

---

**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): February 2, 2021**

**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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of exchange on which registered</b>
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

### *Agreement with the Government of Canada's Strategic Innovation Fund*

On February 2, 2021, Edesa Biotech Research, Inc., a wholly owned subsidiary of Edesa Biotech, Inc. (the "Company"), entered into a multi-year contribution agreement with the Canadian government's Strategic Innovation Fund, or SIF (the "Agreement"). Under this Agreement, the Government of Canada committed up to CAD \$14.05 million (\$11 million USD) in nonrepayable funding toward (i) the Phase 2 portion of the Company's ongoing Phase 2/3 study of its investigation therapy EB05 in hospitalized COVID-19 patients, and (ii) certain pre-clinical research intended to potentially broaden the application of the Company's experimental therapy (collectively, the "Project"). Pursuant to the contribution agreement, Edesa Biotech Research will conduct work, incur expenses and fund all costs from its own cash resources. On a quarterly basis, Edesa Biotech Research may submit claims to the SIF for eligible reimbursable expenses.

Under the Agreement, Edesa Biotech Research has agreed to certain obligations in relation to the completion of the Project. In the event that Edesa Biotech Research breaches its obligations under the Agreement, subject to applicable cure, the SIF 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 performance obligations of Edesa Biotech Research under the contribution agreement are guaranteed by the Company.

The foregoing is only a summary of the material terms of the Agreement, does not purport to be complete, and is qualified in its entirety by reference to the text of the Agreement, which is attached as Exhibit 10.1 hereto and incorporated herein in its entirety.

## Item 8.01 Other Events

On February 2, 2021, the Company issued a press release announcing the execution of the Agreement (the "Press Release"). The full text of the Press 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

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">10.1</a> <sup>+</sup>	Strategic Innovation Fund Agreement among Edesa Biotech Research, Inc., Edesa Biotech, Inc., and her Majesty the Queen in right of Canada as represented by the Minister of Industry, dated February 2, 2021
<a href="#">99.1</a>	Press release issued by Edesa Biotech, Inc. dated February 2, 2021.

+ Portions of this exhibit have been omitted pursuant to Rule 601(b)(10)(iv) of Regulation S-K.

**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: February 2, 2021

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

---

**CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

**STRATEGIC INNOVATION FUND**

EB05 Therapeutic

This Agreement made

**Between:**

**HER MAJESTY THE QUEEN IN RIGHT OF CANADA (“Her Majesty”)**

as represented by the Minister of Industry

(the “**Minister**”)

**And:**

Edesa Biotech Research, Inc., a corporation duly incorporated under the laws of Ontario, having its head office located at 100 Spy Court, Markham, Ontario L3R 5H6

(the “**Recipient**”)

**And:**

Edesa Biotech, Inc., a corporation duly incorporated under the laws of British Columbia, having its head office located at 100 Spy Court, Markham, Ontario L3R 5H6

(the “**Guarantor**”)

**RECITALS**

**WHEREAS**

- I-** The Strategic Innovation Fund (“**SIF**”) is designed to encourage research and development, and accelerate the technology transfer and commercialization of innovative products, services, and processes; facilitate the growth and expansion of firms; secure economically significant mandates within or to Canada; and, advance industrial research and technology demonstration activities through collaboration;

- II-** Neither the entering into this Agreement nor the provision by the Minister of the Contribution is contingent upon export performance on the part of the Recipient;
- III-** The Project is in respect to SIF's research and development (R&D) and commercialization Stream 1, and involves:
- activities related to the creation or deployment of medical countermeasures (MCM's), or any activity related to the response to COVID-19;
  - activities related to Canada's long-term emergency preparedness; and
  - obtaining an R&D and/or production mandate which was previously held outside of Canada or is being established for the first time in relation to Canada's emergency preparedness.
- IV-** The Minister has agreed to make a non-repayable contribution to the Recipient in support of the Recipient's Eligible Supported Costs (as defined herein) of the Project with total Project costs of eighteen million, seven hundred and thirty-eight thousand dollars (\$18,738,000).

**NOW, THEREFORE** in accordance with the mutual covenants and agreements herein, Her Majesty and the Recipient agree as follows:

**1. Purpose of the Agreement**

The purpose of this Agreement is to set out respective obligations and the terms and conditions under which the Minister will provide funding in support of the Project (as defined herein).

**2. Interpretation**

**2.1 Definitions.**

In this Agreement, a capitalized term has the meaning given to it in this section, unless otherwise specified:

“**Acquisition or Divestiture**” means an acquisition of a business, the sale of a business or a merger or amalgamation.

“**Activity**” means a significant task that must take place in order to complete the Project. It has duration, during which time the work of that task is performed, and may have resources and costs associated with that task as set out in Form C1- PROJECT COSTS BREAKDOWN of Schedule 1 - *Statement of Work*.

“**Affiliated Person**” means an affiliated person as defined in the *Income Tax Act*, as amended.

“**Agreement**” means this contribution agreement including all the schedules attached hereto, as such may be amended, restated or supplemented, from time to time.

“**Background Intellectual Property**” means Intellectual Property that is not Project Intellectual Property and that is required for the carrying out of the Project or the exploitation of the Project Intellectual Property.

“**Background Intellectual Property Rights**” means the Intellectual Property Rights in Background Intellectual Property.

“**Benefits Commitments**” means those activities described in Subsection 6.3 of this Agreement that will generate benefits to Canada.

“**Benefits Phase**” means the period from the Project Completion Date to and including the last day of the Term.

“**Change in Control**” of the Recipient means:

- (a) if the Recipient is a public company, the acquisition by an individual or company (or two or more of them acting in concert) that results in its or their direct or indirect beneficial ownership of 20% or more of outstanding shares of voting stock of the Recipient; or
- (b) if the Recipient is a private company, the acquisition by an individual or company (or two or more of them acting in concert) that results in its or their direct or indirect beneficial ownership of 50% or more of the voting stock in the Recipient; or
- (c) if the Recipient enters into a binding obligation to sell, sells or otherwise disposes of all or substantially all of its assets.

“**Claim Period**” means the following quarters of a calendar year: January 1 to March 31, April 1 to June 30, July 1 to September 30 and October 1 to December 31.

“**Collaboration**” means the Recipient’s association with one or more Collaboration Partners for the purpose of research and development.

“**Collaboration Partner**” means, other than the Recipient and sub-contractors, any small and medium-sized Canadian based enterprise, any Canadian research institute, any licensed or accredited academic, post-secondary institution in Canada that is/are involved in the Collaboration.

“**Contribution**” means the funding, in Canadian dollars, made available by the Minister under this Agreement.

“**CO-OP Term**” means a four (4) month full-time position.

“**Dispose**” means, as regards a Project Asset, the transferring outside Canada, selling, leasing or otherwise disposing including, in the case of a prototype or pilot plant, the transfer to commercial production, but in any event, shall not include abandoning the Project Asset for legitimate business reasons, such as the disposal of obsolete or disused equipment or materials.

“**Eligibility Date**” means [\_\_\_\_\_]. [*Eligibility date omitted as competitively sensitive information.*]

“**Eligible Costs**” means the costs associated with work performed in Canada, or outside of Canada to the extent explicitly permitted in this Agreement that are incurred and paid by the Recipient in respect of the Project, and in accordance with Schedule 3 - *Cost Principles*, excluding any costs prohibited or deemed ineligible elsewhere in this Agreement.

“**Eligible Not-Supported Costs**” means those Eligible Costs that are specifically identified in Schedule 1 - *Statement of Work* as not being supported, including those Eligible Costs that are in excess of limits imposed on indirect (overhead) costs under Schedule 3 – *Cost Principles* of this Agreement.

“**Eligible Supported Costs**” means any Eligible Costs, excluding Eligible Not-Supported Costs.

“**Event of Default**” means the events of default listed in Subsection 14.1 of this Agreement.

“**Execution Date**” means the date of the last signature to this Agreement such that the Agreement is signed and dated by all Parties.

“**Fair Market Value**” means the price that would be agreed to in an open and unrestricted market between knowledgeable and willing parties dealing at arm’s length, who are fully informed and not under any compulsion to transact.

“**Force Majeure**” means any cause which is unavoidable or beyond the reasonable control of the Recipient, including war, riot, insurrection, strikes, or any act of God or other similar circumstance and which could not have been reasonably circumvented by the Recipient without incurring unreasonable cost.

“**FTE**” or “**Full Time Equivalent**” means each employee or, where applicable, intern, who works for the Recipient on a full-time basis (i.e. they are responsible to work at least 2,000 hours for the Recipient when calculated on an annual basis) and, in the case of hourly paid employees or interns who are responsible to work for the Recipient less than on a full-time basis, each equivalent to such a full-time worker, where the number of such equivalents is calculated by dividing (a) by (b) where (a) = the aggregate of all hours worked by such individuals for the Recipient including hours taken by them as paid vacation, sick leave, and for other similar reasons, calculated on an annual basis, and (b) = 2,000 hours.

“**Government Fiscal Year**” means the period from April 1 of one year to March 31 of the following year.

“**Highly Skilled**” means an employee that requires specialized training in order to operate, manage or participate in the Project. This may include scientists, engineers, managers and specialized trades.

