

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_ to \_\_\_\_

Commission file number: 001-37619

**EDESA BIOTECH, INC.**

(Exact name of registrant as specified in its charter)

**British Columbia, Canada**

(State or other jurisdiction of  
incorporation or organization)

**N/A**

(I.R.S. Employer  
Identification No.)

**100 Spy Court, Markham, ON, Canada L3R 5H6**

(Address of principal executive  
offices and zip code)

**(289) 800-9600**

(Registrant's telephone number,  
including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
Common Shares, without par value	EDSA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

As of August [10], 2022, the registrant had 15,462,287 common shares issued and outstanding.

EDESA BIOTECH, INC.  
QUARTERLY REPORT ON FORM 10-Q  
Quarter Ended June 30, 2022

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**PART 1 – FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Edesa Biotech, Inc.**  
**Condensed Interim Consolidated Balance Sheets**  
**(Unaudited)**

	<u>June 30, 2022</u>	<u>September 30, 2021</u>
<b>Assets:</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 12,808,712	\$ 7,839,259
Accounts and other receivable	1,403,661	3,302,827
Prepaid expenses and other current assets	<u>968,061</u>	<u>948,645</u>
Total current assets	15,180,434	12,090,731
<b>Non-current assets:</b>		
Property and equipment, net	15,245	14,989
Intangible asset, net	2,306,485	2,382,364
Operating lease right-of-use assets	<u>39,037</u>	<u>96,571</u>
Total assets	<u>\$ 17,541,201</u>	<u>\$ 14,584,655</u>
<b>Liabilities and shareholders' equity:</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued liabilities	\$ 5,617,206	\$ 1,379,842
Short-term operating lease liabilities	<u>40,123</u>	<u>78,808</u>
Total current liabilities	5,657,329	1,458,650
<b>Non-current liabilities:</b>		
Long-term payables	46,536	47,202
Long-term operating lease liabilities	<u>-</u>	<u>20,512</u>
Total liabilities	5,703,865	1,526,364

**Shareholders' equity:**

## Capital shares

Authorized unlimited common and preferred shares without par value

Issued and outstanding:

15,462,287 common shares (September 30, 2021 - 13,295,403)	40,264,080	34,887,721
Additional paid-in capital	12,929,686	4,871,461
Accumulated other comprehensive loss	(125,788)	(205,262)
Accumulated deficit	<u>(41,230,642)</u>	<u>(26,495,629)</u>

Total shareholders' equity	<u>11,837,336</u>	<u>13,058,291</u>
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Total liabilities and shareholders' equity	<u>\$ 17,541,201</u>	<u>\$ 14,584,655</u>
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The accompanying notes are an integral part of these condensed interim consolidated financial statements.

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**Edesa Biotech, Inc.**  
**Condensed Interim Consolidated Statements of Operations**  
(Unaudited)

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>June 30, 2022</u>	<u>June 30, 2021</u>	<u>June 30, 2022</u>	<u>June 30, 2021</u>
<b>Expenses:</b>				
Research and development	4,547,543	4,464,347	11,541,404	13,819,305
General and administrative	<u>1,249,982</u>	<u>1,608,232</u>	<u>3,993,075</u>	<u>4,377,507</u>
<b>Loss from operations</b>	<b>(5,797,525)</b>	<b>(6,072,579)</b>	<b>(15,534,479)</b>	<b>(18,196,812)</b>
<b>Other income (loss):</b>				
Reimbursement grant income	-	1,306,796	780,257	8,477,261
Interest income	17,518	2,610	27,386	4,279
Foreign exchange gain (loss)	<u>(7,013)</u>	<u>3,663</u>	<u>(7,377)</u>	<u>58,963</u>
	<u>10,505</u>	<u>1,313,069</u>	<u>800,266</u>	<u>8,540,503</u>
<b>Loss before income taxes</b>	<b>(5,787,020)</b>	<b>(4,759,510)</b>	<b>(14,734,213)</b>	<b>(9,656,309)</b>
Income tax expense	<u>-</u>	<u>-</u>	<u>800</u>	<u>800</u>
<b>Net loss</b>	<b>(5,787,020)</b>	<b>(4,759,510)</b>	<b>(14,735,013)</b>	<b>(9,657,109)</b>
Exchange differences on translation	<u>34,559</u>	<u>174,128</u>	<u>79,474</u>	<u>267,075</u>
<b>Net comprehensive loss</b>	<b>\$ (5,752,461)</b>	<b>\$ (4,585,382)</b>	<b>\$ (14,655,539)</b>	<b>\$ (9,390,034)</b>
Weighted average number of common shares	15,462,287	13,251,999	14,227,538	11,680,294
Loss per common share - basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.36)</u>	<u>\$ (1.04)</u>	<u>\$ (0.83)</u>

The accompanying notes are an integral part of these condensed interim consolidated financial statements.

