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 28, 2021

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 28, 2021, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended September 30, 2021 (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 No.	Description
99.1	Press release issued by Edesa Biotech, Inc. dated December 28, 2021.

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 28, 2021

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

Edesa Biotech Reports Fiscal Year 2021 Results

TORONTO, ON / ACCESSWIRE / December 28, 2021/ 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, 2021 and provided an update on its business.

During the fiscal year, Edesa reported favorable interim results for both of the company's leading drug candidates, EB05 and EB01. EB05 is being developed as a potential treatment for ARDS, a life-threatening form of respiratory failure that accounts for approximately 10% of all ICU admissions (pre-pandemic) and is the leading cause of death among COVID-19 patients. In September 2021, the Phase 2 part of an international Phase 2/3 study of EB05 was preemptively unblinded due to an important efficacy signal, and an independent monitoring board determined the study had met its objective. Earlier this year, the company also achieved a key interim milestone in a Phase 2b study evaluating another Edesa anti-inflammatory drug, designated EB01, for chronic allergic contact dermatitis, a common, potentially debilitating disease. In December 2021, the company reported that more than 75% of the subjects in the primary cohort of the Phase 2b study of EB01 have been randomized.

“The past twelve months have been transformational for Edesa as we validated our technologies in the clinic, received high-level recognition from the federal government, established an international acute-care trialing network, and broadened our strategic outreach,” said Par Nijhawan, MD, Chief Executive Officer of Edesa. “In the coming quarters we look forward to building on our momentum and presenting topline results for our EB05 and EB01 product candidates. Success in either of these two later-stage programs – each of which represents a separate anti-inflammatory technology – could provide a game-changing opportunity for the company.”

Edesa’s Chief Financial Officer Kathi Niffenegger said that the company’s year-end results reflect the company’s increased clinical activities, which included the launch and completion of the Phase 2 part of the company’s EB05 study. She noted that these research activities were funded in part by a federal innovation grant from the Canadian government. For the year ended September 30, 2021, Edesa recorded $10.34 million in grant income.

"Our fiscal year results demonstrate the positive impact of the government grant funding and the targeted approach we are taking to efficiently reach clinical milestones," Ms. Niffenegger said.

Financial Results for the Fiscal Year Ended September 30, 2021

There were no revenues for the year ended September 30, 2021 compared to $0.33 million for the prior year, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

Total operating expenses increased by $16.95 million to $23.68 million for the year ended September 30, 2021 compared to $6.73 million for the prior year:

- Research and development expenses increased by $14.62 million to $17.95 million for the year ended September 30, 2021 compared to $3.33 million for the prior year primarily due to milestone payments related to advancement of the company’s EB05 clinical program, increased external research expenses related to accelerated activity in ongoing clinical studies, increased investigational drug product expenses and an increase in noncash share-based compensation. Higher salary and related personnel expenses and patent fees also contributed to the increase.

- General and administrative expenses increased by $2.35 million to $5.73 million for the year ended September 30, 2021 compared to $3.38 million for the prior year primarily as a result of higher salary and related personnel expenses, noncash share-based compensation and increased headcount. Higher legal and other professional services also contributed to the increase.

Total other income increased by $10.30 million to $10.34 million for the year ended September 30, 2021 compared to $0.04 million for the prior year primarily due to increased grant income under the company’s federal reimbursement grant with the Canadian government’s Strategic Innovation Fund.

For the fiscal year ended September 30, 2021, Edesa reported a net loss of $13.34 million, or $1.10 per common share, compared to a net loss of $6.36 million, or $0.74 per common share, for the year ended September 30, 2020.

Working Capital

At September 30, 2021, Edesa had working capital of $10.63 million. Cash and cash equivalents totaled $7.84 million. Subsequent to the end of the fiscal year, the company received gross proceeds of approximately $1.29 million from the issuance of common shares under an equity distribution agreement with RBC Capital Markets.

Calendar

Edesa management plans to participate in the11th Annual LifeSci Partners Corporate Access Event scheduled for January 5-7, 2022, as well as the H.C. Wainwright BioConnect Conference scheduled for January 10-13, 2022. Investors interested in meetings with management can schedule one-on-one meetings by contacting the conference organizers or 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 later stage clinical studies. EB05 is a monoclonal antibody therapy that we are developing as a treatment for Acute Respiratory Distress Syndrome (ARDS). ARDS is a life-threatening form of respiratory failure, and the leading cause of death among COVID-19 patients. Edesa is also developing an sPLA2 inhibitor, designated as EB01, as a topical treatment for chronic allergic contact dermatitis (ACD), a common, potentially debilitating condition and occupational illness. 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. The company is based in Markham, Ontario, Canada, with a U.S. subsidiary located in Southern California. Sign up for news alerts. Connect with us on 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 build on its past performance momentum and present topline results from our EB05 and EB01 product candidates in the coming quarters; the company's belief that success in either of its two later-stage clinical development programs could provide a game-changing opportunity for the company; the potential efficacy of its drug candidates; 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.

Contacts
Gary Koppenjan
Edesa Biotech, Inc.
(805) 488-2800 ext. 150
investors@edesabiotech.com

Consolidated Statements of Operations

	Years Ended	
	September 30, 2021	**September 30, 2020**
Total Revenues	**$ -**	$ 328,801
Expenses:		
Cost of sales	**-**	17,601
Research and development	**17,947,072**	3,329,451
General and administrative	**5,734,260**	3,382,591
	23,681,332	6,729,643
Loss from operations	**(23,681,332)**	(6,400,842)
Other Income (Loss):		
Reimbursement grant income	**10,340,839**	-
Other income (loss)	**(1,857)**	37,412
Loss before income taxes	**(13,342,350)**	(6,363,430)
Income tax expense	**800**	800
Net loss	**(13,343,150)**	(6,364,230)
Exchange differences on translation	**81,942**	54,870
Net comprehensive loss	**$ (13,261,208)**	$ (6,309,360)

Weighted average number of common shares	**12,077,822**	8,607,161
Loss per common share - basic and diluted	**$ (1.10)**	$ (0.74)

Consolidated Balance Sheets

	September 30, 2021	**September 30, 2020**
Assets:		
Cash and cash equivalents	**$ 7,839,259**	$ 7,213,695
Other current assets	**4,251,472**	890,323
Non-current asset	**2,493,924**	2,658,357
Total Assets	**$ 14,584,655**	$ 10,762,375
Liabilities, shareholders' equity and temporary equity:		
Current liabilities	**$ 1,458,650**	$ 1,529,857
Non-current liabilities	**67,714**	124,388
Temporary equity	**-**	2,476,955
Shareholders' equity	**13,058,291**	6,631,175
Total liabilities, shareholders' equity and temporary equity	**$ 14,584,655**	$ 10,762,375

Consolidated Statements of Cash Flows

	Years Ended	
	September 30, 2021	**September 30, 2020**
Cash flows from operating activities:		
Net loss	**$ (13,343,150)**	$ (6,364,230)
Adjustments for non-cash items	**3,314,257**	655,922
Change in working capital items	**(3,636,038)**	721,968
Net cash used in operating activities	**(13,664,931)**	(4,986,340)
Net cash provided by (used in) investing activities	**(6,146)**	19,073
Net cash provided by financing activities	**14,174,740**	7,092,749
Effect of exchange rate changes on cash and cash equivalents	**121,901**	57,630
Increase in cash and cash equivalents during the year	**625,564**	2,183,112
Cash and cash equivalents, beginning of year	**7,213,695**	5,030,583
Cash and cash equivalents, end of period	**$ 7,839,259**	$ 7,213,695