“**Intellectual Property**” means all inventions, whether or not patented or patentable, all commercial and technical information, whether or not constituting trade secrets, and all copyrightable works, industrial designs, integrated circuit topographies, and distinguishing marks or guises, whether or not registered or registrable.

“**Intellectual Property Rights**” means all rights recognized by law in or to Intellectual Property, including but not limited to Intellectual Property rights protected through legislation. These shall include patents, copyrights, industrial design rights, integrated circuit topography rights, rights in trademarks and trade names, all rights in applications and registrations for any of the foregoing, and all rights in trade secrets and confidential information.

“**Interest Rate**” means the Bank Rate, as defined in the *Interest and Administrative Charges Regulations*, in effect on the due date, plus 300 basis points, compounded monthly. The Interest Rate for a given month can be found at:

<http://www.tpsgc-pwpsc.gc.ca/recgen/txt/taux-rates-eng.html>

“**Master Schedule**” means a summary-level Project schedule that identifies the major Activities and work breakdown structure components and Milestones as reflected in Form A – MASTER SCHEDULE (Gantt Chart) of Schedule 1 - *Statement of Work*.

“**Material Change**” is a significant change in the scope, objectives, outcomes or benefits of the Project including without limitation, the following:

- (a) The Project is not completed or not expected to be completed by the Project Completion Date;
- (b) the estimated Total Eligible Supported Costs set out in Form C2 – ESTIMATED COST BREAKDOWN BY FISCAL YEAR of Schedule 1 – *Statement of Work* are expected to be reduced or are expected to be exceeded by twenty percent (20%) or more;
- (c) a change in the locations where the Project is to be performed as identified in Form D – PROJECT LOCATION AND COSTS of Schedule 1 – *Statement of Work*.



“**Milestone**” means a significant point or event in the Project as set forth in Form B - MILESTONES of Schedule 1 - *Statement of Work*.

“**Party**” means the Minister, or the Recipient or any Guarantor, and “**Parties**” means all of them.

“**Project**” means the project as described in Schedule 1 - *Statement of Work*.

“**Project Asset**” means an asset which, in whole or in part, has been acquired, created, developed, advanced and/or contributed to by the Contribution.

“**Project Completion Date**” means [\_\_\_\_\_]. [*Project completion date omitted as competitively sensitive information.*]

“**Project Intellectual Property**” means all Intellectual Property conceived, produced, developed or reduced to practice in carrying out the Project by the Recipient and/or any Affiliated Persons of the Recipient, or any of their employees, agents, contractors or assigns.

“**Project Intellectual Property Rights**” means the Intellectual Property Rights in the Project Intellectual Property.

“**Public Office Holder**” means a public office holder as defined in the *Lobbying Act*, as amended.

“**Recipient Fiscal Year**” means the period for which the Recipient’s accounts in respect of its business or property are prepared for purposes of assessment under the *Income Tax Act*, as amended.

“**Resulting Products**” means all products, services or processes that:

- a. are produced using the Project Intellectual Property;
- b. incorporate any of the Project Intellectual Property; or
- c. result from or are used to carry out the Project.

“**Schedule**” means a schedule to this Agreement, including any amendments or supplements.

“**Similar Goods**” means goods or services that closely resemble the goods or services being transferred, in respect of their component materials, form, function and characteristics, and are capable of performing an equivalent function as, and of being commercially interchangeable with, the goods being transferred.

“**Technology Readiness Level**” or “**TRL**” means technology readiness according to the Technology Readiness Level scale described below.

**Technology Readiness Level****Description****TRL 1—Basic principles observed and reported**

Lowest level of technology readiness. Scientific research begins to be translated into applied research and development (R&D). Examples might include paper studies of a technology's basic properties.

**TRL 2—Technology concept and/or application formulated**

Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions.

**TRL 3—Analytical and experimental critical function and/or characteristic proof of concept**

Active R&D is initiated. This includes analytical studies and laboratory studies to physically validate the analytical predictions of separate elements of the technology.

**TRL 4—Product and/or process validation in laboratory environment**

Basic technological products and/or processes are tested to establish that they will work.

**TRL 5—Product and/or process validation in relevant environment**

Reliability of product and/or process innovation increases significantly. The basic products and/or processes are integrated so they can be tested in a simulated environment.

**TRL 6—Product and/or process prototype demonstration in a relevant environment**

Prototypes are tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a simulated operational environment.

**TRL 7—Product and/or process prototype demonstration in an operational environment**

Prototype near or at planned operational system and requires demonstration of an actual prototype in an operational environment (e.g. in a vehicle).

**TRL 8—Actual product and/or process completed and qualified through test and demonstration**

Innovation has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development.

**TRL 9—Actual product and/or process proven successful**

Actual application of the product and/or process innovation in its final form or function.

“**Term**” means the duration of this Agreement as set out in Subsection 3.2 of this Agreement.

“**Work Phase**” means the period of time from the Eligibility Date to and including the Project Completion Date.

2.2 **Singular/Plural.** Wherever from the context it appears appropriate, each term stated in either the singular or plural shall include the singular and the plural.

2.3 **Entire Agreement.** Unless amended in writing by the Parties, this Agreement comprises the entire agreement between the Parties in relation to the Project. No prior document, negotiation, provision, undertaking or agreement in relation to the subject matter of this Agreement has legal effect. No representation or warranty, whether express, implied or otherwise, has been made by the Minister to the Recipient, except as expressly set out in this Agreement.

2.4 **Inconsistency.** In case of inconsistency or conflict between a provision contained in the part of the Agreement preceding the signatures and a provision contained in any of the Schedules to this Agreement, the provision contained in the part of the Agreement preceding the signatures will prevail.

2.5 **Schedules.** This Agreement contains the following Schedules as described below, which form an integral part of this Agreement:

- Schedule 1 - *Statement of Work*
- Schedule 2 - *Communications Obligations*
- Schedule 3 - *Cost Principles*
- Schedule 4 - *Reporting Requirements*
- Schedule 5 - *Resolution Process*

### 3. **Duration of Agreement**

3.1 **Execution.** This Agreement must be signed by the Recipient and received by the Minister within thirty (30) days of its signature by the Minister, failing which it will be null and void.

3.2 **Duration of Agreement.** This Agreement will commence on the Execution Date and will expire, subject to Subsection 3.3, [\_\_\_\_\_] years following the Project Completion Date unless terminated earlier in accordance with the terms of this Agreement. [*Expiration date omitted as competitively sensitive information.*]

3.3 **Survival Period.** Notwithstanding the provisions of Subsection 3.2 above, the rights and obligations described in the following Sections or Subsections will survive for a period of three (3) years beyond the Term or early termination of the Agreement:

Section 7 - Government Funding  
 Subsection 8.5 - Overpayment by Minister  
 Section 9 - Reporting, Monitoring, Audit and Evaluation  
 Subsection 10.2(d) - Disposal of Assets  
 Subsection 13.1 - Indemnification  
 Subsection 13.2 - Limitation of Liability  
 Section 14 - Default and Remedies  
 Subsection 17.2 - Interest  
 Subsection 17.3 - Set-off Rights of Minister  
 Subsection 17.8 - Applicable Law

#### 4. **The Contribution**

- 4.1 **Contribution.** Subject to the terms and conditions of this Agreement, the Minister agrees to make a non-repayable Contribution to the Recipient in respect of the Project in an amount not exceeding the lesser of (a) and (b) as follows:
- (a) seventy-five percent (75%) of the Eligible Supported Costs; and
  - (b) fourteen million fifty-three thousand and five hundred dollars (\$14,053,500).
- 4.2 **Funding Period.** The Minister will not contribute to any Eligible Supported Costs incurred by the Recipient prior to the Eligibility Date or after the Project Completion Date. In no event will Eligible Supported Costs incurred prior to the Execution Date exceed [\_\_\_\_\_] percent ([\_\_\_\_\_]%) of the “estimated Total Eligible Supported Costs” set out in Form C2 - ESTIMATED COST BREAKDOWN BY FISCAL YEAR of Schedule 1 - *Statement of Work*. [*Percentage of estimated Total Eligible Supported Costs omitted as competitively sensitive information.*]
- 4.3 **Fiscal Year.** The payment of the Contribution per Government Fiscal Year is estimated at amounts specified in Form C2 - ESTIMATED COST BREAKDOWN BY FISCAL YEAR of Schedule 1 - *Statement of Work*. The Minister will have no obligation to pay any amounts in any Government Fiscal Year other than those specified in Form C2 - ESTIMATED COST BREAKDOWN BY FISCAL YEAR of Schedule 1 - *Statement of Work*. If, for a given Government Fiscal Year, the Recipient claims an amount less than the estimated Contribution for that Government Fiscal Year specified in Form C2 - ESTIMATED COST BREAKDOWN BY FISCAL YEAR of Schedule 1 - *Statement of Work*, the Minister may consider any request to reprofile the excess funds to future Government Fiscal Years before the Project Completion Date.
- 4.4 **Overruns.** The Recipient shall be responsible for all costs of the Project, including costoverruns, if any.
- 4.5 **Holdbacks.** Notwithstanding any other provisions of this Agreement, the Minister may, at the Minister's sole discretion, withhold up to ten percent (10%) of the Contribution until:
- (a) the Project is completed to the satisfaction of the Minister;

(b) the final report described in Subsection 8.3(c) has been submitted to the satisfaction of the Minister;

(c) the Minister has approved the final claim described in Subsection 8.3.