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**Edesa Biotech, Inc.**  
**Condensed Interim Consolidated Statements of Cash Flows**  
(Unaudited)

	<u>Nine Months Ended</u>	
	<u>June 30, 2022</u>	<u>June 30, 2021</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (14,735,013)	\$ (9,657,109)
Adjustments for:		
Depreciation and amortization	89,228	89,853

Share-based compensation	1,804,670	2,290,794
Changes in working capital items:		
Accounts and other receivable	1,900,776	(4,008,512)
Prepaid expenses and other current assets	(28,858)	(1,389,083)
Accounts payable and accrued liabilities	4,318,102	(635,554)
Net cash used in operating activities	<u>(6,651,095)</u>	<u>(13,309,611)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(5,697)	(7,610)
Net cash used in investing activities	<u>(5,697)</u>	<u>(7,610)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common shares and warrants	11,957,567	12,793,591
Proceeds from exercise of warrants	-	1,467,536
Proceeds from exercise of share options	-	41,985
Payments for issuance costs of common shares and warrants	(327,653)	(349,408)
Net cash provided by financing activities	<u>11,629,914</u>	<u>13,953,704</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(3,669)</u>	<u>202,396</u>
Net change in cash and cash equivalents	<u>4,969,453</u>	<u>838,879</u>
Cash and cash equivalents, beginning of period	<u>7,839,259</u>	<u>7,213,695</u>
<b>Cash and cash equivalents, end of period</b>	<b><u>\$ 12,808,712</u></b>	<b><u>\$ 8,052,574</u></b>
<b>Supplemental Disclosure of Noncash Financing Activities:</b>		
Preferred shares converted from temporary equity to common shares	\$ -	\$ 2,496,480
Issuance costs withheld from gross proceeds from issuance of common shares and warrants	393,461	955,950
Fair value of placement agent/underwriter warrants	408,059	407,023

The accompanying notes are an integral part of these condensed interim consolidated financial statements.

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**Edesa Biotech, Inc.**  
**Condensed Interim Consolidated Statements of Changes in Shareholders' Equity**  
(Unaudited)

	Shares #	Common Shares	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
<b>Three Months Ended June 30, 2022</b>						
<b>Balance - March 31, 2022</b>	15,462,287	\$ 40,264,080	\$ 12,364,302	\$ (160,347)	\$ (35,443,622)	\$ 17,024,413
Share-based compensation	-	-	565,384	-	-	565,384
Net loss and comprehensive loss	-	-	-	34,559	(5,787,020)	(5,752,461)
<b>Balance - June 30, 2022</b>	<u>15,462,287</u>	<u>\$ 40,264,080</u>	<u>\$ 12,929,686</u>	<u>\$ (125,788)</u>	<u>\$ (41,230,642)</u>	<u>\$ 11,837,336</u>
<b>Three Months Ended June 30, 2021</b>						
<b>Balance - March 31, 2021</b>	13,246,559	\$ 34,602,637	\$ 2,914,482	\$ (194,257)	\$ (18,050,078)	\$ 19,272,784
Issuance of common shares upon exercise of share options	9,000	24,488	(8,585)	-	-	15,903
Share-based compensation	-	-	1,100,450	-	-	1,100,450
Net loss and comprehensive loss	-	-	-	174,128	(4,759,510)	(4,585,382)
<b>Balance - June 30, 2021</b>	<u>13,255,559</u>	<u>\$ 34,627,125</u>	<u>\$ 4,006,347</u>	<u>\$ (20,129)</u>	<u>\$ (22,809,588)</u>	<u>\$ 15,803,755</u>
<b>Nine Months Ended June 30, 2022</b>						
<b>Balance - September 30, 2021</b>	13,295,403	\$ 34,887,721	\$ 4,871,461	\$ (205,262)	\$ (26,495,629)	\$ 13,058,291
Issuance of common shares and warrants in equity offering	2,166,884	6,239,180	6,702,293	-	-	12,941,473
Issuance costs including fair value of placement agent warrants	-	(862,821)	(448,738)	-	-	(1,311,559)
Share-based compensation	-	-	1,804,670	-	-	1,804,670
Net loss and comprehensive loss	-	-	-	79,474	(14,735,013)	(14,655,539)

<b>Balance - June 30, 2022</b>	<u>15,462,287</u>	<u>\$40,264,080</u>	<u>\$12,929,686</u>	<u>\$ (125,788)</u>	<u>\$ (41,230,642)</u>	<u>\$ 11,837,336</u>
<b>Nine Months Ended June 30, 2021</b>						
<b>Balance - September 30, 2020</b>	<b>9,615,119</b>	<b>\$18,500,853</b>	<b>\$ 1,550,480</b>	<b>\$ (287,204)</b>	<b>\$ (13,132,954)</b>	<b>\$ 6,631,175</b>
Issuance of common shares and warrants in equity offering	2,148,963	13,749,541	-	-	-	13,749,541
Issuance costs including fair value of underwriter warrants	-	(1,871,220)	407,023	-	-	(1,464,197)
Issuance of common shares upon exercise of warrants	341,806	1,681,936	(214,400)	-	-	1,467,536
Issuance of common shares upon exercise of share options	19,746	69,535	(27,550)	-	-	41,985
Preferred return on convertible preferred shares	-	-	-	-	(19,525)	(19,525)
Conversion of convertible preferred shares	1,129,925	2,496,480	-	-	-	2,496,480
Share-based compensation	-	-	2,290,794	-	-	2,290,794
Net loss and comprehensive loss	-	-	-	267,075	(9,657,109)	(9,390,034)
<b>Balance - June 30, 2021</b>	<u>13,255,559</u>	<u>\$34,627,125</u>	<u>\$ 4,006,347</u>	<u>\$ (20,129)</u>	<u>\$ (22,809,588)</u>	<u>\$ 15,803,755</u>

The accompanying notes are an integral part of these condensed interim consolidated financial statements.

