**UNITED STATES**
ONG><<>ONT size=2>SECURITIES AND EXCHANGE COMMISSION ONT>ONG>
**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 12, 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 August 12, 2022, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended June 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 No.** | **Description** |
|---|---|

| | |
|---|---|
| 99.1 | Press release issued by Edesa Biotech, Inc. dated August 12, 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: August 12, 2022

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

**Edesa Biotech Reports Fiscal 3rd Quarter 2022 Results**

- *Phase 3 ARDS drug study in hospitalized Covid-19 patients expanded*
- *Company reaffirms guidance on completion of Phase 2b dermatology drug study*

TORONTO, ON / ACCESSWIRE / August 12, 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 nine months ended June 30, 2022 and provided an update on its business.

During the quarter, the company expanded an international Phase 3 study of its critical care drug candidate in hospitalized Covid-19 patients with Acute Respiratory Distress Syndrome (ARDS). The company is now recruiting a second cohort of subjects in parallel to its critically severe cohort. For its dermatology drug candidate, Edesa reported that recruitment in its Phase 2b clinical study in chronic Allergic Contact Dermatitis (ACD) has continued at a robust pace, and the company expects to randomize all planned 210 subjects by the fourth calendar quarter of 2022, as previously guided, with initial topline data available as early as the first calendar quarter of 2023.

“We continue to be excited about the momentum we demonstrated in the first nine months of the fiscal year. Our focus is squarely on accelerating our two active clinical programs toward full enrollment and topline data, increasing our business development activities, applying for non-dilutive grant funding, where applicable, and, as we approach our initial clinical targets, setting our sights on adjacent and secondary disease indications for our current clinical assets,” said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech.

Edesa's Chief Financial Officer Kathi Niffenegger reported that financial results for the quarter and nine months ended June 30, 2022 reflected reduced operational expenditures compared to prior year periods and a continued the trend of prudent management of working capital.

“Operational expenditures for the quarter and the first nine months of fiscal 2022 were in line with management's expectations and benefitted from our continued focus on core development and commercialization activities,” she said.

**Financial Results for the Three Months Ended June 30, 2022**

Total operating expenses decreased by $0.27 million to $5.80 million for the three months ended June 30, 2022 compared to $6.07 million for the same period last year:

- Research and development expenses increased by $0.08 million to $4.55 million for the three months ended June 30, 2022 compared to $4.46 million for the same period last year primarily due to a contractual payment for bulk drug product of EB05, which was substantially offset by decreased external research expenses related to the company’s ongoing clinical studies and drug manufacturing.

- General and administrative expenses decreased by $0.36 million to $1.25 million for the three months ended June 30, 2022 compared to $1.61 million for the same period last year primarily due to a decrease in noncash share-based compensation.

---

Total other income decreased by $1.30 million to $0.01 million for the three months ended June 30, 2022 compared to $1.31 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 quarter ended June 30, 2022, Edesa reported a net loss of $5.79 million, or $0.37 per common share, compared to a net loss of $4.76 million, or $0.36 per common share, for the three months ended June 30, 2021.

**Financial Results for the Nine Months Ended June 30, 2022**

Total operating expenses decreased by $2.67 million to $15.53 million for the nine months ended June 30, 2022 compared to $18.20 million for the same period last year:

- Research and development expenses decreased by $2.28 million to $11.54 million for the nine months ended June 30, 2022 compared to $13.82 million for the same period last year primarily due to decreased milestone payments, which were partially offset by higher external research expenses related to the company’s ongoing clinical studies and increased personnel expenses.

- General and administrative expenses decreased by $0.39 million to $3.99 million for the nine months ended June 30, 2022 compared to $4.38 million for the same period last year primarily due to a decrease in noncash share-based compensation.

Total other income decreased by $7.74 million to $0.80 million for the nine months ended June 30, 2022 compared to $8.54 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 nine months ended June 30, 2022, Edesa reported a net loss of $14.74 million, or $1.04 per common share, compared to a net loss of $9.66 million, or $0.83 per common share, for the nine months ended June 30, 2021.

**Working Capital**

At June 30, 2022, Edesa had cash and cash equivalents of $12.81 million and working capital of $9.52 million.

**Calendar**

Edesa management plans to participate in the H.C. Wainwright Global Investment Conference scheduled for September 12-14, 2022 in New York City. Attendees interested in meeting with management can schedule one-on-one meetings through the conference website 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. 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. Among the results, critically ill hospitalized Covid-19 patients given EB05 plus standard of care treatment had a 68.5% reduction in the risk of dying when compared to placebo plus standard of care at 28 days.

Edesa is evaluating two study cohorts based on the World Health Organization Covid-19 Severity Index for the Phase 3 part of a Phase 2/3 clinical trial. The first cohort will assess the efficacy and safety of EB05 among critically ill COVID-19 patients receiving extracorporeal membrane oxygenation (ECMO) and/or invasive mechanical ventilation plus additional organ support (WHO Level 7). The primary endpoint for the Level 7 patients will be 28-day mortality. The second cohort is enrolling hospitalized patients on invasive mechanical ventilation alone (WHO Level 6 patients). The primary endpoint for the Level 6 patients will be the number of ventilator free days at 28 days.

