

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): May 13, 2022

Edesa Biotech, Inc.

(Exact Name of Registrant as Specified in its Charter)

British Columbia, Canada

(State or Other Jurisdiction
of Incorporation)

001-37619

(Commission
File Number)

N/A

(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

Common Shares

Trading Symbol(s)

EDSA

Name of exchange on which registered

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 May 13, 2022, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three and six months ended March 31, 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 No. **Description**

[99.1](#) [Press release issued by Edesa Biotech, Inc. dated May 13, 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: May 13, 2022

By: /s/ Kathi Niffenegger

Name: Kathi Niffenegger

Title: Chief Financial Officer



Edesa Biotech Reports Fiscal 2nd Quarter 2022 Results

TORONTO, ON / ACCESSWIRE / May 13, 2022 / Edesa Biotech, Inc. (Nasdaq:EDSA), a clinical-stage biopharmaceutical company focused on inflammatory and immune-related diseases, today reported financial results for the three and six months ended March 31, 2022 and provided an update on its business.

For its critical care drug candidate, Edesa reported during the quarter that more than 25% of the subjects have been randomized for the Phase 3 part of the company's clinical study in critically ill Covid-19 patients with Acute Respiratory Distress Syndrome (ARDS). The final Phase 3 study protocol has been approved in Canada, Poland and Colombia. Discussions with U.S. regulators on the final Phase 3 design are ongoing. Recruitment for the Phase 3 study has followed Covid-19-related ICU admissions and seasonality, and the company is positioning additional investigational centers to be available for current and future waves of hospitalizations.

For its dermatology drug candidate, the company recently announced that its Phase 2b clinical study in chronic Allergic Contact Dermatitis (ACD) reached an enrollment milestone of 75% subjects randomized, and that recruitment was proceeding at a more accelerated pace than planned. Edesa anticipates that enrollment will be completed by the fourth calendar quarter of 2022, with initial topline data available as early as the first calendar quarter of 2023.

"This is an exciting time for Edesa as we prepare for the most meaningful milestones since our inception," said Edesa Chief Executive Officer Par Nijhawan, MD. "Edesa management remains focused on fundamental value creation through the advancement of these later stage clinical assets. Successful results for one of these programs could significantly change the growth trajectory of the company and validate the broad potential utility of our underlying technologies." He added that the company continues to explore strategic business development opportunities to further bolster the growth opportunities of Edesa's clinical assets.

Edesa's Chief Financial Officer Kathi Niffenegger reported that during first half of fiscal 2022 Edesa raised net cash proceeds of approximately \$11.6 million from equity sales under an at-the-market offering program and a direct investment with a healthcare-focused institutional fund.

"With a stronger balance sheet, we are well positioned to maintain our operational momentum and advance our two later-stage clinical programs toward completion," said Ms. Niffenegger. She added that for the three and six-month periods, operational expenditures were in line with management's expectations and benefitted from the flexibility of the company's business model to manage working capital and prioritize core development and commercialization activities.

Financial Results for the Three Months Ended March 31, 2022

Total operating expenses decreased by \$4.93 million to \$4.58 million for the three months ended March 31, 2022 compared to \$9.51 million for the same period last year:

- Research and development expenses decreased by \$4.94 million to \$3.04 million for the three months ended March 31, 2022 compared to \$7.98 million for the same period last year primarily due to decreased milestone and bulk drug substance payments, lower license fees and decreased external research expenses, which were partially offset by higher manufacturing expenses, and increased salary and related personnel expenses.
- General and administrative expenses remained relatively unchanged at \$1.53 million for the three months ended March 31, 2022 compared to \$1.54 million for the same period last year.

Total other income (loss) decreased by \$7.24 million to an overall gain of \$0.01 million for the three months ended March 31, 2022 compared to an overall gain of \$7.25 million for the same period last year primarily due to a decrease in grant income associated with the completion of clinical study activities under the company's federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the quarter ended March 31, 2022, Edesa reported a net loss of \$4.57 million, or \$0.33 per common share, compared to a net loss of \$2.26 million, or \$0.19 per common share, for the three months ended March 31, 2021.

Financial Results for the Six Months Ended March 31, 2022

Total operating expenses decreased by \$2.38 million to \$9.74 million for the six months ended March 31, 2022 compared to \$12.12 million for the same period last year:

- Research and development expenses decreased by \$2.36 million to \$6.99 million for the six months ended March 31, 2022 compared to \$9.35 million for the same period last year primarily due to decreased milestone and bulk drug substance payments and lower license fees, which were partially offset by higher external research expenses, higher manufacturing expenses and increased salary and related personnel expenses.
- General and administrative expenses decreased by \$0.03 million to \$2.74 million for the six months ended March 31, 2022 compared to \$2.77 million for the same period last year primarily due to lower salary and related personnel expenses, which were partially offset by increased legal and other professional service fees.