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**Edesa Biotech, Inc.**  
**Notes to Condensed Interim Consolidated Financial Statements**  
**(Unaudited)**

**1. Nature of Operations**

Edesa Biotech, Inc. (the “Company” or “Edesa”) is a biopharmaceutical company focused on acquiring, developing and commercializing clinical-stage drugs for inflammatory and immune-related diseases with clear unmet medical needs. The Company is organized under the laws of British Columbia, Canada and is headquartered in Markham, Ontario, Canada.

The Company’s common shares trade on The Nasdaq Capital Market in the United States under the symbol “EDSA”.

*Impact of COVID-19*

The ongoing COVID-19 pandemic has severely impacted global economic activity and has caused material disruptions to almost every industry directly or indirectly. The full impact of the pandemic remains uncertain and ongoing developments related to the pandemic may cause material impacts to the Company’s future operations, clinical study timelines and financial results. While the full impact of the COVID-19 pandemic to business and operating results presents additional uncertainty, the Company’s management continues to use reasonably available information to assess impacts to the Company’s business plans and financial condition.

**2. Basis of Presentation**

The accompanying unaudited condensed interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q. They do not include all information and footnotes necessary for a fair presentation of financial position, results of operations and cash flows in conformity with U.S. GAAP for complete financial statements. These unaudited condensed interim consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes contained in the Company’s Annual Report on Form 10-K for the year ended September 30, 2021, which was filed with the Securities and Exchange Commission (SEC) on December 28, 2021.

The accompanying unaudited condensed interim consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Edesa Biotech Research, Inc., an Ontario corporation, and Edesa Biotech USA, Inc., a California corporation in the U.S. All intercompany balances and transactions have been eliminated on consolidation. All adjustments (consisting of normal recurring adjustments and accruals) considered necessary for a fair presentation of the results of operations for the periods presented have been included in the interim periods. Operating results for the three and nine months ended June 30, 2022 are not necessarily indicative of the results that may be expected for other interim periods or the fiscal year ending September 30, 2022.

*Use of estimates*

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period or year. Actual results could differ from those estimates. Areas where significant judgment is involved in making estimates are valuation of accounts and other receivable; valuation and useful lives of property and equipment; intangible assets; right-of-use assets; deferred income taxes; the determination of fair value of share-based compensation; the determination of fair value of warrants in order to allocate proceeds from equity issuances; and forecasting future cash flows for assessing the going concern assumption.

*Functional and reporting currencies*

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### 3. Intangible Assets

#### Acquired License

In April 2020, the Company entered into a license agreement with a pharmaceutical development company to obtain exclusive world-wide rights to know-how, patents and data relating to certain monoclonal antibodies (the Constructs), including sublicensing rights. Unless earlier terminated, the term of the license agreement will remain in effect for 25 years from the date of first commercial sale of licensed products containing the Constructs. Subsequently, the license agreement will automatically renew for five-year periods unless either party terminates the agreement in accordance with its terms.

Under the license agreement, the Company is exclusively responsible, at its expense, for the research, development, manufacture, marketing, distribution and commercialization of the Constructs and licensed products and to obtain all necessary licenses and rights. The Company is required to use commercially reasonable efforts to develop and commercialize the Constructs in accordance with the terms of a development plan established by the parties.

The Company has determined that the license has multiple alternative future uses in research and development projects and sublicensing in other countries or for other disease indications. The value of the acquired license is recorded as an intangible asset with amortization over the estimated useful life of 25 years and evaluation for impairment at the end of each reporting period.

The required upfront license payment of \$2.5 million was paid by issuance of Series A-1 Convertible Preferred Shares which were subsequently converted to common shares. The value of the license includes acquisition legal costs. See Note 5 for license commitments.

Intangible assets, net consisted of the following:

	<u>June 30, 2022</u>	<u>September 30, 2021</u>
The Constructs	\$ 2,529,483	\$ 2,529,483
Less: accumulated amortization	<u>(222,998)</u>	<u>(147,119)</u>
Total intangible assets, net	<u>\$ 2,306,485</u>	<u>\$ 2,382,364</u>

Amortization expense amounted to \$0.25 million for each of the three months ended June 30, 2022 and 2021 and \$0.76 million for each of the nine months ended June 30, 2022 and 2021.

Total estimated future amortization of intangible assets for each fiscal year is as follows:

<b>Year Ending</b>	
September 30, 2022	\$ 25,293
September 30, 2023	101,172
September 30, 2024	101,172
September 30, 2025	101,172
September 30, 2026	101,172
Thereafter	<u>1,876,504</u>
	<u>\$ 2,306,485</u>

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### 4. Lease with Related Party

The Company leases facilities used for executive offices from a company controlled by the Company's CEO for a six-year term through December 2022, with an option to renew for another two-year term. The option period is not included in the right-of-use assets and related lease obligation.