## 5. **Recipient's Obligations**

5.1 **Project Completion Date.** The Recipient agrees to carry out the Project in a diligent and professional manner using qualified personnel, and complete same on or before the Project Completion Date.

5.2 **Project Location.** Except as otherwise permitted in Subsection 6.4 below, the Recipient agrees to carry out the Project exclusively in Canada located in Toronto and the Greater Toronto Area, Ontario, and Montreal, Quebec.

5.3 **Benefits Commitments.** The Recipient agrees to conduct Benefits Commitments exclusively in Canada, as per Subsection 6.3.

5.4 **Compliance.** The Recipient agrees to satisfy and comply with all other terms, conditions and obligations contained in this Agreement.

## 6. **Special Conditions**

The Recipient covenants and agrees to the following:

### 6.1 **Guarantee**

(a) **Guarantee.** In consideration of the Minister providing the Contribution, the Guarantor guarantees the complete performance and fulfillment of every obligation of the Recipient under this Agreement, including without limitation, the completion of the Project in accordance with this Agreement. If the Recipient fails to perform or otherwise satisfy any of its obligations related to the Agreement, immediately after receiving a written demand from the Minister, the Guarantor must perform or satisfy, or arrange for the performance or satisfaction of, all outstanding obligations of the Recipient. The Guarantor's obligations under this Guarantee are as a primary obligor and not only as a surety. The Minister is not required to resort to or exhaust any recourse that it may have against the Recipient or any other person before being entitled to make claim against the Guarantor. As a result of the forgoing, the Guarantor or the Recipient may be compelled separately to perform any obligation contained in this Agreement.

(b) **Taxes.** Any payment to be made by the Guarantor in respect of this Agreement shall be made free and clear of and without deduction or withholding for or on account of any present and future taxes, levies, imposts, stamp taxes, duties, charges, fees deductions, withholdings, penalties or interest (collectively, "Taxes") provided that if the Guarantor is required to withhold or deduct any taxes from such payments, the sum payable shall be increased as necessary so that after making all required withholdings or deductions, the Minister receives an amount equal to the sum he/she would have received had no such withholding or deduction been made.

- (c) **Costs.** The Guarantor agrees to reimburse the costs and expenses incurred by the Minister in enforcing the guarantee under Paragraph 6.1(a).
- (d) **Representations.** The Guarantor represents to the Minister that it has the power and authority, and has met all legal requirements to grant the guarantee under Paragraph 6.1(a) and that such guarantee is enforceable against it in accordance with its terms.

## 6.2 Pre-Disbursement

The Recipient covenants and agrees to the following:

- 6.2.1 (a) **First Claim.** Upon submission of the first claim, the Recipient shall provide evidence to the Minister, to the Minister's satisfaction, that it has available funds to carry out the Project and continue operating for the remainder of the Government Fiscal Year in which the claim is received by the Minister, or for a period of six months from the day the claim is received by the Minister, whichever is greater. No disbursement of the Contribution shall be made prior to the Recipient providing such satisfactory evidence. If the Recipient fails to satisfy such condition within one hundred and twenty (120) days of the receipt of the first claim, the Minister may, at his discretion, terminate the Agreement upon written notice.
- (b) **Annual.** At the beginning of each new Government Fiscal Year during the Work Phase, the Recipient shall provide evidence to the Minister, to the Minister's satisfaction, that it has available funds to carry out the Project and continue operating for that Government Fiscal Year. No disbursement of the Contribution shall be made prior to the Recipient providing such satisfactory evidence. If the Recipient fails to satisfy such condition within one hundred and twenty (120) days of the beginning of each Government Fiscal Year, the Minister may, at his discretion, terminate the Agreement upon written notice.
- 6.2.2 [\_\_\_\_\_] **Strategy.** Prior to the first disbursement of the Contribution, the Recipient shall develop a [\_\_\_\_\_] plan that will be shared with the Minister, to the Minister's satisfaction, that will outline all efforts undertaken by the Recipient to [\_\_\_\_\_] related to the Project. This plan should also include [\_\_\_\_\_] educational awareness training for employees. The Recipient agrees to report annually on any changes to this plan [\_\_\_\_\_]. [*Nature of strategy and timeframe omitted as competitively sensitive information.*]

### 6.3 **Benefits Commitments.**

#### 6.3.1 **Strengthen Canada's response to COVID-19**

- (a) The Recipient commits to work with [\_\_\_\_\_] to ensure that any treatment developed within the scope of this Project will be accessible and available for the Canadian population on a timely basis. [*Name of party omitted as competitively sensitive information.*]
- (b) The Recipient will [\_\_\_\_\_] to ensure that, once commercially available, the treatment will be made available globally. [*Nature of action omitted as competitively sensitive information.*]
- (c) The Recipient commits to work with [\_\_\_\_\_] and other parties, in good faith and [\_\_\_\_\_] , to increase domestic and global affordability and access to Resulting Products, in accordance with relevant guidance and policies published by the World Health Organization and the United Nations. [*Name of party and nature of commitment omitted as competitively sensitive information.*]

#### 6.3.2 **Create and maintain highly-skilled jobs in Canada**

- (a) The Recipient will create at least six (6) FTEs in Canada [\_\_\_\_\_] while maintaining its existing eight (8) FTEs in Canada, totaling fourteen (14) FTEs [\_\_\_\_\_] . [*Timeframe of creating FTEs omitted as competitively sensitive information.*]
- (b) The Recipient will maintain [\_\_\_\_\_] fourteen (14) FTEs [\_\_\_\_\_] . [*Timeframe and calculation of number of FTEs omitted as competitively sensitive information.*]
- (c) The Recipient will provide [\_\_\_\_\_] . [*Nature, timeframe and recipient of information provided omitted as competitively sensitive information.*]
- (d) To contribute to the development of tomorrow's workforce, the Recipient will employ at least [\_\_\_\_\_] ([\_\_\_\_\_] ) CO-OP Term position in Canada [\_\_\_\_\_] . [*Minimum number of CO-OP Term positions in Canada and timeframe omitted as competitively sensitive information.*]

#### 6.3.3 **Commitment to [\_\_\_\_\_]**

- (a) The Recipient shall implement a [\_\_\_\_\_] , which will stipulate measurable goals and outcomes. The Recipient will report to the Minister on progress achieved regarding its [\_\_\_\_\_] on an annual basis [\_\_\_\_\_] .
- (b) The Recipient will work to increase [\_\_\_\_\_] in Canada and will report annually to the Minister on progress achieved during the Term.
- (c) In addition to [\_\_\_\_\_] , the Recipient will commit to [\_\_\_\_\_] , during the Term.

[*Nature of commitments and timeframe omitted as competitively sensitive information.*]

**6.4 Work Outside of Canada**

- (a) In consideration of the Minister providing the Contribution, the Recipient may incur up to [\_\_\_\_\_] % of Eligible Supported Costs for work outside of Canada which will be identified as foreign costs. Any costs over this threshold will be considered ineligible and will not be subject to claim. *[Percentage of Eligible Supported Costs omitted as competitively sensitive information.]*
- (b) In addition to the foreign costs allowed under Paragraph 6.4(a), up to [\_\_\_\_\_] % of Eligible Supported Costs may [\_\_\_\_\_] , as identified in Schedule 1 – *Statement of Work*. Specifically, [\_\_\_\_\_] . *[Percentage of Eligible Supported Costs and potential use of such costs omitted as competitively sensitive information.]*
- (c) The Recipient will make best efforts to conduct all clinical trials in Canada unless [\_\_\_\_\_] . *[Nature of exception omitted as competitively sensitive information.]*

**6.5 Regulatory approval for clinical trials**

- (a) The Recipient must demonstrate that it is securing the required regulatory approval from Health Canada to undertake clinical trials as outlined within Schedule 1 – *Statement of Work* of the Project by providing the Minister, to his satisfaction, with a copy of the following regulatory approval documents within 30 days of receipt by the Recipient:
  - i. Clinical Trials Phase II: No Objection Letter (NOL) from Health Canada: This NOL will be provided to the Minister no later than the [\_\_\_\_\_]. For clarity, Phase II trials include clinical trials to evaluate the efficacy of the drug in patients with medical conditions to be treated, diagnosed or prevented and to determine the side effects and risks associated with the drug. *[Timeline omitted as competitively sensitive information.]*
- (b) If at any time the Recipient receives a Not Satisfactory Notice (NSN) from Health Canada related to the Project, the Recipient will immediately inform the Minister and the Minister may, at his discretion, terminate the Agreement. Any Project costs incurred by the Recipient after the date of the NSN will not be eligible for reimbursement by the Minister.

**6.6 Monitoring progress of clinical trials**

- (a) The Minister may request that the Recipient provide copies of the pre-clinical and clinical documents submitted to Health Canada within the Clinical Trial Application (CTA) for Phase II.



