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): October 12, 2023

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 1.01 Entry into a Material Definitive Agreement

On October 12, 2023, Edesa Biotech Research, Inc. ("Edesa Biotech Research"), a wholly owned subsidiary of Edesa Biotech, Inc. (the "Company") and the Company, as guarantor, entered into a multi-year contribution agreement (the "Agreement") with the Government of Canada. Pursuant to the Agreement, the Government of Canada committed up to CAD $23 million ($17 million USD) in partially repayable funding toward (i) conducting and completing the Company's Phase 3 clinical study of its experimental drug EB05 (paridiprubart) in critical-care patients with Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19 or other infectious agents, (ii) submitting EB05 for governmental approvals and manufacturing scale-up, following, and subject to, completing the Phase 3 study and (iii) conducting two non-clinical safety studies to assess the potential long-term impact of EB05 exposure (the "Project"). Edesa Biotech Research agreed to complete the Project, which will be conducted exclusively in Canada (except as permitted otherwise under certain circumstances), on or before December 31, 2025. The Company agreed to guarantee the complete performance and fulfillment of Edesa Biotech Research's obligations under the Agreement. In the event Edesa Biotech Research fails to perform or otherwise satisfy any of its obligations related to the Agreement, the Company will become a primary obligor under the Agreement.

Of the CAD $23 million committed by the Government of Canada under the Agreement, CAD $5.75 million is not repayable. The remaining CAD $17.25 million is conditionally repayable starting in 2029 only if and when the Company earns gross revenue. The repayable portion would be payable over fifteen (15) years based on a percentage rate of the Company's annual revenue growth. The maximum amount repayable under the Agreement is 1.4 times the original repayable amount. In addition, the Company is entitled to partial reimbursement of certain eligible expenses under the Agreement.

Under the Agreement, Edesa Biotech Research has agreed to certain financial and non-financial covenants and other obligations in relation to the Project, including (i) the achievement of certain headcount requirements in Canada, (ii) the maintenance of a collaboration with a Canadian research institute or post-secondary institutions, (iii) the maintenance of certain research and development expenditures in Canada, (iv) the maintenance of inclusive hiring practices and employee training and (v) the creation of an environmental sustainability plan. In addition, Edesa Biotech Research has granted notice and consent rights to the Government of Canada upon certain events related to a Change in Control (as defined in the Agreement).

For the term of the Agreement, Edesa Biotech Research must have exclusive ownership of all intellectual property (i) conceived, produced or developed in connection with the Project and (ii) that is required for the carrying out of the Project (the "Intellectual Property"). Pursuant to the Agreement, Edesa Biotech Research is required, subject to certain exceptions, to obtain the consent of the Government of Canada prior to granting any right or license to any of the Intellectual Property. Furthermore, the Government of Canada may require Edesa Biotech Research to assign, transfer or grant a license to use the Intellectual Property to the extent necessary to ensure a sufficient domestically-sourced supply of vaccines and/or treatments in response to COVID-19 if Edesa Biotech Research is unable to ensure such a supply.

Pursuant to the Agreement, certain customary events of default, such as the Company's or Edesa Biotech Research's breach of their covenants and obligations under the Agreement, their insolvency, winding up or dissolution, and other similar events, may permit the Government of Canada to declare an event of default under the Agreement. Upon an event of default, subject to applicable cure, the Government of Canada may exercise a number of remedies, including suspending or terminating funding under the Agreement, demanding repayment of funding previously received and/or terminating the Agreement.

The funding and any associated conditional repayments are not secured by any assets of Edesa Biotech Research or the Company.

The Agreement will expire on the later of December 31, 2042 or the date of the last repayment, unless earlier terminated, subject to certain provisions that extend three (3) years beyond the term or early termination of the Agreement.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the text of the Agreement, a copy of which will be filed with the Company's annual report on Form 10-K for the fiscal year ending September 30, 2023.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant

The information set forth under Items 1.01 and 8.01 is incorporated into this Item 2.03 by reference.

Item 7.01 Regulation FD Disclosure

On October 12, 2023, the Company issued a press release announcing the execution of the Agreement. The full text of the press release is attached hereto as Exhibit 99.1.