The components of lease cost were as follows:

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>June 30, 2022</u>	<u>June 30, 2021</u>	<u>June 30, 2022</u>	<u>June 30, 2021</u>
Operating lease cost, included in general and administrative on the Statements of Operations	<u>\$ 20,105</u>	<u>\$ 20,887</u>	<u>\$ 60,713</u>	<u>\$ 60,828</u>

Lease terms and discount rates were as follows:

<u>June 30, 2022</u>	<u>September 30, 2021</u>
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Remaining lease term (months):	6	15
Estimated incremental borrowing rate:	6.5%	6.5%

The approximate future minimum lease payments under operating leases at June 30, 2022 were as follows:

<b>Year Ending</b>	
September 30, 2022	\$ 20,443
September 30, 2023	20,443
Total lease payment	40,886
Less imputed interest	763
Present value of lease liabilities, short-term	<u>\$ 40,123</u>

Cash flow information was as follows:

	<b>Nine Months Ended</b>	
	<b>June 30, 2022</b>	<b>June 30, 2021</b>
Cash paid for amounts included in the measurement of lease liabilities, included in accounts payable and accrued liabilities on the Statements of Cash Flows	<u>\$ 60,714</u>	<u>\$ 60,830</u>

## 5. Commitments

### *Research and other commitments*

The Company has commitments for contracted research organizations that perform clinical trials for the Company's ongoing clinical studies and other service providers. Aggregate future contractual payments at June 30, 2022 are as follows:

<b>Year Ending</b>	
September 30, 2022	\$ 1,175,000
September 30, 2023	2,053,000
September 30, 2024	43,000
September 30, 2025	5,000
	<u>\$ 3,276,000</u>

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### *License and royalty commitments*

In April 2020, through its Ontario subsidiary, the Company entered into a license agreement with a third party to obtain exclusive world-wide rights to certain know-how, patents and data relating to certain monoclonal antibodies (the Constructs), including sublicensing rights. An intangible asset for the acquired license has been recognized. See Note 3 for intangible assets. Under the license agreement, the Company recorded an expense of \$3.5 million as a result of meeting a milestone during the three and nine months ended June 30, 2021 and is committed to remaining payments of up to an aggregate amount of \$352.5 million contingent upon meeting certain milestones outlined in the license agreement, primarily relating to future potential commercial approval and sales milestones. No milestone payments were made to the third party during the three and nine months ended June 30, 2022. The Company also has a commitment to pay royalties based on any net sales of products containing the Constructs in the countries where the Company directly commercializes the products containing the Constructs and a percentage of any sublicensing revenue received by the Company and its affiliates in the countries where it does not directly commercialize the products containing the Constructs. No royalty or sublicensing payments were made to the third party during the three and nine months ended June 30, 2022 and 2021.

In connection with this license agreement and pursuant to a purchase agreement entered into in April 2020, the Company acquired drug substance of one of the Constructs for an aggregate purchase price of \$5.0 million, payable in two future installments based on the earlier of certain clinical trial progress or fixed dates. The Company recorded expense of \$2.5 million during each of the three and nine months ended June 30, 2022 and 2021.

In 2016, through its Ontario subsidiary, the Company entered into a license agreement with a third party to obtain exclusive rights to certain know-how, patents and data relating to a pharmaceutical product. The Company will use the exclusive rights to develop the product for therapeutic, prophylactic and diagnostic uses in topical dermal applications and anorectal applications. No intangible assets have been recognized under the license agreement with the third party. Under the license agreement, the Company is committed to payments of various amounts to the third party upon meeting certain milestones outlined in the license agreement, up to an aggregate amount of \$18.6 million. Upon divestiture of substantially all of the assets of the Company, the Company would pay the third party a percentage of the valuation of the licensed technology sold as determined by an external objective expert. The Company also has a commitment to pay the third party a royalty based on net sales of the product in countries where the Company, or an affiliate, directly commercializes the product and a percentage of sublicensing revenue received by the Company and its affiliates in the countries where it does not directly commercialize the product. No milestone, license or royalty payments were made to the third party during the three and nine months ended June 30, 2022 and 2021.

In March 2021, through its Ontario subsidiary, the Company entered into a license agreement with the inventor of the same pharmaceutical product to acquire global rights for all fields of use beyond those named under the 2016 license agreement. The Company recorded an expense of \$0.11 million as a result of meeting milestones outlined in the 2021 license agreement for the three months ended June 30, 2021 and \$0.03 million and \$0.11 million for the nine months ended June 30, 2022 and 2021, respectively. No milestones were met during the three months ended June 30, 2022. The Company is committed to remaining payments of up to an aggregate amount of \$68.9 million, primarily relating to future potential commercial approval and sales milestones. In addition, if the Company fails to file an investigational new drug application or foreign equivalent (IND) for the product within a certain

period of time following the date of the agreement, the Company is required to remit to the inventor a fixed license fee annually as long as the requirement to file an IND remains unfulfilled.

## 6. Capital Shares

### Equity offerings

On March 24, 2022, the Company completed a registered direct offering of 1,540,000 common shares, no par value, and pre-funded warrants to purchase up to an aggregate of 1,199,727 common shares. In a concurrent private placement, the Company issued common share purchase warrants to purchase an aggregate of up to 2,739,727 common shares. Aggregate gross proceeds to the Company were approximately \$10.0 million.