- (b) The Recipient acknowledges that the Minister may share, at his discretion, any of the documentation listed above with governmental experts from the Public Health Agency of Canada, the National Research Council, Health Canada, the Canadian Institutes of Health Research, and external advisors on the Minister's Therapeutics Committee for the purpose of validating progress related to the Project.

**6.7 Continued engagement by [\_\_\_\_\_]**

- (a) [\_\_\_\_\_]. This subsection 6.7(a) constitutes an indication of intent only and creates no liability or obligation of any nature whatsoever among the Parties hereto with respect to [\_\_\_\_\_].
- (b) [\_\_\_\_\_]. This subsection 6.7(b) constitutes an indication of intent only and creates no liability or obligation of any nature whatsoever among the Parties hereto with respect to [\_\_\_\_\_].

*[Nature of continued engagement omitted as competitively sensitive information.]*

**6.8 Annual Benefits Reporting**

- (a) In addition to Schedule 4 - *Reporting Requirements*, on an annual basis and for the Term, the Recipient shall provide information identifying the Project's achievements relative to planned outcomes and benefits, including:
- i. Number of therapeutics and vaccines (doses) discovered, developed, manufactured, and/or distributed;
  - ii. Number of FTEs created and maintained with average and range of salary levels;
  - iii. Market share secured or captured;
  - iv. Composition of workforce, including diversity and gender representation;
  - v. Dollars spent on gross Canadian R&D and gross global R&D;
  - vi. Productivity improvement levels;
  - vii. Number and details of post-secondary institution collaborations;
  - viii. Number and activities of CO-OP Term engagements; and
  - ix. Training activities of the workforce.
- (b) In addition to Schedule 4 - *Reporting Requirements*, on an annual basis and for the Term, the Recipient shall provide information on the Project derived benefits but not limited to information on:
- i. Number of therapeutics and vaccines (doses) discovered, developed, manufactured, and/or distributed;
  - ii. Impact to the growth of the Canadian supply chain;
  - iii. New Intellectual Property generated;
  - iv. Licenses granted without consent under Subsection 11.4.2;
  - v. R&D and product development levels as a function of revenue;

- vi. Details of increased collaborations, including associated costs and activities;
- vii. Efforts to reduce environmental footprint and/or increase environmental sustainability of the company;
- viii. Efforts to create opportunities for [\_\_\_\_\_] to scale and enter the [\_\_\_\_\_] ecosystem;
- ix. Details of internal Artificial Intelligence (AI) and Machine Learning (ML) applications and processes; and
- x. Productivity improvement levels.

*[Nature of opportunities omitted as competitively sensitive information.]*

- 6.9. **Amendment.** The Recipient shall provide written notice to the Minister of any changes which may have an impact on Schedule 1 – *Statement of Work* or on the Benefits Commitments in accordance with 6.3 of this Agreement. The Recipient shall provide to the satisfaction of the Minister sufficient written reasons to justify modifications to the Agreement. At the Minister’s sole discretion, the Minister may request a formal amendment to be executed by the Parties. The Parties agree to negotiate in good faith such amendments. If, after following the process in Schedule 5 – *Resolution Process*, failure to agree will result in the Minister declaring an Event of Default in accordance with 14.1 of this Agreement.

## 7. **Government Funding**

- 7.1 The Recipient represents that the list below states all funding from federal, provincial, territorial or municipal governments in Canada (“Government Funding”), requested or received by the Recipient or that the Recipient currently expects to request or receive to cover any of the Eligible Supported Costs. The list below excludes provincial and federal investment tax credits.

Federal	\$ 14,053,500 (SIF)
	\$ [_____]
Provincial	\$ 0
Territorial	\$ 0
Municipal	\$ 0
	_____
Total	\$ [_____]

*[Portion of the funding received by the Recipient from other agencies of the federal government and total amount of government funding omitted as competitively sensitive information.]*

- 7.2 The Recipient shall inform the Minister of any change to the amount of Government Funding identified in Subsection 7.1. The Recipient shall also inform the Minister of any provincial and federal investment tax credits, received or expected to be received by the Recipient for the Eligible Supported Costs. Such notice must be made promptly in writing, and in any case not later than thirty (30) days following any change. In the event of additional Government Funding, the Minister will have the right to either reduce the Contribution to the extent of any additional funding received by the Recipient or require the Recipient to repay the Contribution hereunder equal to the amount of any such additional funding received by the Recipient in accordance with Subsection 8.5.

7.3 In no instance will the total Government Funding (including SIF funding, provincial and federal investment tax credits) towards Eligible Supported Costs of the Project be allowed to exceed [\_\_\_\_\_] percent ([\_\_\_\_\_]%) of total Eligible Supported Costs. [*Percentage of total Eligible Supported Costs omitted as competitively sensitive information.*]

## 8. **Claims and Payments**

8.1 **Separate Records.** The Recipient shall maintain accounting records that account for the Contribution paid to the Recipient and the related Project costs, separate and distinct from any other sources of funding.

8.2 **Claims Procedures.** The Minister will reimburse claims for Eligible Supported Costs submitted for a Claim Period, provided there is no Event of Default and the claims are:

- (a) submitted for each Claim Period, except for the first claim which will start on the Eligibility Date;
- (b) submitted within forty-five (45) days of the end of each Claim Period;
- (c) accompanied with details of all costs being claimed according to Schedule 3 – *Cost Principles*, which have been incurred by the Recipient and which will be substantiated by such documents as may be required by the Minister and presented in accordance with the Activities and the Milestones contained in Schedule 1 - *Statement of Work*;
- (d) certified, in a form satisfactory to the Minister, by the chief financial officer of the Recipient or such other person considered satisfactory to the Minister;
- (e) adjusted, if necessary, by including a deduction for expenses included in a previous claim which were not eligible expenses according to Eligible Supported Costs definition in this Agreement or which were not paid by the Recipient;
- (f) accompanied by a report containing:
  - (i) the Recipient's revised projections of the Project cash flows for the current Government Fiscal Year;
  - (ii) an identification of any planned or completed transfer to commercial production, transfer outside of Canada, sale, lease or other disposal of equipment funded in whole or in part by the Contribution;
  - (iii) an itemized list of foreign sub-contracting costs, if any;

- (iv) the foreign exchange rates used in the claim;
  - (v) progress report as specified in Subsection 1.2 of Schedule 4 - *Reporting Requirements*; and
  - (vi) such other information as the Minister may request from time to time.
- (g) accompanied by a statement from the Recipient repeating and confirming the representations set out in Section 10 of this Agreement as required by Subsection 10.3, and a certification that there are no Events of Defaults (and no state of facts exist which, with the giving of notice or the passing of time, or both, would constitute an Event of Default);
  - (h) substantially ( $\pm$  20 percent (20%)) consistent with the cost estimates of Schedule 1 - *Statement of Work*; and
  - (i) accompanied by the Recipient's travel policy (first claim only).

8.3 **Final Claim Procedures.** The Recipient shall submit, within forty-five (45) days after the Project Completion Date, the final claim along with:

- (a) an itemized statement certified by the Recipient's chief financial officer, or such other person considered satisfactory to the Minister, attesting to the total Eligible Supported Costs for the Project incurred and paid;
- (b) a statement of the total government funding (federal, provincial and municipal funding as well as tax credits) received or requested to cover the Eligible Supported Costs of the Project; and
- (c) a final progress report on the Project, as more fully described in Subsection 1.3 of Schedule 4 - *Reporting Requirements*.

8.4 **Payment Procedures.**

- (a) The Minister shall review and approve the documentation submitted by the Recipient following the receipt of the Recipient's claim and in the event of any deficiency in the documentation, the Minister will notify the Recipient and the Recipient shall immediately take action to address and rectify the deficiency.
- (b) Subject to the maximum Contribution amounts set forth in Subsection 4.1 and all other conditions contained in this Agreement, the Minister shall pay to the Recipient a percentage of the Eligible Supported Costs set forth in the Recipient's claim based on the sharing ratio identified in Paragraph 4.1 (a), in accordance with the Minister's customary practices.

- (c) The Minister may request at any time that the Recipient provide satisfactory evidence to demonstrate that all Eligible Supported Costs claimed have been paid.
- (d) The Minister may [\_\_\_\_\_].
  - (i) [\_\_\_\_\_].
  - (ii) [\_\_\_\_\_].

*[Details of the payment procedures of the Minister omitted as competitively sensitive information.]*

8.5 **Overpayment by Minister.** Where the Minister determines that the amount of the Contribution disbursed exceeds the amount to which the Recipient is entitled, the Recipient shall repay to the Minister, promptly and no later than thirty (30) days from notice from the Minister, the amount of the overpayment together with interest at the Interest Rate from the date of the notice to the day of payment to the Minister in full. Any such amount is a debt due to Her Majesty and is recoverable as such.

## 9. **Reporting, Monitoring, Audit and Evaluation**

9.1 **Reports.** The Recipient agrees to provide the Minister with the reports as described in Schedule 4 - *Reporting Requirements*, to the Minister's satisfaction.

