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 16, 2022

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 December 16, 2022, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended September 30, 2022 (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 (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	**Description**

No.	
99.1	Press release issued by Edesa Biotech, Inc. dated December 16, 2022.

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 16, 2022

By: */s/ Kathi Niffenegger*
Name: Kathi Niffenegger
Title: Chief Financial Officer

Edesa Biotech Reports Fiscal Year 2022 Results

TORONTO, ON / ACCESSWIRE / December 16, 2022 / Edesa Biotech, Inc. (Nasdaq:EDSA), a clinical-stage biopharmaceutical company focused on inflammatory and immune-related diseases, today reported financial results for the fiscal year ended September 30, 2022 and provided an update on its business.

During the fiscal year, Edesa reported positive final results from the Phase 2 part of a Phase 2/3 study of its monoclonal antibody in Covid-19 patients with Acute Respiratory Distress Syndrome (ARDS). Among the results, critically ill patients given EB05 plus standard of care treatment had an 84% reduction in the risk of dying when compared to placebo plus standard of care at 28 days. The company has submitted a Phase 2 Clinical Study Report to the U.S. Food and Drug Administration as part of the review of Edesa's Phase 3 clinical protocol design and statistical plan. In the fourth quarter, the company also completed enrollment in its Phase 2b dermatology study, and expects to report topline data in the next four weeks.

"We believe the significant strides we made in 2022 have positioned us for continued and accelerated progress," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. "With two late-stage studies, a growing development pipeline, large addressable markets and interest from potential partners, we are excited about the opportunities we are bringing into the new year."

Edesa's Chief Financial Officer Kathi Niffenegger reported that operational expenses for fiscal 2022 decreased by more than 20% over the previous year, benefitting from the completion of clinical activities related to the company's Phase 2b dermatitis study and the flexibility of Edesa's business model to manage working capital. "Our full fiscal year results reflect the trend demonstrated in the past three quarters of reduced operating expenses and prudent management of working capital," she said.

Edesa reported that near-term operational objectives include, among others, completing the FDA review of the company's Phase 3 protocol design for EB05; fully enrolling the Phase 3 study of EB05; reporting Phase 2b results for EB01; completing a Phase 2 investigational new drug application in the U.S. for systemic sclerosis; and submitting a clinical trial application for vitiligo in Canada.

Financial Results for the Fiscal Year Ended September 30, 2022

Total operating expenses decreased by $5.31 million to $18.37 million for the year ended September 30, 2022 compared to $23.68 million for the prior year:

- Research and development expenses decreased by $4.61 million to $13.34 million for the year ended September 30, 2022 compared to $17.95 million for the prior year primarily due to decreased milestone payments, external research expenses related to the company's clinical studies and investigational drug product manufacturing expenses, which were partially offset by increased personnel expenses.

- General and administrative expenses decreased by $0.69 million to $5.04 million for the year ended September 30, 2022 compared to $5.73 million for the prior year primarily due to a decrease in noncash share-based compensation.

Total other income decreased by $9.52 million to $0.82 million for year ended September 30, 2022 compared to $10.34 million for the prior year primarily due to a decrease in grant income associated with the completion of clinical study activities under Edesa's federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the fiscal year ended September 30, 2022, Edesa reported a net loss of $17.55 million, or $1.05 per common share, compared to a net loss of $13.34 million, or $1.10 per common share, for the fiscal year ended September 30, 2021.

Working Capital

At September 30, 2022, Edesa had cash and cash equivalents of $7.09 million and working capital of $6.95 million. Subsequent to the end of the fiscal year, the company received gross proceeds of approximately $3.0 million from a private placement of common shares and warrants.

Calendar

Edesa management plans to participate in the 2023 Dermatology Summit on January 8, 2023 and in one-on-one meetings during JP Morgan week on January 9-12, 2023, 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 focused on developing innovative treatments for inflammatory and immune-related diseases with clear unmet medical needs. The company's two lead product candidates, EB05 and EB01, are in late-stage clinical studies. Sign up for news alerts. Connect with us on Twitter and LinkedIn.