The common share purchase warrants were immediately exercisable at an exercise price of \$3.52 per share and will expire on September 24, 2027. The pre-funded warrants were immediately exercisable at an exercise price of \$0.0001 per share and do not expire. In connection with the offering, the Company also issued warrants to purchase an aggregate of 191,780 common shares to certain affiliated designees of the placement agent as part of the placement agent's compensation. The placement agent warrants are exercisable on or after March 24, 2022, at an exercise price of \$4.5625 per share, and will expire on March 21, 2027.

The direct costs related to the issuance of the common shares and warrants were \$0.99 million. These direct costs were recorded as an offset against gross proceeds. The warrants are considered contracts on the Company's own shares and are classified as equity. The Company allocated gross proceeds with \$5.87 million as the value of common shares and pre-funded warrants and \$4.13 million as the value of common share purchase warrants under additional paid-in capital in the unaudited condensed interim consolidated statements of changes in shareholders' equity on a relative fair value basis. The Company also recorded the fair value of underwriter warrants in the amount of \$0.41 million as share-based compensation to non-employees under additional paid-in capital and an offset against gross proceeds.

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On March 2, 2021, the Company closed an underwritten offering of 1,562,500 common shares, no par value, at a price to the public of \$6.40 per share less underwriting discounts and commissions. Gross proceeds from the offering amounted to \$10.0 million. The Company granted to the underwriters a 30-day option to purchase up to an additional 234,375 common shares, which expired with no further shares issued. On the closing date, the Company issued underwriter warrants to purchase an aggregate of up to 109,375 common shares at an exercise price of \$8.00 per share, expiring on February 26, 2026. The direct costs related to the issuance of the common shares were \$0.99 million. These direct costs were recorded as an offset against gross proceeds. The Company also recorded the fair value of underwriter warrants in the amount of \$0.41 million as share-based compensation to non-employees under additional paid-in capital and an offset against gross proceeds.

### Equity distribution agreements

On November 22, 2021, the Company entered into an equity distribution agreement with RBC Capital Markets, LLC (RBCCM), as sales agent. Pursuant to the terms of the agreement, as amended March 4, 2022, the Company could offer and sell common shares having an aggregate offering price of up to \$15.4 million from time to time through RBCCM. From November 22, 2021 to March 21, 2022, the Company sold a total of 626,884 common shares pursuant to the agreement for gross proceeds of \$2.94 million. The commissions and direct costs of the offering program totaled approximately \$0.32 million and were recorded as an offset against gross proceeds. On March 21, 2022, the Company and RBCCM entered into an agreement terminating the agreement effective March 21, 2022.

### Black-Scholes option valuation model

The Company uses the Black-Scholes option valuation model to determine the fair value of share-based compensation for share options and compensation warrants granted and the fair value of warrants issued. Option valuation models require the input of highly subjective assumptions including the expected price volatility. The Company calculates expected volatility based on historical volatility of the Company's share price. When there is insufficient data available, the Company uses a peer group that is publicly traded to calculate expected volatility. The Company adopted interest-free rates by reference to the U.S. treasury yield rates. The Company calculated the fair value of share options granted based on the expected life of 5 years, considering expected forfeitures during the option term of 10 years. Expected life of warrants is based on warrant terms. The Company did not and is not expected to declare any dividends. Changes in the subjective input assumptions can materially affect the fair value estimates, and therefore the existing models do not necessarily provide a reliable single measure of the fair value of the Company's warrants and share options.

### Warrants

A summary of the Company's warrants activity is as follows:

	<u>Number of Warrant Shares (#)</u>	<u>Weighted Average Exercise Price</u>
<b>Nine Months Ended June 30, 2022</b>		
<b>Balance - September 30, 2021</b>	720,446	\$ 5.69
Issued	2,931,507	3.59
<b>Balance - June 30, 2022</b>	<u>3,651,953</u>	<u>\$ 4.00</u>
<b>Nine Months Ended June 30, 2021</b>		
<b>Balance - September 30, 2020</b>	992,721	\$ 4.92
Issued	109,375	8.00
Exercised	<u>(341,806)</u>	<u>4.29</u>

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The weighted average contractual life remaining on the outstanding warrants at June 30, 2022 is 53 months.

The following table summarizes information about the warrants outstanding at June 30, 2022:

Number of Warrants (#)	Exercise Prices	Expiry Dates
28,124	\$ 15.90	May 2023
563,685	\$ 4.80	July 2023
7,484	\$ 4.81	June 2024
11,778	\$ 3.20	January 2025
109,375	\$ 8.00	February 2025
191,780	\$ 4.56	March 2027
2,739,727	\$ 3.52	September 2027
3,651,953		

The fair value of warrants granted during the three and nine months ended June 30, 2022 and 2021 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Nine Months Ended June 30, 2022		Nine Months Ended June 30, 2021
	Common Warrants	Placement Agent Warrants	Underwriter Warrants
Risk free interest rate	2.37%	2.37%	0.67%
Expected life	5.5 years	5 years	5 years
Expected share price volatility	87.09%	87.09%	94.20%
Expected dividend yield	0.00%	0.00%	0.00%

*Pre-funded Warrants*

A summary of the Company's pre-funded warrant activity is as follows:

	Number of Pre-funded Warrant Shares (#)
Balance - September 30, 2021	-
Issued	1,199,727
Balance - June 30, 2022	1,199,727

[Table of Contents](#)*Share Options*

The Company adopted an Equity Incentive Compensation Plan in 2019 (the 2019 Plan) administered by the independent members of the Board of Directors, which amended and restated the 2017 Incentive Compensation Plan (the 2017 Plan). Options, restricted shares and restricted share units are eligible for grant under the 2019 Plan. The remaining number of options available for grant is 422,252. The total number of shares available for issuance is 2,625,951 including shares available for the exercise of outstanding options under the 2019 and 2017 Plans as described below.