Total other income (loss) decreased by \$6.44 million to an overall gain of \$0.79 million for the six months ended March 31, 2022 compared to an overall gain of \$7.23 million for the same period last 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 six months ended March 31, 2022, Edesa reported a net loss of \$8.95 million, or \$0.66 per common share, compared to a net loss of \$4.90 million, or \$0.45 per common share, for the six months ended March 31, 2021

Working Capital

At March 31, 2022, Edesa had working capital of \$14.66 million. Cash and cash equivalents totaled \$15.89 million.

Calendar

Edesa management plans to participate in the H.C. Wainwright Global Investment Conference scheduled for May 23-25, 2022 and the BIO International Conference scheduled for June 13-16, 2022. Edesa will also join panel discussions at the 2nd ARDS Drug Development Summit scheduled for July 13-15, 2022. Members of the investment or biopharma community who are interested in meeting with management can schedule one-on-one calls or meetings through the conference websites 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 later stage clinical studies. EB05 is a monoclonal antibody therapy that Edesa is 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 belief that enrollment in the Phase 2b study of EB01 can be completed by the fourth calendar quarter of 2022, with initial topline data available as early as the first calendar quarter of 2023; the company's belief that recruitment for its Phase 3 study will continue to follow Covid-19-related ICU admissions and seasonality, and the company will be successful in positioning additional investigational centers to be available for current and future waves of hospitalizations; the company's belief that it is nearing the most meaningful milestones since its inception; management's efforts to remain focused on fundamental value creation; the company's belief that successful results for even one of its clinical programs could significantly change the growth trajectory of the company and validate the broad potential utility of its underlying technologies; the company plans to explore strategic business development opportunities to further bolster the growth opportunities; the company's belief that it is well positioned financially to maintain its operational momentum and advance its two later-stage clinical programs toward completion; 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

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	<u>March 31, 2022</u>	<u>March 31, 2021</u>	<u>March 31, 2022</u>	<u>March 31, 2021</u>
Expenses:				
Research and development	3,042,815	7,975,304	6,993,861	9,354,958
General and administrative	1,532,416	1,535,127	2,743,093	2,769,275
Loss from operations	(4,575,231)	(9,510,431)	(9,736,954)	(12,124,233)
Other income (loss):				
Reimbursement grant income	-	7,170,465	780,257	7,170,465
Other income (loss)	6,715	80,779	9,504	56,969
Income tax expense	800	800	800	800
Net loss	(4,569,316)	(2,259,987)	(8,947,993)	(4,897,599)
Exchange differences on translation	13,066	(10,480)	44,915	92,947
Net comprehensive loss	\$ (4,556,250)	\$ (2,270,467)	\$ (8,903,078)	\$ (4,804,652)
Weighted average number of common shares	13,867,345	11,641,201	13,610,164	10,894,441
Loss per common share - basic and diluted	\$ (0.33)	\$ (0.19)	\$ (0.66)	\$ (0.45)

Condensed Interim Consolidated Balance Sheets
(Unaudited)

	<u>March 31, 2022</u>	<u>September 30, 2021</u>
Assets:		
Cash and cash equivalents	\$ 15,887,199	\$ 7,839,259
Other current assets	2,112,690	4,251,472
Non-current assets	2,407,734	2,493,924
Total Assets	\$ 20,407,623	\$ 14,584,655
Liabilities and shareholders' equity:		
Current liabilities	\$ 3,335,240	\$ 1,458,650
Non-current liabilities	47,970	67,714
Shareholders' equity	17,024,413	13,058,291
Total liabilities and shareholders' equity	\$ 20,407,623	\$ 14,584,655

Condensed Interim Consolidated Statements of Cash Flows
(Unaudited)

	<u>Six Months Ended</u>	
	<u>March 31, 2022</u>	<u>March 31, 2021</u>
Cash flows from operating activities:		
Net loss	\$ (8,947,993)	\$ (4,897,599)
Adjustments for non-cash items	1,298,919	1,248,994
Change in working capital items	4,024,806	(6,541,452)
Net cash used in operating activities	(3,624,268)	(10,190,057)
Net cash used in investing activities	(4,339)	(4,098)
Net cash provided by financing activities	11,629,914	13,937,798
Effect of exchange rate changes on cash and cash equivalents	46,633	8,856

Net change in cash and cash equivalents	8,047,940	3,752,499
Cash and cash equivalents, beginning of period	7,839,259	7,213,695
Cash and cash equivalents, end of period	<u>\$ 15,887,199</u>	<u>\$ 10,966,194</u>
