June 30, 2023**
Cash flows from operating activities:		
Net loss	**$ (5,207,994)**	$ (6,654,072)
Adjustments for non-cash items	**570,636**	866,881

Change in working capital items	**714,192**	618,730
Net cash used in operating activities	**(3,923,166)**	(5,168,461)
Net cash provided by financing activities	**623,466**	4,417,646
Effect of exchange rate changes on cash and cash equivalents	**(20,813)**	117,066
Net change in cash and cash equivalents	**(3,320,513)**	(633,749)
Cash and cash equivalents, beginning of year	**5,361,397**	7,090,919
Cash and cash equivalents, end of year	**$ 2,040,884**	$ 6,457,170