9.2 **Additional Information.** Upon request of the Minister and at no cost to the Minister, the Recipient shall promptly elaborate upon any report submitted or provide such additional information as may be requested.

9.3 **Minister's Right to Audit Accounts and Records.** The Recipient shall, at its own expense, maintain and preserve in Canada and make available for audit and examination by the Minister or the Minister's representatives all books, accounts and records relating to this Agreement or the Project held by the Recipient, its Affiliated Persons, agents and contractors and of the information necessary to ensure compliance with the terms and conditions of this Agreement, including repayment to the Minister. The Minister will have the right to conduct such audits at the Minister's expense as may be considered necessary.

Unless otherwise agreed to in writing by the Minister, the Recipient and its Affiliated Persons, agents and contractors shall maintain and preserve all books, accounts, invoices, receipts and records and all other documentation related to this Agreement until the end of the Recipient Fiscal Year that ends seven (7) years after the fiscal year of the date on which they were created.

9.4 **Auditor General Rights.** The Recipient recognizes, acknowledges and accepts that the Auditor General of Canada may, at the Auditor General's cost, after consultation with the Recipient, conduct an inquiry under the authority of subsection 7.1 (1) of the *Auditor General Act* in relation to any funding agreement (as defined in subsection 42 (4) of the *Financial Administration Act*) with respect to the use of the Contribution received.

For the purposes of any such inquiry undertaken by the Auditor General, the Recipient shall provide, upon request and in a timely manner, to the Auditor General or anyone acting on behalf of the Auditor General,

- (a) all records held by the Recipient, its Affiliated Persons, agents or contractors relating to this Agreement and the use of the Contribution provided under this Agreement; and
- (b) such further information and explanations as the Auditor General, or anyone acting on behalf of the Auditor General, may request relating to this Agreement or the use of the Contribution.

9.5 **Access to Records.** The Recipient shall, at all times, ensure that its agents, employees, assigns, contractors, and Affiliated Persons are obligated to provide to the Minister or the Auditor General or their authorized representatives records and other information that are in possession of those agents, employees, assigns, contractors, and Affiliated Persons and that relate to this Agreement or to the use of the Contribution.

9.6 **Access to Premises.** The Recipient and its Affiliated Persons shall provide the representatives of the Minister reasonable access to premises to inspect and assess the progress of the Project or any element thereof and supply promptly on request such data as the Minister may reasonably require for statistical or Project evaluation purposes.

9.7 **Evaluation.** The Recipient shall, at its own expense, participate in the preparation of case studies reporting on the outcomes of the Project, to be completed by the Minister or the Minister's agents, in order to assist in the Minister's preparation of an overall evaluation of the value and effectiveness of SIF.

**10. Representations, Warranties and Covenants**

10.1 **Representations.** The Recipient represents and warrants that:

- (a) it is duly incorporated under Canadian law and validly existing and in good standing and has the power and authority to carry on its business, to hold property and to enter into this Agreement and undertakes to take all necessary action to maintain itself in good standing, to preserve its legal capacity and to remain incorporated in a Canadian jurisdiction;
- (b) signatories to the Agreement have been duly authorized to execute and deliver this Agreement;
- (c) the execution, delivery and performance of this Agreement have been duly and validly authorized and that when executed and delivered, the Agreement will constitute a legal, valid and binding obligation enforceable in accordance with its terms;
- (d) it is under no obligation or prohibition, nor is it subject to or threatened by any actions, suits or proceedings that could or would prevent compliance with the Agreement. The Recipient shall inform the Minister forthwith of any such occurrence;
- (e) the execution and delivery of this Agreement and the performance by the Recipient of its obligations hereunder will not, with or without the giving of notice or the passage of time or both:
  - (i) violate the provisions of the Recipient's by-laws, any other corporate governance document subscribed to by the Recipient or any resolution of the Recipient;
  - (ii) violate any judgment, decree, order or award of any court, government agency, regulatory authority or arbitrator; or
  - (iii) conflict with or result in the breach or termination of any material term or provision of, or constitute a default under, or cause any acceleration under, any license, permit, concession, franchise, indenture, mortgage, lease, equipment lease, contract, permit, deed of trust or any other instrument or agreement by which it is bound;
- (f) it has obtained or will obtain all necessary licences and permits in relation to the Project, which satisfy the requirements of all regulating bodies of appropriate jurisdiction;
- (g) it owns or holds sufficient rights in any Intellectual Property required to carry out the Project; and,

(h) the description of the Project in Schedule 1 - *Statement of Work* is complete and accurate.

10.2 **Covenants.** The Recipient covenants and agrees that:

- (a) it is solely responsible for providing or obtaining the funding, in addition to the Contribution, required to carry out the Project and the fulfilment of the Recipient's other obligations under this Agreement;
- (b) no Material Change within the control of the Recipient will be made without the prior written consent of the Minister. In the event that the Minister does not consent to such a Material Change, the Minister may exercise the remedies set out in Subsection 14.3;
- (c) no Change in Control will be made without the prior written consent of the Minister.
- (i) In the case where the Recipient is a private company, the Recipient shall notify the Minister, in writing, no later than thirty (30) days prior to the date from which the Recipient expects to have a Change in Control, and the Minister will confirm if it consents to the Change in Control. Subject to subsection 17.13, consent will not be unreasonably withheld.
- (ii) In the case where the Recipient is a public company, the Recipient shall notify the Minister, in writing, of any Change in Control no later than thirty (30) days following any Change in Control.
- (iii) Prior to providing consent, the Minister may, as a result of notification of the Change in Control, require additional due diligence to determine the impacts of the Change in Control, such as the following, but not be limited to: the legal status of the Recipient pursuant to the Strategic Innovation Fund's program terms and conditions; the impact on the recipient's finances and the Project to ensure that the Recipient is able to complete the Project; and, any other considerations that may emerge. The purpose of the due diligence is to ensure that the Minister can fully evaluate any additional considerations that were not identified at the time of authorizing the funding. In the event that the Minister does not consent to such a Change in Control, the Minister may exercise the remedies set out in Subsection 14.3;
- (d) it shall retain possession and control of all Project Assets the cost of which has been contributed to by the Minister under the Agreement, and the Recipient shall not Dispose of the same without the prior written consent of the Minister, other than in the ordinary course of business where the aggregate book value of such Project Assets for each occurrence is no greater than [\_\_\_\_\_] dollars (\$[\_\_\_\_\_]); [*Dollar amount omitted as competitively sensitive information.*]



- (e) it shall, in advance and in writing, and subject to Paragraphs 10.2 (c) and (d) of this Agreement, notify the Minister in the event of any Acquisition or Divestiture. In the case where the Recipient is a public company, the Recipient shall notify the Minister in writing of any Acquisition or Divestiture contemporaneously with any press release, or filing of a public regulatory notice in respect of such Acquisition or Divestiture;
- (f) that it shall not make any dividend payments or other shareholder distributions that would prevent it from implementing the Project or satisfying any other of the Recipient's obligations under this Agreement, including, without limitation, the making of repayments to the Minister hereunder;
- (g) it shall comply with the federal visibility requirements set out in Schedule 2 - *Communications Obligations*; and
- (h) it shall comply with all laws and regulations applicable to it.

10.3 **Renewal of Representations.** It is a condition precedent to any disbursement under this Agreement that the representations, warranties and covenants contained in this Agreement are true at the time of payment and that the Recipient is not in default of compliance with any terms of this Agreement.

## 11. **Intellectual Property**

11.1 **Background Intellectual Property.** The Recipient must own the Background

Intellectual Property or hold sufficient Background Intellectual Property Rights to permit the Project to be carried out.

11.2 **Project Intellectual Property and Improvements.** The Recipient must exclusively own, and retain ownership thereof in Canada, the Project Intellectual Property, the Project Intellectual Property Rights and improvements to products, processes and equipment as a result of the Project for the Term, unless otherwise agreed to by the Minister.

11.3 **Exploitation of Project Intellectual Property.** Unless otherwise agreed to by the Minister, the Recipient must own or have sufficient Intellectual Property Rights to use the Project Intellectual Property and to make, construct, cause the construction, sell and cause the sale of the Resulting Products.

11.4 **License of Project Intellectual Property and Background Intellectual Property.**

11.4.1 **Restriction on Licenses.** Except as provided in Subsection 11.4.2, the Recipient agrees not to grant any right or license to any of the Project Intellectual Property or Background Intellectual Property without the prior written consent of the Minister.

11.4.2 **Permitted Licenses Without Consent.** If all the requirements in Subsection 11.4.3 are satisfied, the Recipient may grant a right or license to any of the Project Intellectual Property or Background Intellectual Property provided that one or more of the following conditions is met:

- (a) the right or license is [\_\_\_\_\_];
- (b) the right or license is [\_\_\_\_\_]; and
- (c) the right or license is [\_\_\_\_\_].

[Conditions are omitted as competitively sensitive information.]

11.4.3 **Requirements For Licenses Without Consent.** The requirements (for the purposes of Subsection 11.4.2) are:

- (a) the right or license cannot prevent the Recipient from fulfilling its obligations in this Agreement; and
- (b) the right or license cannot prevent access, in any way, to treatments in response to COVID-19 or Resulting Products in Canada or by Canadians.

