**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 10, 2024**

# 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) | (Zip Code) |

**(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 May 10, 2024, Edesa Biotech, Inc. (the "Company") issued a press release announcing its financial results for the three and six months ended March 31, 2024 (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, as amended (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 10, 2024. |

| | |
|---|---|
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |



**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 10, 2024

By: */s/ Stephen Lemieux*
Name: Stephen Lemieux
Title: Chief Financial Officer


**Edesa Biotech Reports Fiscal 2nd Quarter 2024 Results**

TORONTO, ON / ACCESSWIRE / May 10, 2024 / Edesa Biotech, Inc. (Nasdaq:EDSA), a clinical-stage biopharmaceutical company focused on developing host-directed therapeutics for immuno-inflammatory diseases, today reported financial results for the three and six months ended March 31, 2024 and provided an update on its business.

During the quarter, the company expanded site selection activities for a Phase 3 study of its ARDS (Acute Respiratory Distress Syndrome) drug candidate, EB05 (paridiprubart). Edesa previously secured up to C$23 million from the Canadian government toward the development of EB05, a portion of which is conditionally repayable. The company also intends to evaluate EB05, an anti-TLR4 monoclonal antibody, separately in a broader ARDS population and plans to file an investigational new drug application (IND) for a Phase 2 study in pulmonary fibrosis.

“We are positioning our anti-TLR4 respiratory technology for both acute and chronic conditions,” said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. “With governments now focusing on host-directed therapeutics as part of their pandemic preparedness and biodefense plans, and strong scientific rationale for evaluating EB05 in both ARDS and chronic lung fibrosis, we believe we can significantly expand the medical opportunities for this promising antibody as well as enhance its attractiveness for commercial development and partnering.”

For its medical dermatology technologies, Edesa reported that it plans to seek regulatory approval in the U.S for a Phase 2 study of its anti-CXCL10 monoclonal antibody in patients with moderate-to-severe nonsegmental vitiligo, common autoimmune disorder that causes skin to lose its color in patches. The protocol has been approved previously in Canada. The company also intends to seek strategic arrangements to further develop and/or monetize its EB01 asset, following favorable Phase 2b results of 1.0% EB01 cream.

Edesa's Chief Financial Officer Stephen Lemieux reported that financial results for the three and six months ended March 31, 2024 reflected consistent operational efficiency and prudent management of working capital. He noted that during the quarter the company deployed additional resources to its current Phase 3 ARDS study and has engaged a new clinical research organization with increased analytical and recruitment capabilities.

“With government funding in place, we believe we are in a stronger position to efficiently manage our Phase 3 ARDS study, while remaining opportunistic to ramp up our development activities in vitiligo and pulmonary fibrosis,” he said. “We have continued to demonstrate our ability to execute on our plans, and we are working towards a rich set of milestones over the next 12 to 24 months.”

**Financial Results for the Three Months Ended March 31, 2024**

Total operating expenses decreased by $0.2 million to $2.2 million for the three months ended March 31, 2024 compared to $2.4 million for the same period last year.

- Research and development expenses decreased by $0.3 million to $1.2 million for the three months ended March 31, 2024 compared to $1.5 million for the same period last year primarily due to decreased external research expenses related to the company’s completed dermatitis study and a reduction in noncash share-based compensation, which was partially offset by an increase in expenses for the company’s ongoing ARDS study.

- General and administrative expenses increased by $0.1 million to $1.0 million for the three months ended March 31, 2024 compared to $0.9 million for the same period last year primarily due to increased fees for professional services, which was partially offset by a decrease in noncash share-based compensation.

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Total other income increased by $283,000 to $360,000 for the three months ended March 31, 2024 compared to $77,000 for the same period last year primarily due to an increase in reimbursement funding from the Canadian government's Strategic Innovation Fund.

For the quarter ended March 31, 2024, Edesa reported a net loss of $1.9 million, or $0.58 per common share, compared to a net loss of $2.3 million, or $0.82 per common share, for the quarter ended March 31, 2023.

**Financial Results for the Six Months Ended March 31, 2024**

Total operating expenses decreased by $0.7 million to $4.1 million for the six months ended March 31, 2024 compared to $4.8 million for the same period last year:

- Research and development expenses decreased by $0.9 million to $1.9 million for the six months ended March 31, 2024 compared to $2.8 million for the same period last year primarily due to decreased external research expenses related to the company’s completed dermatitis study and a reduction in noncash share-based compensation, which was partially offset by an increase in expenses for the company’s ongoing ARDS study.

- General and administrative expenses increased by $0.2 million to $2.2 million for the six months ended March 31, 2024 compared to $2.0 million for the same period last year primarily due to increased fees for professional services, which was partially offset by a decrease in non-cash share-based compensation.

Total other income decreased by $0.4 million to $0.5 million for the six months ended March 31, 2024 compared to $0.1 million for the same period last year primarily due to an increase in reimbursement funding from the Canadian government's Strategic Innovation Fund.

For the six months ended March 31, 2024, Edesa reported a net loss of $3.5 million, or $1.12 per common share, compared to a net loss of $4.7 million, or $1.70 per common share, for the six months ended March 31, 2023.

**Working Capital**

At March 31, 2024, Edesa had cash and cash equivalents of $2.8 million and working capital of $2.1 million. Subsequent to the quarter end, the company received $0.7 million in reimbursement funding the Canadian government's Strategic Innovation Fund.

