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): June 5, 2026

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 8.01 Other Events.

On June 5, 2026, Edesa Biotech, Inc. (the "Company") reported favorable exploratory data for paridiprubart, its first-in-class anti-TLR4 monoclonal antibody, in patients with acute kidney injury ("AKI") and respiratory distress.

The data, which expand upon previously reported Phase 3 clinical results through new exploratory analyses, will be presented today in a scientific oral presentation at the 63rd European Renal Association ("ERA") Congress in Glasgow, Scotland. These new analyses are based on exploratory evaluations from the Company's completed clinical studies in hospitalized patients with acute respiratory distress syndrome ("ARDS").

Because TLR4-mediated inflammation plays a central role in both lung and kidney injury, the Company conducted additional analyses to evaluate paridiprubart's effect in patients with concurrent AKI, a high-mortality complication that currently lacks approved, targeted pharmacological therapies. Patients with AKI and ARDS represent a high-risk population, with substantially elevated mortality relative to patients without renal dysfunction. Among the findings, paridiprubart plus standard of care treatments ("SOC") was associated with a 32% relative reduction in mortality in these AKI patients at 28 days. The observed reductions in mortality were supported by concordant improvements in kidney-specific outcomes, including the MAKE30 composite endpoint.

The AKI findings reported here expand on previously reported exploratory results in 48 AKI patients from the Phase 3 ITT population by incorporating additional patients from the Phase 2 study and the broader 278-patient treatment population, for a combined AKI cohort of 101 patients. The AKI subgroup included all patients with AKI present at baseline, and outcomes were analyzed using the same multivariate methodology prespecified in the Phase 3 statistical analysis plan for ARDS.

Patients in this AKI cohort were severely ill, with approximately 90% having moderate-to-severe ARDS at baseline and approximately 50% requiring invasive mechanical ventilation or ECMO, consistent with a population at high risk of mortality. Mean age was 58 years.

28-Day Mortality

Paridiprubart + SOC reduced adjusted 28-day mortality to 33% (95% CI: 28%–39%), from 49% (95% CI: 41%–57%) with placebo + SOC, a 32% relative reduction in the risk of death (nominal $p<0.005$).

MAKE30 (Major Adverse Kidney Events at 30 days)

Using the same multivariate logistic regression methodology, paridiprubart + SOC reduced the adjusted incidence of MAKE30 at Day 30 to 41% (95% CI: 36%–46%) from 53% (95% CI: 47%–60%) with placebo + SOC, a 23% relative reduction in MAKE30 incidence (nominal $p<0.005$). MAKE30 is a composite endpoint comprising all-cause mortality, initiation of renal replacement therapy, or persistent renal dysfunction through Day 30.

Safety and Tolerability

Paridiprubart was well tolerated in the AKI subpopulation. Overall rates of adverse events, serious adverse events, and infections were low and showed no significant differences between the paridiprubart and placebo groups. The safety profile was consistent with more than 400 patients treated across clinical studies to date.

These exploratory findings are consistent with the hypothesis that modulation of TLR4-mediated inflammation may influence multi-organ dysfunction in critically ill patients, and are directionally consistent with the previously reported Phase 3 results. Since AKI represents a high-mortality subgroup within ARDS, the Company believes the consistency of benefit observed here reinforces the rationale for Paridiprubart's ongoing development in ARDS. In addition, the Company believes these data support further evaluation of paridiprubart in prospective studies specifically targeting patients with AKI and may inform the design of future clinical trials in this high-unmet need population.

** Estimated using multivariate logistic regression-derived risk differences (95% confidence intervals). Nominal p-values, not adjusted for multiplicity. These analyses are exploratory in nature and were not prespecified. Results should be interpreted with caution and are intended to generate hypotheses for further clinical evaluation. Confirmatory studies would be required to establish efficacy in AKI.*

Cautionary Language Concerning Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are made on the basis of the current beliefs, expectations and assumptions of management, are not guarantees of performance and are subject to significant risks and uncertainty. These forward-looking statements should, therefore, be considered in light of various important factors, including those set forth in the Company's reports that it files from time to time with the Securities and Exchange Commission and which you should review, including those statements under "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the year ended September 30, 2025.

Because forward-looking statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the timing and success of the Company's clinical trials and regulatory approvals.

These forward-looking statements should not be relied upon as predictions of future events and the Company cannot assure you that the events or circumstances discussed or reflected in these statements will be achieved or will occur. If such forward-looking statements prove to be inaccurate, the inaccuracy may be material. You should not regard these statements as a representation or warranty by the Company or any other person that the Company will achieve its objectives and plans in any specified timeframe, or at all. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this filing. The Company disclaims any obligation to publicly update or release any revisions to these forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this filing or to reflect the occurrence of unanticipated events, except as required by law.

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: June 5, 2026

By: */s/ Peter J. Weiler*
Name: Peter J. Weiler
Title: Chief Financial Officer