**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 contract dermatitis (ACD) - Phase 2b: Enrolling*

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, and has demonstrated anti-inflammatory activity in a variety of in vitro and in vivo preclinical pharmacology models.

Edesa is enrolling the final cohorts of patients in a double-blind, placebo-controlled confirmatory Phase 2b study evaluating the safety and efficacy of 2.0% EB01 topical cream. In addition to the primary cohort, the company has included an exploratory, dose-ranging component of the study, which will separately evaluate lower-strength concentrations of EB01. At the interim analysis for the Phase 2b study, an independent data monitoring board reported an approximately 1.7-fold difference between the treatment arms for the primary efficacy endpoint, which is the mean percent change from baseline on the Contact Dermatitis Severity Index (CDSI) at day 29. The monitoring board also reported an approximately 1.8-fold difference between the treatment arms in the proportion of patients achieving success on the ISGA (Investigator's Static Global Assessment), a key secondary efficacy endpoint. A decrease in the ISGA score relates to an improvement in signs and symptoms.



**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 that enrollment in the Phase 2b study of EB01 will 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; the company's belief that it will be successful in positioning additional investigational centers to be available for current and future waves of hospitalizations; the company's plans to explore strategic business development opportunities; the company's interest in expanding its drug development activities for adjacent and secondary disease indications for its current clinical assets; the company's*

*plans to accelerate its clinical programs toward full enrollment; the company's plans to manage its working capital; 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 Interim Consolidated Statements of Operations**
(Unaudited)

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | **June 30, 2022** | **June 30, 2021** | **June 30, 2022** | **June 30, 2021** |
| **Expenses:** | | | | |
| Research and development | **4,547,543** | 4,464,347 | **11,541,404** | 13,819,305 |
| General and administrative | **1,249,982** | 1,608,232 | **3,993,075** | 4,377,507 |
| **Loss from operations** | **(5,797,525)** | (6,072,579) | **(15,534,479)** | (18,196,812) |
| **Other Income (Loss):** | | | | |
| Reimbursement grant income | **-** | 1,306,796 | **780,257** | 8,477,261 |
| Other income (loss) | **10,505** | 6,273 | **20,009** | 63,242 |
| **Income tax expense** | **-** | **-** | **800** | 800 |
| **Net loss** | **(5,787,020)** | (4,759,510) | **(14,735,013)** | (9,657,109) |
| Exchange differences on translation | **34,559** | 174,128 | **79,474** | 267,075 |
| **Net comprehensive loss** | **$ (5,752,461)** | $ (4,585,382) | **$ (14,655,539)** | $ (9,390,034) |
| Weighted average number of common shares | **15,462,287** | 13,251,999 | **14,227,538** | 11,680,294 |
| **Loss per common share - basic and diluted** | **$ (0.37)** | $ (0.36) | **$ (1.04)** | $ (0.83) |



**Condensed Interim Consolidated Balance Sheets**
(Unaudited)

| | **June 30, 2022** | **September 30, 2021** |
|---|---|---|
| **Assets:** | | |
| Cash and cash equivalents | **$ 12,808,712** | $ 7,839,259 |
| Other current assets | **2,371,722** | 4,251,472 |
| Non-current assets | **2,360,767** | 2,493,924 |
| **Total Assets** | **$ 17,541,201** | $ 14,584,655 |
| **Liabilities and shareholders' equity:** | | |
| Current liabilities | **$ 5,657,329** | $ 1,458,650 |
| Non-current liabilities | **46,536** | 67,714 |
| Shareholders' equity | **11,837,336** | 13,058,291 |

| | | |
|---|---|---|
| **Total liabilities and shareholders' equity** | **$ 17,541,201** | $ 14,584,655 |



**Condensed Interim Consolidated Statements of Cash Flows**
(Unaudited)

| | Nine Months Ended | |
|---|---|---|
| | **June 30, 2022** | June 30, 2021 |
| **Cash flows from operating activities:** | | |
| Net loss | **$ (14,735,013)** | $ (9,657,109) |
| Adjustments for non-cash items | **1,893,898** | 2,380,647 |
| Change in working capital items | **6,190,020** | (6,033,149) |
| **Net cash used in operating activities** | **(6,651,095)** | (13,309,611) |
| **Net cash used in investing activities** | **(5,697)** | (7,610) |
| **Net cash provided by financing activities** | **11,629,914** | 13,953,704 |
| Effect of exchange rate changes on cash and cash equivalents | **(3,669)** | 202,396 |
| Net change in cash and cash equivalents | **4,969,453** | 838,879 |
| Cash and cash equivalents, beginning of period | **7,839,259** | 7,213,695 |
| **Cash and cash equivalents, end of period** | **$ 12,808,712** | $ 8,052,574 |