11.4.4 **Clarification Regarding Background Intellectual Property.** Notwithstanding Subsections 11.4.1, 11.4.2 and 11.4.3, nothing herein shall limit the Recipient's ability to use, commercialize and/or exploit the Background Intellectual Property, including licensing it to third parties, outside of and separate from the Project in a manner that would not restrict the development, commercialization or exploitation of the Project Intellectual Property or making or selling Resulting Products by the Recipient.

11.5 **Protection of Project Intellectual Property.** The Recipient shall take appropriate steps to protect and enforce the Project Intellectual Property. The Recipient shall provide information to the Minister in that regard, upon request.

11.6 **Crown Ownership of Intellectual Property.** The Crown will not have an ownership interest in the Project Intellectual Property nor will the Crown acquire new rights in Background Intellectual Property by virtue solely of having provided the Contribution. Rights attributed to the Crown in any other way including under the *Public Servants Inventions Act* are not in any way affected by this Agreement.

11.7 **Intellectual Property Strategy.** The Recipient will develop an Intellectual Property (IP) strategy that will be shared with the Minister within [\_\_\_\_\_] ([\_\_\_\_\_] months of the Execution Date. This strategy will support the creation, retention and protection of Intellectual Property ownership in Canada; include training for employees that increases Intellectual Property educational awareness and identify any planned Intellectual Property training activities; include a plan to commercialize Resulting Products domestically, including Intellectual Property commercialization activities, such as licensing, and anticipated collaboration activities, if any; and include a current list of Background Intellectual Property. The Recipient agrees to report annually on any changes to this strategy [\_\_\_\_\_]. [Number of months and timeframe omitted as competitively sensitive information.]

- 11.8 **Project Intellectual Property Use in Response to COVID-19.** The Minister may require the Recipient to assign, transfer or grant a license to use the (i) Project Intellectual Property and Project Intellectual Property Rights; and (ii) Background Intellectual Property and Background Intellectual Property Rights owned by the Recipient, or licensed by the Recipient with the right to sub-license, to a third party approved by the Minister upon written request from the Minister, but only to the extent necessary to ensure a sufficient domestically-sourced supply of treatments in response to COVID-19 should the Recipient be unable to ensure such a supply.
12. **Environmental and Other Requirements**
- 12.1 The Recipient represents that the Project is not a “designated project” and is not being carried out on “federal lands” as such terms are defined in the *Impact Assessment Act, 2019* (“IAA”).
- 12.2 The Recipient shall, in respect of the Project, comply with all federal, provincial, territorial, municipal and other applicable laws, including but not limited to, statutes, regulations, by-laws, rules, orders, ordinances and decrees governing the Recipient or the Project, or both, relating to environmental protection and the successful implementation of and adherence to any mitigation measures, monitoring or follow-up program that may be prescribed by the Minister or other federal, provincial, territorial, municipal tribunals or bodies, and certifies to the Minister that it has done so to date.
- 12.3 The Recipient will provide the Minister with reasonable access to any Project site for the purpose of ensuring that the terms and conditions of any environmental approval are met, and that any mitigation, monitoring or follow-up measure required has been carried out.
- 12.4 If as a result of changes to the Project or otherwise, an assessment is required in accordance with IAA for the Project, the Minister and the Recipient agree that the Minister’s obligations under this Agreement will be suspended from the moment that the Minister informs the Recipient, until (i) a decision statement has been issued to the Recipient or, if applicable, the Minister has decided that the Project is not likely to cause significant adverse environmental effects or the Governor in Council has decided that the significant adverse environmental effects are justified in the circumstances, and (ii) if required, an amendment to this Agreement has been signed, setting out any conditions included in the decision statement.
- 12.5 **Aboriginal consultation.** The Recipient acknowledges that the Minister’s obligation to pay the Contribution is conditional upon Her Majesty satisfying any obligation that Her Majesty may have to consult with or to accommodate any Aboriginal groups, which may be affected by the terms of this Agreement.
- 12.6 **Official Languages.** The Recipient agrees that any public acknowledgement of the Minister’s public support for the Project will be expressed in both official languages.

**13. Indemnification and Limitation of Liability**

13.1 **Indemnification.** Except for any claims arising from the gross negligence of, or willful misconduct by, the Minister's employees, officers, agents or servants, the Recipient agrees, at all times, to indemnify and save harmless, the Minister and any of his officers, servants, employees or agents from all and against all claims and demands, actions, suits or other proceedings (and all losses, costs and damages relating thereto) by whomsoever made, brought or prosecuted (all of the foregoing collectively, the "Claims"), where such Claims are asserted or arise from the Minister being a Party to this Agreement and exercising his rights and performing his obligations under this Agreement, to the extent such Claims result from:

- (a) the Project, its operation, conduct or any other aspect thereof;
- (b) the performance or non-performance of this Agreement, or the breach or failure to comply with any term, condition, representation or warranty of this Agreement by the Recipient, its Affiliated Persons, its officers, employees and agents, or by a third party or its officers, employees, or agents;
- (c) the design, construction, operation, maintenance and repair of any part of the Project; or,
- (d) any omission or other wilful or negligent act or delay of the Recipient, its Affiliated Person or a third party and their respective employees, officers, or agents.

13.2 **Limitation of Liability.** Notwithstanding anything to the contrary contained herein, the Minister shall not be liable for any direct, indirect, special or consequential damages of the Recipient nor for the loss of revenues or profits arising from, based upon, occasioned by or attributable to the execution of this Agreement, regardless of whether such a liability arises in tort (including negligence), contract, fundamental breach or breach of a fundamental term, misrepresentation, breach of warranty, breach of fiduciary duty, indemnification or otherwise.

13.3 Her Majesty, her agents, employees and servants will not be held liable in the event the Recipient enters into a loan, a capital or operating lease or other long-term obligation in relation to the Project for which the Contribution is provided.

**14. Default and Remedies**

14.1 **Event of Default.** The Minister may declare that an Event of Default has occurred if:

- (a) the Recipient has failed or neglected to pay Her Majesty any amount due in accordance with this Agreement;

- (b) the Project is not completed in accordance with Schedule 1 – *Statement of Work* to the Minister’s satisfaction by the Project Completion Date or the Project is abandoned in whole or in part;
- (c) the Recipient has not, in the opinion of the Minister, met or satisfied a term, covenant or condition of this Agreement;
- (d) the Recipient becomes bankrupt or insolvent, goes into receivership, or takes the benefit of any statute, from time to time in force, relating to bankrupt or insolvent debtors;
- (e) an order is made or the Recipient has passed a resolution for the winding up or dissolution of the Recipient, or the Recipient is dissolved or wound up;
- (f) the Recipient has, in the opinion of the Minister, ceased to carry on business or has sold all or substantially all of its assets or enters into a letter of intent or binding obligation to sell all or substantially all of its assets;
- (g) the Recipient has not met or satisfied a term or condition under any other contribution agreement or agreement of any kind with Her Majesty;
- (h) the Recipient fails to fulfill any of the contractual obligations set out in this Agreement;
- (i) a representation, covenant, warranty or statement contained herein or in any document, report or certificate delivered to the Minister hereunder or in connection therewith is false or misleading at the time it was made; and
- (j) the Recipient fails to comply with the obligations regarding audit and evaluation, as set out in Section 9.

14.2 **Notice and Rectification Period.** Except in the case of an Event of Default under paragraphs (d), (e) and (f) of Subsection 14.1 above, the Minister will not declare that an Event of Default has occurred unless the Parties have attempted to resolve the issue in accordance with Schedule 5 – *Resolution Process*. If the Parties are unable to resolve this issue, the Minister may give written notice to the Recipient of the occurrence which, in the Minister’s opinion, constitutes an Event of Default and the Recipient fails, within thirty (30) days of receipt of the notice, either to correct the condition or event or demonstrate, to the satisfaction of the Minister that it has taken such steps as are necessary to correct the condition, failing which the Minister may declare that an Event of Default has occurred.

