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 7, 2020

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 7, 2020, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended September 30, 2020 (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 7, 2020.

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 7, 2020

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

Exhibit 99.1

Edesa Biotech Reports Fiscal Year 2020 Results

TORONTO, ON / ACCESSWIRE / December 7, 2020 / Edesa Biotech, Inc. (Nasdaq: EDSA), a clinical-stage biopharmaceutical company, today reported financial results for the fiscal year ended September 30, 2020 and provided an update on its business.

During the fiscal year, Edesa added two Phase 2-ready biologics to its development pipeline, with a focus on COVID-19 and other strategic indications. Last month, the company initiated a Phase 2/Phase 3 study of the most advanced one of these acquired monoclonal antibodies in hospitalized COVID-19 patients, and is currently enrolling subjects in the U.S. and Canada. In response to the pandemic, Edesa also took actions to facilitate enrollment for an ongoing Phase 2b clinical study of its EB01 drug candidate in chronic allergic contact dermatitis patients, and recently announced that that the project had reached an enrollment milestone.

“While 2020 brought unexpected challenges, it also brought opportunities for Edesa to demonstrate the flexibility and breadth of our clinical development strategy. In a matter of months, we achieved new regulatory approvals in two jurisdictions and launched a Phase 2/3 study of a potential best-in-class anti-TLR4 antibody treatment for Acute Respiratory Distress Syndrome – the leading cause of death in COVID-19 patients,” said Dr. Par Nijhawan, Chief Executive Officer of Edesa. "Our team continues to operate at a high level and we are looking forward to building on our momentum, achieving our near-term milestones and, ultimately, building value for shareholders.”

Chief Financial Officer Kathi Niffenegger reported that Edesa’s year-end results reflect the company’s increased clinical activities and growth-related expenditures, which included COVID-19 study preparations, fill-finish expenses for its EB05 drug product, increased staffing and enrollment-based expenses for the company’s ongoing dermatitis study. “Our fiscal year results demonstrate the efficiency of our business model and the disciplined approach we are taking to deploying our working capital to studies with near-term inflection points,” she said.

Ms. Niffenegger reported that cash and cash equivalents totaled approximately $7.2 million at September 30, 2020. In addition, she noted that subsequent to end of the fiscal year, Edesa received cash proceeds of approximately $2.0 million as a result of warrant exercises and issuances of common shares under the company’s at-the-market equity distribution program.

Financial Results for the Fiscal Year Ended September 30, 2020*

Total revenues for fiscal year 2020 were $0.33 million compared to $0.41 million for the nine-month period ended September 30, 2019, reflecting a reduction in sales of product inventory obtained in the June 2019 reverse acquisition. The company expects such product sales to continue to decline as a result of the discontinuation of legacy operations.

Total operating expenses increased by $3.49 million to $6.73 million for fiscal year 2020 compared to $3.24 million for the nine-month period ended September 30, 2019:

- Cost of sales was $0.02 million for fiscal year 2020 compared to $0.10 million for the nine-month period ended September 30, 2019, reflecting a reduction in sales of product inventory obtained in the reverse acquisition.

- Research and development expenses were $3.33 million for the year ended September 30, 2020, reflecting increased external research expenses related to the clinical study of the company's EB01 drug candidate and increased activities and preparations related to the company's Phase 2/3 clinical study of EB05 as a potential treatment for hospitalized COVID-19 patients, as well as increased salary and related personnel expenses. Research and development expenses were $1.10 million for the nine-month period ended September 30, 2019.

- General and administrative expenses were $3.38 million for the year ended September 30, 2020, reflecting increased salary and related personnel expenses, and increased public company expenses. General and administrative expenses were $2.05 million for the nine-month period ended September 30, 2019.

For the fiscal year ended September 30, 2020, Edesa reported a net loss of $6.36 million, or $0.74 per common share, compared to a net loss of $2.78 million, or $0.55 per common share, for the nine-month period ended September 30, 2019.