On October 12, 2023, the Company issued a press release announcing that it has entered into a binding commitment letter with Dr. Par Nijhawan, MD, the Company's Chief Executive Officer and member of the Board of Directors of the Company related to a $10 million revolving credit facility agreement. The full text of the press release is attached hereto as Exhibit 99.2.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibits 99.1 and 99.2, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the 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, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events

On October 12, 2023, the Company announced that it has entered into a binding commitment letter with Dr. Par Nijhawan, MD, the Company's Chief Executive Officer and member of the Board of Directors of the Company related to a $10 million revolving credit facility agreement. The binding commitment letter provides for a revolving line of credit in the amount of up to $10 million, with $3.5 million available immediately upon the execution of the definitive agreement for the credit facility. Advances under the revolving credit facility will be subject to compliance with all applicable laws, and tied to a borrowing base consisting of eligible grant reimbursement receivables, future potential license fee receivables and any other accounts receivable. The binding commitment letter provides for an interest rate of the CIBC US Base-Interest Rate plus 300bps and a maturity date of March 31, 2026. The availability of the credit facility will be subject to finalization and execution of a definitive credit agreement and related documents.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 12, 2023.
99.2	Press Release, dated October 12, 2023.
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: October 12, 2023

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

Exhibit 99.1

Edesa Biotech to Receive Up To C$23 Million in Funding from Federal Government

TORONTO, ON / ACCESSWIRE / October 12, 2023 / Edesa Biotech, Inc. (Nasdaq:EDSA), a clinical-stage biopharmaceutical company focused on inflammatory and immune-related diseases, has secured a commitment of up to C$23 million from the Government of Canada for a pivotal Phase 3 clinical study of the company's first-in-class therapeutic candidate.

Edesa's experimental drug, called EB05 (paridiprubart), represents a new class of emerging therapies called Host-Directed Therapeutics (HDTs) that are designed to modulate the body's own immune response when confronted with infectious diseases or even chemical agents. Importantly, these therapies are agnostic to the causal agent and can be stockpiled preemptively for seasonal outbreaks and unexpected emergencies and threats.

"This project has the potential to increase survival rates, reduce ICU costs and improve outcomes for critically ill patients," said Par Nijhawan, MD, Chief Executive Officer of Edesa Biotech. "With this validation and the continued support from the federal government, we believe we are in a position to accelerate research, expand our reach to more hospitals and move another significant step closer to commercialization."

Edesa's current project builds on the success of a government-supported Phase 2 clinical study completed during the pandemic which demonstrated that paridiprubart reduced mortality by 84% among critically ill patients with a severe form of respiratory disease called Acute Respiratory Distress Syndrome (ARDS). A parallel *in vitro* study at the University of Toronto also demonstrated recently that paridiprubart inhibits inflammation from influenza and other pathogens.

"We are proud of our track record of delivering successful results on time and on budget for our government-supported projects," said Dr. Nijhawan. "The development of breakthrough medicines – especially in the critical care fields – is key to building a strong biopharma sector, creating jobs and most importantly improving patient outcomes at home and abroad. We are honored to be a part of these efforts."

The Honorable François-Philippe Champagne, Minister of Innovation, Science and Industry said that the Strategic Innovation Fund (SIF) funding announced today is part of the government's plan to grow a strong and competitive life sciences sector, and ensure the nation's readiness for future pandemics or other health emergencies.

"This project is a prime example of Canada's determination to the development of the next generation of medicine, while creating good jobs and securing long-term economic growth," said Minister Champagne.

Edesa intends to use the SIF funding toward study expenses, including hospital and physician expenditures, as well as scale-up of commercial drug product should the development program be successful. Funding is provided under the federal government's Strategic Innovation Fund (SIF) following a competitive review process.

Additional information regarding the funding are outlined in the company's Current Report on Form 8-K, which Edesa expects to file with the U.S. Securities and Exchange Commission and on the SEDAR+ system in Canada.

About ARDS

ARDS involves an exaggerated immune response leading to inflammation and injury to the lungs that prevents the lungs from oxygenating blood and ultimately deprives the body of oxygen. For moderate to severe cases, there are currently few meaningful treatments, other than supplemental oxygen and mechanical ventilation, and patients suffer high mortality rates. In addition to virus-induced pneumonia, ARDS can be caused by smoke/chemical inhalation, sepsis, chest injury and other causes. Prior to the pandemic, ARDS accounted for 10% of intensive care unit admissions, representing more than 3 million patients globally each year.