The Company's 2019 Plan allows options to be granted to directors, officers, employees and certain external consultants and advisers. Under the 2019 Plan, the option term is not to exceed 10 years and the exercise price of each option is determined by the independent members of the Board of Directors.

Options have been granted under the 2019 Plan allowing the holders to purchase common shares of the Company as follows:

Number of Options (#)	Weighted Average Exercise Price	Weighted Average
-----------------------	---------------------------------	------------------

			<b>Grant Date Fair Value</b>
<b>Nine Months Ended June 30, 2022</b>			
<b>Balance - September 30, 2021</b>	1,776,219	\$ 5.06	\$ 3.79
Granted	500,083	3.66	2.48
Forfeited	(26,954)	6.56	4.97
Expired	(45,649)	8.05	6.48
<b>Balance - June 30, 2022</b>	<u>2,203,699</u>	<u>\$ 4.66</u>	<u>\$ 3.42</u>
<b>Nine Months Ended June 30, 2021</b>			
<b>Balance - September 30, 2020</b>	675,437	\$ 3.30	\$ 2.56
Granted	1,138,000	6.21	4.65
Exercised	(19,746)	2.12	1.35
Forfeited	(19,066)	6.07	4.76
Expired	(1,906)	102.49	135.66
<b>Balance - June 30, 2021</b>	<u>1,772,719</u>	<u>\$ 5.07</u>	<u>\$ 3.67</u>

During the nine months ended June 30, 2022, the independent members of the Board of Directors granted a total of 415,083 options to employees of the Company pursuant to the 2019 Plan. The options have a term of 10 years with vesting in equal proportions over 36 months beginning on the monthly anniversary of the grant date (following 90 days of employment for new employees), and an exercise price equal to the Nasdaq closing price on the grant dates.

During the nine months ended June 30, 2022, the independent directors of the Board of Directors granted a total of 85,000 options, respectively, to directors of the Company pursuant to the 2019 Plan. The options have a term of 10 years and an exercise price equal to the Nasdaq closing price on the grant dates. Options for directors have monthly vesting in equal proportions over 12 months beginning on the grant date.

The weighted average contractual life remaining on the outstanding options at June 30, 2022 is 99 months.

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The following table summarizes information about the options under the 2019 Plan outstanding and exercisable at June 30, 2022:

<b>Number of Options (#)</b>	<b>Exercisable at June 30, 2022 (#)</b>	<b>Range of Exercise Prices</b>	<b>Expiry Dates</b>
238	238	\$ 304.08	Dec 2022
3,499	3,499	\$ 35.28 - 93.24	Sep 2023-Mar 2025
296,403	296,403	C\$ 2.16	Aug 2027-Dec 2028
323,976	275,723	\$ 3.16	Feb 2030
397,000	231,457	\$ 7.44 - 8.07	Sep 2030-Oct 2030
682,500	334,995	\$ 5.25 - 5.65	Jan 2031-Sep 2031
500,083	90,560	\$ 2.94 - 3.71	Feb 2032-Mar 2032
<u>2,203,699</u>	<u>1,232,875</u>		

The fair value of options granted during the nine months ended June 30, 2022 and 2021 was estimated using the Black-Scholes option valuation model using the following assumptions:

	<b>Nine Months Ended</b>	
	<b>June 30, 2022</b>	<b>June 30, 2021</b>
Risk free interest rate	1.71% - 2.54%	0.31% - 0.90%
Expected life	5 years	5 years
Expected share price volatility	85.91% -	94.27% -
Expected dividend yield	86.59%	97.28%
	0.00%	0.00%

The Company recorded \$0.57 million and \$1.10 million of share-based compensation expenses for the three months ended June 30, 2022 and 2021, respectively and \$1.80 million and \$2.29 million for the nine months ended June 30, 2022 and 2021, respectively.

As of June 30, 2022, the Company had approximately \$1.49 million of unrecognized share-based compensation expense, which is expected to be recognized over a period of 31 months.

## **7. Reimbursement Grant Income and Receivable**

Reimbursement grant income for the Company's federal grant with the Canadian government's Strategic Innovation Fund (SIF) is recorded based on the claim period of eligible costs. At June 30, 2022, grant reimbursements receivable of \$1.1 million were included in accounts and other receivable.

## **8. Financial Instruments**

(a) *Fair values*

The Company uses the fair value measurement framework for valuing financial assets and liabilities measured on a recurring basis in situations where other accounting pronouncements either permit or require fair value measurements.