- 14.3 **Remedies on Default.** If, after following the process in Schedule 5 – *Resolution Process*, the Minister declares that an Event of Default has occurred, the Minister may immediately exercise one or more of the following remedies, in addition to any remedy available at law:
- (a) suspend or terminate any obligation by the Minister to contribute or continue to contribute to the Eligible Supported Costs including any obligation to pay any amount owing prior to the date of such suspension;
  - (b) require the Recipient to repay to the Minister all or part of the Contribution paid by the Minister, together with interest from the day of demand at the Interest Rate;
  - (c) require the Recipient to pay the Minister the total of all amounts required to be repaid pursuant to this Agreement less any amount already repaid to the Minister together with interest from the day of demand at the Interest Rate;
  - (d) terminate the Agreement; and
  - (e) post a notice on a Government of Canada website disclosing that the Recipient has committed an Event of Default under the provisions of this Agreement and describing generally the remedies, if any, that the Minister has accordingly exercised.
- 14.4 The Recipient acknowledges the policy objectives served by the Minister’s agreement to make the Contribution, that the Contribution comes from the public monies, and that the amount of damages sustained by Her Majesty in an Event of Default is difficult to ascertain and therefore, that it is fair and reasonable that the Minister be entitled to exercise any or all of the remedies provided for in this Agreement and to do so in the manner provided for in this Agreement, if an Event of Default occurs.
15. **Miscellaneous**
- 15.1 **Compliance with *Lobbying Act*.** The Recipient warrants and represents:
- (a) that it has filed all *Lobbying Act* returns required to be filed in respect of persons employed by the Recipient who communicate and/or arrange meetings with Public Office Holders as part of their employment duties, and that it will continue to do so;
  - (b) that it has not contracted with any person to communicate and/or arrange meetings with Public Office Holders for remuneration that is or would be contingent in any way upon the success of such person arranging meetings with Public Office Holders, or upon the approval of the Recipient’s application for SIF funding, or upon the amount of SIF funding paid or payable to the Recipient under this Agreement;

- (c) that it will not contract with any person to communicate and/or arrange meetings with Public Office Holders for remuneration that is or would be contingent upon the success of such person arranging meetings with Public Office Holders, or upon the amount of SIF funding paid or payable to the Recipient under this Agreement;
  - (d) all persons who are or have been contracted by the Recipient to communicate and/or arrange meetings with Public Office Holders in respect of this Agreement are in full compliance with the registration and other requirements of the Lobbying Act; and
  - (e) it shall at all times ensure that any persons contracted to communicate and/or arrange meetings with Public Office Holders in respect of the Agreement are in full compliance with the requirements of the Lobbying Act.
- 15.2 **Members of Parliament.** The Recipient represents and warrants that no member of the House of Commons will be admitted to any share or part of this Agreement or to any benefit to arise therefrom. No person who is a member of the Senate will, directly or indirectly, be a party to or be concerned in this Agreement.
- 15.3 **Compliance with Post-Employment Provisions.** The Recipient confirms that no current or former public servant or public officeholder to whom the *Values and Ethics Code for the Public Service*, the *Values and Ethics Code for the Public Sector*, the *Policy on Conflict of Interest and Post-Employment* or the *Conflict of Interest Act* apply, will derive a direct benefit from this Agreement unless the provision or receipt of such benefits is in compliance with such legislation and codes.
- 15.4 The Recipient acknowledges that the representations and warranties in this section are fundamental terms of this Agreement. In the event of breach of these, the Minister may exercise the remedies set out in Subsection 14.3.
- 16. Confidentiality**
- 16.1 **Consent Required.** Subject to Schedule 2 - *Communications Obligations*, the *Access to Information Act*, the *Privacy Act* and the *Library and Archives Act of Canada*, each Party shall keep confidential and shall not without the consent of the other Party disclose the contents of the Agreement and the documents pertaining thereto, whether provided before or after the Agreement was entered into, or of the transactions contemplated herein.

- 16.2 **International Dispute.** Notwithstanding Subsection 16.1 of this Agreement, the Recipient waives any confidentiality rights to the extent such rights would impede Her Majesty from fulfilling her notification obligations to a world trade panel for the purposes of the conduct of a dispute, in which Her Majesty is a party or a third party intervener. The Minister is authorized to disclose the contents of this Agreement and any documents pertaining thereto, whether predating or subsequent to this Agreement, or of the transactions contemplated herein, where in the opinion of the Minister, such disclosure is necessary to the defence of Her Majesty's interests in the course of a trade remedy investigation conducted by a foreign investigative authority, and is protected from public dissemination by the foreign investigative authority. The Minister shall notify the Recipient of such disclosure.
- 16.3 **Financing, Licensing and Subcontracting.** Notwithstanding Subsection 16.1 of this Agreement, the Minister hereby consents to the Recipient disclosing this Agreement, and any portion or summary thereof, for any of the following purposes:
- (a) securing additional financing;
  - (b) licensing for commercial exploitation; or
  - (c) confirming to agents, contractors and subcontractors of the Recipient that all agents, contractors and subcontractors must agree to provide the Minister and the Auditor-General with access to their records and premises, provided that any person to whom this Agreement or any portion or summary thereof is disclosed shall execute a non-disclosure agreement prior to such disclosure.
- 16.4 **Repayments.** Notwithstanding Subsection 16.1 of this Agreement, the Minister may disclose any information relating to the amount of each repayment made by the Recipient whether due or paid.
17. **General**
- 17.1 **Debt due to Canada.** Any amount owed to Her Majesty under this Agreement shall constitute a debt due to Her Majesty and shall be recoverable as such. Unless otherwise specified herein, the Recipient agrees to make payment of any such debt forthwith on demand.
- 17.2 **Interest.** Debts due to Her Majesty will accrue interest in accordance with the *Interest and Administrative Charges Regulations*, in effect on the due date, compounded monthly on overdue balances payable, from the date on which the payment is due, until payment in full is received by Her Majesty. Any such amount is a debt due to Her Majesty and is recoverable as such.
- 17.3 **Set-off Rights of Minister.** Without limiting the scope of the set-off rights provided for under the *Financial Administration Act*, it is understood that the Minister may set off against the Contribution any amounts owed by the Recipient to the Minister under legislation or contribution agreements and the Recipient shall declare to the Minister all amounts outstanding in that regard when making a claim under this Agreement.



- 17.4 **No Assignment of Agreement.** No Party shall assign the Agreement or any part thereof without the prior written consent of the Minister. Any attempt by a Party to assign this Agreement or any part thereof, without the express written consent of the Minister, is void.
- 17.5 **Annual Appropriation.** Any payment by the Minister under this Agreement is subject to there being an appropriation for the Government Fiscal Year in which the payment is to be made; and to cancellation or reduction in the event that departmental funding levels are changed by Parliament. If the Minister is prevented from disbursing the full amount of the Contribution due to a lack or reduction of appropriation or departmental funding levels, the Minister and the Recipient agree to review the effects of such a shortfall in the Contribution on the implementation of this Agreement.
- 17.6 **Successors and Assigns.** This Agreement is binding upon the Recipient, its successors and permitted assigns.
- 17.7 **Event of Force Majeure.** The Recipient will not be in default by reason only of any failure in the performance of the Project in accordance with Schedule 1 – *Statement of Work* if such failure arises without the fault or negligence of the Recipient and is caused by any event of Force Majeure.
- 17.8 **Applicable Law.** This Agreement will be interpreted in accordance with the laws of the province of Ontario and federal laws of Canada applicable therein. The word “law” used herein has the same meaning as in the *Interpretation Act*, as amended.
- 17.9 **Dispute Resolution.** If a dispute arises concerning the application or interpretation of this Agreement, the Parties will attempt to resolve the matter through good faith negotiation, and may, if necessary and the Parties consent in writing, resolve the matter through mediation or arbitration by a mutually acceptable mediator or by arbitration in accordance with the Commercial Arbitration Code set out in the schedule to the *Commercial Arbitration Act (Canada)*, as amended, and all regulations made pursuant to that Act.
- 17.10 **No Amendment.** No amendment to this Agreement shall be effective unless it is made in writing and signed by the Parties hereto.
- 17.11 **Contribution Agreement Only.** This Agreement is a contribution agreement only, not a contract for services or a contract of service or employment, and nothing in this Agreement, the Parties relationship or actions is intended to create, or be construed as creating, a partnership, employment or agency relationship between them. The Recipient is not in any way authorized to make a promise, agreement or contract and to incur any liability on behalf of Her Majesty or to represent itself as an agent, employee or partner of Her Majesty, including in any agreement with a third party, nor shall the Recipient make a promise, agreement or contract and incur any liability on behalf of Her Majesty, and the Recipient shall be solely responsible for all deductions and remittances required by law in relation to its employees.

- 17.12 **No Waiver.** The rights and remedies of the Minister under this Agreement shall be cumulative and not exclusive of any right or remedy that he or she would otherwise have. The fact that the Minister refrains from exercising a remedy he or she is entitled to exercise under this Agreement will not constitute a waiver of such right and any partial exercise of a right will not prevent the Minister in any way from later exercising any other right or remedy under this Agreement or other applicable law.
- 17.13 **Consent of the Minister.** Whenever this Agreement provides for the Minister to render a decision or for the Recipient to obtain the consent or agreement of the Minister, such decision shall be reasonable on the facts and circumstance and such consent or agreement will not be unreasonably withheld but the Minister may make the issuance of such consent or agreement subject to reasonable conditions.
- 17.14 **No conflict of interest.** The Recipient and its Affiliated Persons, consultants and any of their respective advisors, partners, directors, officers, shareholders, employees, agents and volunteers shall not engage in any activity where such activity creates a real, apparent or potential conflict of interest in the sole opinion of the Minister, with the carrying out of the Project. For greater certainty, and without limiting the generality of the foregoing, a conflict of interest includes a situation where anyone associated with the Recipient owns or has an interest in an organization that is carrying out work related to the Project.
- 17.15 **Disclose potential conflict of interest.** The Recipient shall disclose to the Minister without delay any actual or potential situation that may be reasonably interpreted as either a conflict of interest or a potential conflict of interest.
- 17.16 **Severability.** Any provision of this Agreement which is prohibited by law or otherwise deemed ineffective will be ineffective only to the extent of such prohibition or ineffectiveness and will be severable without invalidating or otherwise affecting the remaining provisions of the Agreement.
- 17.17 **Signature in Counterparts.** This Agreement may be signed in counterparts and such counterparts may be delivered by acceptable electronic transmission, including portable document format (PDF), each of which when executed and delivered is deemed to be an original, and when taken together, will constitute one and the same Agreement.
- 17.18 **Currency.** Unless otherwise indicated, all dollar amounts referred to in this Agreement are to the currency of Canada.
- 17.19 **Tax.** The Recipient acknowledges that financial funding from government programs may have tax implications for its organization and that advice should be obtained from a qualified tax professional.