**Calendar**

Edesa management plans to participate in the RBC Capital Markets Global Healthcare Conference on May 14-15, 2024 in New York, NY, and the BIO International Convention being held June 5-8, 2023 in San Diego, Calif. 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 developing innovative ways to treat inflammatory and immune-related diseases. The company's most advanced drug candidate is EB05 (paridiprubart), a monoclonal antibody developed for acute and chronic disease indications that involve dysregulated innate immune responses. Edesa is currently evaluating EB05 in a Phase 3 study as a potential treatment for Acute Respiratory Distress Syndrome (ARDS), a life-threatening form of respiratory failure. The company has also received regulatory approval to conduct a Phase 2 trial its EB06 (anti-CXCL10) monoclonal antibody as a treatment for vitiligo, a life-altering autoimmune disease that causes skin to lose its color in patches. In addition, Edesa is developing an sPLA2 inhibitor, EB01 (1.0% daniluromer cream), as a topical treatment for chronic Allergic Contact Dermatitis (ACD), a common occupational skin condition. Sign up for news alerts. Connect with us on X (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 intention to evaluate EB05 in a broader ARDS population as well as file an investigational new drug application for a Phase 2 study in pulmonary fibrosis; the Company's plans to position its anti-TLR4 respiratory technology for both acute and chronic conditions; the Company's belief that it can significantly expand the medical opportunities for paridiprubart, as well as increase its attractiveness for partnering and commercial development; the Company's plans to seek regulatory approval in the U.S for a Phase 2 study of its anti-CXCL10 monoclonal antibody in vitiligo patients; the Company's intention to seek strategic arrangements to further develop and/or monetize its EB01 asset; the Company's belief that its financial results reflect consistent operational efficiency and prudent management of working capital; the Company's belief that its new clinical research organization has increased analytical and recruitment capabilities; the Company's belief that with government funding in place, it is in a stronger position to efficiently manage its Phase 3 ARDS study, while remaining opportunistic to ramp up its development activities in vitiligo and pulmonary fibrosis; the Company's belief that it has continued to demonstrate its ability to execute on its plans and that it is working towards a rich set of milestones over the next 12 to 24 months; 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. 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.
(289) 800-9600
investors@edesabiotech.com



**Condensed Interim Consolidated Statements of Operations**
(Unaudited)

| | Three Months Ended | | Six Months Ended | |
|---|---|---|---|---|
| | **March 31, 2024** | **March 31, 2023** | **March 31, 2024** | **March 31, 2023** |

| | | | | |
|---|---|---|---|---|
| **Expenses:** | | | | |
| Research and development | **1,176,337** | 1,458,190 | **$ 1,880,795** | $ 2,815,528 |
| General and administrative | **1,044,137** | 952,391 | **2,197,108** | 1,973,358 |
| **Loss from operations** | **(2,220,474)** | (2,410,581) | **(4,077,903)** | (4,788,886) |
| **Other Income (Loss):** | | | | |
| Reimbursement grant income | **304,002** | - | **424,836** | - |
| Other income (loss) | **55,941** | 77,032 | **114,085** | 120,520 |
| **Income tax expense** | **800** | 800 | **800** | 800 |
| **Net loss** | **(1,861,331)** | (2,334,349) | **(3,539,782)** | (4,669,166) |
| Exchange differences on translation | **(11,183)** | 8,643 | **(11,755)** | (16,424) |
| **Net comprehensive loss** | **$ (1,872,514)** | $ (2,325,706) | **$ (3,551,537)** | $ (4,685,590) |
| Weighted average number of common shares | **3,192,688** | 2,853,331 | **3,160,179** | 2,738,848 |
| **Loss per common share - basic and diluted** | **$ (0.58)** | $ (0.82) | **$ (1.12)** | $ (1.70) |



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

| | **March 31, 2024** | **September 30, 2023** |
|---|---|---|
| **Assets:** | | |
| Cash and cash equivalents | **$ 2,799,631** | $ 5,361,397 |
| Other current assets | **1,442,587** | 1,075,455 |
| Non-current assets | **2,232,838** | 2,453,585 |
| **Total Assets** | **$ 6,475,056** | $ 8,890,437 |
| **Liabilities and shareholders' equity:** | | |
| Current liabilities | **$ 2,150,723** | $ 1,821,864 |
| Non-current liabilities | **-** | 19,773 |
| Shareholders' equity | **4,324,333** | 7,048,800 |
| **Total liabilities and shareholders' equity** | **$ 6,475,056** | $ 8,890,437 |



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

| | **Six Months Ended** | |
|---|---|---|
| | **March 31, 2024** | **March 31, 2023** |
| **Cash flows from operating activities:** | | |
| Net loss | **$ (3,539,782)** | $ (4,669,166) |
| Adjustments for non-cash items | **409,715** | 675,723 |
| Change in working capital items | **63,380** | 630,203 |
| **Net cash used in operating activities** | **(3,066,687)** | (3,363,240) |
| **Net cash provided by financing activities** | **517,441** | 3,676,415 |
| Effect of exchange rate changes on cash and cash equivalents | **(12,520)** | 67,158 |
| Net change in cash and cash equivalents | **(2,561,766)** | 380,333 |
| Cash and cash equivalents, beginning of period | **5,361,397** | 7,090,919 |
| **Cash and cash equivalents, end of period** | **$ 2,799,631** | $ 7,471,252 |