** As a result of the acquisition accounting for the business combination completed on June 7, 2019, and the subsequent change in year end of the company's subsidiary Edesa Biotech Research, Inc., the comparative year-end data represent the twelve month period ended September 30, 2020 and the nine-months ended September 30, 2019, which should be taken into account when reviewing comparative results. Financial results for any periods ended prior to June 7, 2019 reflect the financials of the company's subsidiary Edesa Biotech Research, Inc. on a standalone basis.*

Working Capital

At September 30, 2020, Edesa had working capital of $6.57 million. Cash and cash equivalents totaled $7.21 million. From October 1 to December 2, 2020, the exercise of common share purchase warrants resulted in cash proceeds to the company of approximately $1.0 million. During this same period, the company also received cash proceeds of approximately $1.0 million from the issuance of common shares under an equity distribution agreement with RBC Capital Markets, LLC.

Calendar

From January 11-14, 2021, Edesa is scheduled to participate in the H.C. Wainwright Bioconnect Conference. Investors and biopharma executives interested in meetings with management can schedule one-on-one teleconference and video meetings through the conference website or by contacting Edesa 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) in COVID-19 patients. 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. EB01 employs a novel, non-steroidal mechanism of action and in two clinical studies has demonstrated statistically significant improvement of multiple symptoms in ACD patients. The company is based in Markham, Ontario, Canada, with a U.S. subsidiary located in Southern California. Sign up for news alerts.

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: upcoming milestones in the company's clinical studies and the expectation that legacy product sales will continue to decline. 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

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Consolidated Statements of Operations

	Year Ended September 30, 2020	Nine-MonthPeriod Ended September 30, 2019
Total Revenues	**$ 328,801**	$ 410,870
Expenses:		
Cost of sales	**17,601**	101,286
Research and development	**3,329,451**	1,096,426
General and administrative	**3,382,591**	2,045,296
	6,729,643	3,243,008
Loss from operations	**(6,400,842)**	(2,832,138)
Other income	**37,412**	55,404
Income tax expense	**800**	-
Net loss	**(6,364,230)**	(2,776,734)
Exchange differences on translation	**54,870**	87,899
Net comprehensive loss	**$ (6,309,360)**	$ (2,688,835)
Weighted average number of common shares outstanding	8,607,161	5,036,331
Loss per common share - basic and diluted	**$ (0.74)**	$ (0.55)

Consolidated Balance Sheets

	September 30, 2020	September 30, 2019
Assets:		
Cash and cash equivalents	**$ 7,213,695**	$ 5,030,583
Other current assets	**890,323**	614,123
Intangible assets, net	**2,483,536**	-
Operating lease right-of-use assets	**160,006**	-
Property and equipment, net	**14,815**	73,058
Total Assets	**$ 10,762,375**	$ 5,717,764
Liabilities, shareholders' equity and temporary equity:		
Current liabilities	**$ 1,529,857**	$ 461,634
Noncurrent liabilities	**124,388**	-
Temporary equity	**2,476,955**	-
Shareholders' equity	**6,631,175**	5,256,130
Total liabilities, shareholders' equity and temporary equity	**$ 10,762,375**	$ 5,717,764

Consolidated Statements of Cash Flows

	Year Ended September 30, 2020	Nine-MonthPeriod Ended September 30, 2019
Cash flows from operating activities:		
Net loss	**$ (6,364,230)**	$ (2,776,734)
Adjustments for non-cash items	**655,922**	39,853
Change in working capital items	**721,968**	(2,108,906)
Net cash used in operating activities	**(4,986,340)**	(4,845,787)
Net cash provided by investing activities	**19,073**	6,417,968
Net cash provided by financing activities	**7,092,749**	-
Effect of exchange rate changes on cash and cash equivalents	**57,630**	91,304
Net change in cash and cash equivalents	**2,183,112**	1,663,485
Cash and cash equivalents, beginning of period	**5,030,583**	3,367,098
Cash and cash equivalents, end of period	**$ 7,213,695**	$ 5,030,583