**18. Contact Information & Notices**

18.1 **Form and Timing of Notice.** Any notice or other communication under this Agreement shall be made in writing. The Minister or the Recipient may send any written notice by any pre-paid method, including regular or registered mail, courier or email. Notice will be considered as received upon delivery by the courier, upon the Party confirming receipt of the email or one (1) day after the email is sent, whichever the sooner or five (5) calendar days after being mailed.

18.2 Any notices to the Minister in fulfillment of obligations such as claims, reporting, and any other documents stipulated under this Agreement, will be addressed to:

Strategic Innovation Fund  
 Attn: Senior Director  
 8th Floor  
 235 Queen Street  
 Ottawa, Ontario K1A 0H5  
 Fax No: (613) 954-5649  
 Email address: to be provided by SIF upon request from the Recipient.

Notwithstanding the foregoing, claims forms will not be sent by email unless otherwise agreed to in writing by the Minister.

18.3 Any notices to the Recipient will be addressed to:

Edesa Biotech Research, Inc.  
 Attn: President  
 100 Spy Court  
 Markham, ON L3R 5H6  
 Email address: to be provided by the Recipient to SIF.

Any notices to the Guarantor will be addressed to:

Edesa Biotech, Inc.  
 Attn: CEO  
 100 Spy Court  
 Markham, ON L3R 5H6  
 Email address: to be provided by the Recipient to SIF.

18.4 **Change of Contact Information.** Each of the Parties may change the address, which they have stipulated in this Agreement by notifying in writing the other Party of the new address, and such change shall be deemed to take effect fifteen (15) calendar days after receipt of such notice.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

**IN WITNESS WHEREOF** the Parties hereto have executed this Agreement through duly authorized representatives.

**HER MAJESTY THE QUEEN IN RIGHT OF CANADA**

as represented by the Minister of Industry

Per: /s/Colette Kaminsky  
Strategic Innovation Fund  
Colette Kaminsky, Director General

January 9, 2021  
Date

**Edesa Biotech Research, Inc.**

Per: /s/ Michael Brooks  
Michael Brooks, President

February 2, 2021  
Date

I have the authority to bind the Corporation.

**Edesa Biotech, Inc.**

Per: /s/Pardeep Nijhawan  
Pardeep Nijhawan, CEO

February 1, 2021  
Date

I have the authority to bind the Corporation.

**SCHEDULE 1 - STATEMENT OF WORK (SOW)**

[\_\_\_\_\_]

*[Statement of Work, including the nature of work related to the Project, timeframes, milestones and cost breakdowns, omitted as competitively sensitive information.]*

**SCHEDULE 2 - COMMUNICATIONS OBLIGATIONS**

[\_\_\_\_\_]

*[Nature of communications obligations pursuant to this Agreement omitted as competitively sensitive information.]*

**SCHEDULE 3 - COST PRINCIPLES**

[\_\_\_\_\_]

*[Nature of cost principles pursuant to this Agreement omitted as competitively sensitive information.]*

**SCHEDULE 4 - REPORTING REQUIREMENTS**

[ ]

*[Nature of reporting requirements pursuant to this Agreement omitted as competitively sensitive information.]*



**SCHEDULE 5 – RESOLUTION PROCESS**

[\_\_\_\_\_]

*[Nature of resolution process omitted as competitively sensitive information.]*

## Edesa Biotech Receives C\$14 million for COVID-19 Study

**TORONTO, ON / ACCESSWIRE / February 2, 2021** / Edesa Biotech, Inc. (NASDAQ:EDSA), a clinical-stage biopharmaceutical company, has secured a commitment of up to C\$14 million (US\$ 11 million) from the Government of Canada to complete the Phase 2 portion of a Phase 2/Phase 3 clinical study of its investigational drug, EB05, for the treatment of hospitalized COVID-19 patients. The funding will also help fund certain pre-clinical research intended to broaden the utility of the company's experimental therapy, including treatments for other respiratory pathogens. The funds were awarded under the federal government's Strategic Innovation Fund following a multi-disciplinary review of Edesa's drug technology and plans.

"The award of this competitive funding is an important validation of the therapeutic potential of EB05 and the scientific rationale behind our efforts. The funds will be targeted toward rapidly getting EB05 into the hands of physicians on the front line of this health crisis," said Dr. Par Nijhawan, Chief Executive Officer of Edesa. "By targeting the body's underlying response, our experimental drug offers a potential solution that could be effective despite variations in the virus."

The Honorable François-Philippe Champagne, Minister of Innovation, Science and Industry, said that Strategic Innovation Fund (SIF) funding announced today is part of the government's plan to support the development of novel medical countermeasures for COVID-19 patients. "As countries around the world begin to distribute and administer COVID-19 vaccines to their populations, we cannot lose sight of the importance of developing treatments to limit the long-term impacts of the virus on Canadians. Today's contribution will support Edesa as they take their promising treatment through clinical trials and subsequent approvals. Once approved, this therapy has the potential to be an important tool in treating and preventing lung injuries caused by COVID-19. As the government continues to protect and support Canadians through this pandemic, it must also lay the foundation for a better-prepared, healthier and more prosperous future," he said.

EB05 is an experimental monoclonal antibody that Edesa believes could regulate the overactive immune response associated with Acute Respiratory Distress Syndrome (ARDS) - the leading cause of death in COVID-19 patients. Specifically, the drug inhibits toll-like receptor 4 (TLR4) signaling - an important mediator of inflammation responsible for acute lung injury that has been shown to be activated by SARS-CoV2, SARS-CoV1 and Influenza viruses. The goal of the experimental treatment is to suppress inflammation, fluid accumulation and lung injury, thereby reducing the number of ICU patients and intubation/ventilation procedures, and ultimately saving lives.

The company intends to use the SIF funding for Phase 2 study expenses. Edesa's ongoing Phase 2/3 study is an adaptive, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of EB05 in adult hospitalized COVID-19 patients. Up to 316 patients will be enrolled in the first phase of the trial. Patients will be infused intravenously with a single dose of EB05 or placebo. Should the antibody treatment demonstrate promising results at the Phase 2 readout, the company plans to continue with a pivotal Phase 3 study.

"We greatly appreciate the support of the Government of Canada and the effort of the staff of the Innovation, Science and Economic Development (ISED) department in leading the technical review of our application," said Michael Brooks, PhD, President of Edesa Biotech. "We look forward to working with the government on the next steps in the program and continuing to build on Canada's emergency preparedness capabilities."

In addition to the ongoing clinical study, the SIF funding will also be used to support a research project at a Canadian university. Among other objectives, the *in vitro* pre-clinical study will examine the potential therapeutic utility of EB05 against a panel of pathogens, including coronavirus variants and influenza strains.

Hospitals and physicians interested in participating in the Phase 2/3 study of EB05 should contact [info@edesabiotech.com](mailto:info@edesabiotech.com) or visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: NCT04401475)

---

## About ARDS

Acute Respiratory Distress Syndrome is the leading cause of death in COVID-19 patients. The U.S. Centers for Disease Control (CDC) reports that 20% to 42% of hospitalized COVID-19 patients develop ARDS, which increases to 67% to 85% for patients admitted to the ICU. Mortality among patients admitted to the ICU ranges from 39% to 72% depending on the study and characteristics of patient population, according to the CDC. ARDS involves an exaggerated immune response leading to inflammation and injury to the lungs that results in edema that 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 COVID-19, ARDS accounted for approximately 10% of intensive care unit admissions, representing more than 3 million patients globally each year.

## 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. Edesa's lead product candidate, EB01, is a novel non-steroidal anti-inflammatory molecule (sPLA2 inhibitor) for the treatment of chronic allergic contact dermatitis which has demonstrated statistically significant improvements in multiple clinical studies. The company is developing late-stage monoclonal antibodies that block certain immune signaling proteins, known as TLR4 and CXCL10. These molecules are associated with a broad range of diseases, including the inflammation associated infectious diseases. Due to the global health emergency, Edesa has prioritized the development of EB05 as a potential treatment for hospitalized COVID-19 patients. The company is based in Markham, Ontario, Canada, with a U.S. subsidiary located in Southern California. Sign up for [news alerts](#).

## 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 EB05 could regulate the overactive immune response associated with ARDS, the company's belief that EB05 could modulate the TLR4 signaling pathway for the benefit of patients, the company's belief that EB05 could provide effective treatment for current and future variations of the SARS-CoV2 virus, and the company's plans regarding its Phase 2/3 study and the use of SIF funding. 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](mailto:investors@edesabiotech.com)

**SOURCE:** Edesa Biotech

---