Fair value of a financial instrument is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The Company follows the fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs are inputs that reflect assumptions market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

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There are three levels of inputs that may be used to measure fair value:

- Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets and liabilities in markets that are not active.
- Level 3 - Unobservable inputs for the asset or liability that are supported by little or no market activity.

The carrying value of certain financial instruments such as cash and cash equivalents, accounts and other receivable, accounts payable and accrued liabilities approximates fair value due to the short-term nature of such instruments. The fair value of lease obligations on right-of-use assets approximates carrying value due to a fixed lease rate, which represents market rate.

(b) *Interest rate and credit risk*

Interest rate risk is the risk that the value of a financial instrument might be adversely affected by a change in interest rates. The Company does not believe that the results of operations or cash flows would be affected to any significant degree by a significant change in market interest rates, relative to interest rates on cash and cash equivalents due to the short-term nature of these balances.

The Company is also exposed to credit risk at period end from the carrying value of its cash and cash equivalents and accounts and other receivable. The Company manages this risk by maintaining bank accounts with Canadian Chartered Banks, U.S. banks believed to be credit worthy and money market mutual funds of U.S. government securities. The Company's cash is not subject to any external restrictions. The Company assesses the collectability of accounts receivable through a review of the current aging, as well as an analysis of historical collection rates, general economic conditions and credit status of customers. Credit risk for reimbursement grant and HST refunds receivable are not considered significant since amounts are due from the Canadian government's Strategic Innovation Fund (SIF) and the Canada Revenue Agency.

(c) *Foreign exchange risk*

The Company and its subsidiary have balances in Canadian dollars that give rise to exposure to foreign exchange (FX) risk relating to the impact of translating certain non-U.S. dollar balance sheet accounts as these statements are presented in U.S. dollars. A strengthening U.S. dollar will lead to a FX loss while a weakening U.S. dollar will lead to a FX gain. The Company has not entered into any agreements or purchased any instruments to hedge possible currency risks. At June 30, 2022, the Company and its Canadian subsidiary had assets denominated in Canadian dollars of approximately C\$7 million and the U.S. dollar exchange rate as at this date was equal to 1.2893 Canadian dollars. Based on the exposure at June 30, 2022, a 10% annual change in the Canadian/U.S. exchange rate would impact the Company's loss and other comprehensive loss by approximately \$541,000.

(d) *Liquidity risk*

Liquidity risk is the risk that the Company will encounter difficulty raising liquid funds to meet commitments as they fall due. In meeting its liquidity requirements, the Company closely monitors its forecasted cash requirements with expected cash drawdown.

**9. Loss per Share**

The Company had securities outstanding which could potentially dilute basic EPS in the future but were excluded from the computation of diluted loss per share in the periods presented, as their effect would have been anti-dilutive.

**10. Related Party Transactions**

The Company incurred rent expense of \$0.20 million and \$0.21 million for the three months ended June 30, 2022 and 2021, respectively, and \$0.61 million for each of the nine months ended June 30, 2022 and 2021, from a company controlled by the Company's CEO. These transactions are in the normal course of operations and are measured at the exchange amount, which is the amount of consideration established and agreed to by both parties.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following management's discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed interim consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q as of June 30, 2022 and our audited consolidated financial statements for the year ended September 30, 2021 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on December 28, 2021.*

*This Quarterly Report on Form 10-Q contains forward-looking statements. When used in this report, the words "expects," "anticipates," "suggests," "believes," "intends," "estimates," "plans," "projects," "continue," "ongoing," "potential," "expect," "predict," "believe," "intend," "may," "will," "should," "could," "would" and similar expressions are intended to identify forward-looking statements. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in the forward-looking statements for many reasons, including the risks described in our Annual Report on Form 10-K for the year ended September 30, 2021 and other reports we file with the Securities and Exchange Commission. Although we believe the expectations reflected in the forward-looking statements are reasonable, they relate only to events as of the date on which the statements are made. We do not intend to update any of the forward-looking statements after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.*

*The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed interim consolidated financial statements as of June 30, 2022 and September 30, 2021, and for the three and nine months ended June 30, 2022 and 2021 included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which we have prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.*

### Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing clinical-stage drugs for inflammatory and immune-related diseases with clear unmet medical needs. Our two lead product candidates, EB05 and EB01, are in later stage clinical studies.

EB05 is a monoclonal antibody therapy that we are developing as a treatment for Acute Respiratory Distress Syndrome (ARDS), a life-threatening form of respiratory failure. ARDS can be caused by viral diseases (including Covid-19), bacterial pneumonia, sepsis, chest injury and other causes. Specifically, EB05 inhibits toll-like receptor 4 (TLR4), a key immune signaling protein and an important mediator of inflammation that has been shown to be activated by SARS-COV2 as well as other respiratory infections such as influenza. In multiple third-party studies, high serum levels of alarmins (damage signaling molecules) that bind to and activate TLR4 are associated with poor outcomes and disease progression in Covid-19 patients. Since EB05 has demonstrated the ability to block signaling irrespective of the presence or concentration of the various molecules that frequently bind with TLR4, we believe that EB05 could ameliorate TLR4-mediated inflammation cascades in ARDS patients, thereby reducing lung injury, ventilation rates and mortality. In September 2021, an independent data and safety monitoring board pre-emptively unblinded the Phase 2 part of a Phase 2/3 study of EB05 in hospitalized Covid-19 patients and identified "a clinically important" mortality benefit. The monitoring board further recommended continuation of the study into a Phase 3 confirmatory trial, which is ongoing. The Phase 2 part of the study was funded primarily by a \$11 million (C\$14 million) reimbursement grant that was awarded by the Canadian government's Strategic Innovation Fund (SIF) following a multi-disciplinary technical review of our drug technology and plans.