ARDS Clinical Program

EB05, a novel monoclonal antibody targeting Toll-like Receptor 4 (TLR4) as a critical care therapy for Acute Respiratory Distress Syndrome (ARDS) - Phase 3: Enrolling

EB05 inhibits signaling through TLR4 - a key pattern recognition receptor involved in the activation of the innate immune system. Excessive TLR4 pathway activation can be pathological and has been linked to various inflammatory conditions, including viral-mediated acute lung injury. EB05 has extensive preclinical and clinical experience, including evaluations in more than 600 hospitalized Covid-19 subjects. In an international Phase 2 study, a single dose of EB05 demonstrated compelling preliminary evidence of the drug's ability to reduce mortality in target patient populations.

Contact Dermatitis Clinical Program

EB01, a non-steroidal anti-inflammatory compound that inhibits secretory phospholipase 2 (sPLA2) as a treatment for the symptoms of chronic allergic contact dermatitis (ACD) - Phase 2b: Fully Enrolled.

EB01 exerts its anti-inflammatory activity through the inhibition of sPLA2 pro-inflammatory enzymes. The sPLA2 enzyme family plays a key role in initiating inflammation associated with numerous diseases. By targeting sPLA2 with enzyme inhibitors - at the inception of inflammation rather than after inflammation has occurred - Edesa believes that drugs based on this technology could provide a powerful anti-inflammatory therapeutic strategy for treating diverse inflammatory/allergic conditions. EB01 has demonstrated efficacy for the treatment of ACD in two previous clinical trials.

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 expectation to report preliminary topline data from its Phase 2b study of EB01 by mid-January 2023; the company's belief that the significant accomplishments it made in 2022 have positioned it for continued and accelerated progress; the company's belief that its product candidates have large addressable markets, and will draw continued interest from potential partners; the company's plans to complete the FDA review process of the its Phase 3 protocol design for EB05; the company's plans to fully enroll the Phase 3 study of EB05; the company's plans to complete a Phase 2 investigational new drug application in the U.S. for systemic sclerosis; the company's plans to submit a clinical trial application for vitiligo in Canada; 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
Gary Koppenjan
Edesa Biotech, Inc.
(805) 488-2800 ext. 150
investors@edesabiotech.com

Condensed Consolidated Statements of Operations

	Years Ended	
	September 30, 2022	**September 30, 2021**
Expenses:		
Research and development	**$ 13,335,334**	$ 17,947,072
General and administrative	**5,035,456**	5,734,260
	18,370,790	23,681,332
Loss from operations	**(18,370,790)**	(23,681,332)
Other Income (Loss):		
Reimbursement grant income	**780,257**	10,340,839
Other income (loss)	**42,409**	(1,857)
Loss before income taxes	**(17,548,124)**	(13,342,350)

Income tax expense	**800**	800
Net loss	**(17,548,924)**	(13,343,150)
Exchange differences on translation	**(8,340)**	81,942
Net comprehensive loss	**$ (17,557,264)**	$ (13,261,208)
Weighted average number of common shares	**16,662,014**	12,077,822
Loss per common share - basic and diluted	**$ (1.05)**	$ (1.10)

Condensed Consolidated Balance Sheets

	September 30, 2022	September 30, 2021
Assets:		
Cash and cash equivalents	**$ 7,090,919**	$ 7,839,259
Other current assets	**2,000,994**	4,251,472
Non-current asset	**2,483,815**	2,493,924
Total Assets	**$ 11,575,728**	$ 14,584,655
Liabilities, shareholders' equity and temporary equity:		
Current liabilities	**$ 2,140,777**	$ 1,458,650
Non-current liabilities	**43,662**	67,714
Shareholders' equity	**9,391,289**	13,058,291
Total liabilities, shareholders' equity and temporary equity	**$ 11,575,728**	$ 14,584,655

Condensed Consolidated Statements of Cash Flows

	Years Ended	
	September 30, 2022	September 30, 2021
Cash flows from operating activities:		
Net loss	**$ (17,548,924)**	$ (13,343,150)
Adjustments for non-cash items	**2,378,822**	3,314,257
Change in working capital items	**2,890,800**	(3,636,039)
Net cash used in operating activities	**(12,279,302)**	(13,664,932)
Net cash provided by (used in) investing activities	**(5,656)**	(6,146)
Net cash provided by financing activities	**11,629,628**	14,174,741
Effect of exchange rate changes on cash and cash equivalents	**(93,010)**	121,901
Increase in cash and cash equivalents during the period	**(748,340)**	625,564
Cash and cash equivalents, beginning of period	**7,839,259**	7,213,695
Cash and cash equivalents, end of period	**$ 7,090,919**	$ 7,839,259