About EB05 (Paridiprubart)

Paridiprubart is a first-in-class monoclonal antibody developed for acute and chronic disease indications that involve dysregulated innate immune responses. This host-directed therapeutic (HDT) candidate inhibits toll-like receptor 4 (TLR4), a key immune signaling protein that has been shown to be activated both by viruses, like SARS-CoV2, SARS-CoV1 and Influenza, as well as in the pathogenesis of chronic autoimmune diseases.

About Phase 3 Clinical Study

Edesa's Phase 3 study of EB05 (paridiprubart) is a multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of EB05 in critical-care patients. The current protocol calls for treatment of ARDS subjects hospitalized with SARS-CoV2 infections who are on invasive mechanical ventilation, both with and without additional organ support. The primary endpoint is the mortality rate at 28 days. In addition to SARS-CoV2 induced ARDS, Edesa is currently exploring various approaches to evaluate EB05 in a general ARDS population.

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. In addition, Edesa is developing an sPLA2 inhibitor, EB01 (daniluromer), as a topical treatment for chronic Allergic Contact Dermatitis (ACD), a common occupational skin condition. The Company has also received regulatory approval to conduct a Phase 2 trial its EB06 monoclonal antibody as a treatment for vitiligo, a life-altering autoimmune disease that causes skin to lose its color in patches. Edesa is also planning to file an investigational new drug application for a future Phase 2 study of paridiprubart for systemic sclerosis (scleroderma), an autoimmune rheumatic disorder that causes fibrosis, (scarring/hardening) of skin and internal organs such as the lungs, heart and kidneys. 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. 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.
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investors@edesabiotech.com

Exhibit 99.2

Edesa Biotech Secures $10 Million Credit Facility with Company Founder

- *Revolving Line of Credit to Support Completion of Government-Funded ARDS Study*

TORONTO, ON / ACCESSWIRE / October 12, 2023 / Edesa Biotech, Inc. (Nasdaq:EDSA) ("Edesa", or the "Company"), a clinical-stage biopharmaceutical company focused on inflammatory and immune-related diseases, today announced it has entered into a binding commitment letter in respect of a $10 million revolving credit facility agreement with Dr. Par Nijhawan, MD, the Company's Chief Executive Officer and Founder. The binding commitment letter was executed in parallel with a C$23 million commitment from the Government of Canada to support a pivotal Phase 3 clinical study of the Company's first-in-class therapeutic candidate.

Stephen Lemieux, Chief Financial Officer of the Company, said that the credit facility will be an important part of the Company's growth strategy, and in particular, its development and commercialization plans for EB05 (paridiprubart), a monoclonal antibody that Edesa is developing as a treatment for a severe form of respiratory failure known as Acute Respiratory Distress Syndrome (ARDS).

"We greatly appreciate this vote of confidence from our Founder, and the attractive terms of the agreement," said Mr. Lemieux. "With this financial milestone and the funding commitment from the Government of Canada, we will be in a significantly stronger position to move forward toward the completion of our pivotal Phase 3 study of EB05 and prepare for potential approval."

The binding commitment letter with Dr. Nijhawan provides for a revolving line of credit in the amount of up to $10 million, with $3.5 million available immediately upon the execution of the definitive agreement for the credit facility. Advances under the revolving credit facility will be subject to compliance with all applicable laws, and tied to a borrowing base consisting of eligible grant reimbursement receivables, future potential license fee receivables and any other accounts receivable. The binding commitment letter provides for an interest rate of the CIBC US Base-Interest Rate plus 300 bps and a maturity date of March 31, 2026. The availability of the credit facility will be subject to finalization and execution of a definitive credit agreement and related documents.

"I'm pleased to provide both financial support and leadership to the company as it builds on its recent operational and clinical successes," said Dr. Nijhawan. "Edesa has a strong development pipeline and I'm confident that we can continue to successfully execute on our plans to commercialize innovative drug therapies for large, underserved patient populations."

Additional details on the revolving credit facility will be outlined in the Company's Current Report on Form 8-K, which the Company expects to file with the U.S. Securities and Exchange Commission and on the SEDAR+ system in Canada.

The entering into of the binding commitment letter with respect to the credit facility constitutes a "related party transaction" within the meaning of Multilateral Instrument 61-101 – *Protection of Minority Securityholders in Special Transactions.* The Company will file a material change report less than 21 days before the credit facility will be entered into, which shorter period is necessary in the circumstances in order for the Company to access working capital in the short term to continue its development and commercialization plans.

About Edesa Biotech, Inc.

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