In addition to EB05, we are developing an sPLA2 inhibitor, designated as EB01, as a topical treatment for chronic allergic contact dermatitis (ACD), a common, potentially debilitating condition and occupational illness. EB01 employs a novel, non-steroidal mechanism of action and in two clinical studies has demonstrated statistically significant improvement of multiple symptoms in ACD patients. EB01 is currently being evaluated in a Phase 2b clinical study.

In addition to our current clinical programs, we intend to expand the utility of our technologies and clinical-stage assets across other indications.

### Recent Developments

#### EB01 Clinical Study

Based on current enrollment trends, we anticipate that we will complete enrollment of the 210 subjects planned for our Phase 2b clinical study in chronic ACD by the fourth calendar quarter of 2022, with preliminary topline data available as early as the first calendar quarter of 2023.

#### EB05 Clinical Study

During the quarter, we initiated enrollment for a second cohort of patients in the Phase 3 part of our Phase 2/3 study evaluating EB05 in hospitalized Covid-19 patients. The company's first study cohort is recruiting the most critically severe patients receiving mechanical ventilation plus additional organ support, including extracorporeal membrane oxygenation (ECMO) therapy, also known as Level 7 patients under the World Health Organization's (WHO) Covid-19 Severity Scale. This new, second cohort is open to hospitalized patients on invasive mechanical ventilation alone (WHO Level 6 patients). The protocol for the Level 6 cohort calls for approximately 500 evaluable subjects. The evaluation of EB05 in both the Level 6 and Level 7 patient populations was previously approved by regulators in Canada, Colombia and Poland. Enrollment for both cohorts is now running in parallel, and results will be evaluated independently. For the U.S., we are currently preparing a Phase 2 clinical study report (CSR) for the Food and Drug Administration (FDA) in support of their review of our Phase 3 study design. This report, which was not part of the Phase 2/3 design or requested by other jurisdictions, requires substantial processing and quality review, and we anticipate submitting the CSR data package to the FDA in the third calendar quarter of 2022.

## Results of Operations

### *Comparison of the Three Months Ended June 30, 2022 and 2021*

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

- Research and development expenses increased by \$0.08 million to \$4.55 million for the three months ended June 30, 2022 compared to \$4.46 million for the same period last year primarily due to a contractual payment for bulk drug product of EB05, which was substantially offset by decreased external research expenses related to our ongoing clinical studies and drug manufacturing.
- General and administrative expenses decreased by \$0.36 million to \$1.25 million for the three months ended June 30, 2022 compared to \$1.61 million for the same period last year primarily due to a decrease in noncash share-based compensation.

Total other income decreased by \$1.30 million to \$0.01 million for the three months ended June 30, 2022 compared to \$1.31 million for the same period last year primarily due to a decrease in grant income associated with the completion of clinical study activities under our federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the three months ended June 30, 2022, our net loss was \$5.79 million, or \$0.37 per common share, compared to a net loss of \$4.76 million, or \$0.36 per common share, for the three months ended June 30, 2021.

### *Comparison of the Nine Months Ended June 30, 2022 and 2021*

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

- Research and development expenses decreased by \$2.28 million to \$11.54 million for the nine months ended June 30, 2022 compared to \$13.82 million for the same period last year primarily due to decreased milestone payments, which were partially offset by higher external research expenses related to our ongoing clinical studies, and increased personnel expenses.
- General and administrative expenses decreased by \$0.39 million to \$3.99 million for the nine months ended June 30, 2022 compared to \$4.38 million for the same period last year primarily due to a decrease in noncash share-based compensation.

Total other income decreased by \$7.74 million to \$0.80 million for the nine months ended June 30, 2022 compared to \$8.54 million for the same period last year primarily due to a decrease in grant income associated with the completion of clinical study activities under our federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the nine months ended June 30, 2022, our net loss was \$14.74 million, or \$1.04 per common share, compared to a net loss of \$9.66 million, or \$0.83 per common share, for the nine months ended June 30, 2021.

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## Capital Expenditures

Our capital expenditures primarily consist of computer and office equipment. There were no significant capital expenditures for the nine months ended June 30, 2022 and 2021.

## Liquidity and Capital Resources

As a clinical-stage company we have not generated significant revenue, and we expect to incur operating losses as we continue our efforts to acquire, develop, seek regulatory approval for and commercialize product candidates and execute on our strategic initiatives. Our operations have historically been funded through issuances of common shares, exercises of common share purchase warrants, convertible preferred shares, convertible loans, government grants and tax incentives. For the nine-month periods ended June 30, 2022 and 2021, we reported net losses of \$14.73 million and \$9.66 million, respectively.

On March 24, 2022, we completed a registered direct offering of 1,540,000 common shares, no par value, and pre-funded warrants to purchase up to an aggregate of 1,199,727 common shares. In a concurrent private placement, we issued common share purchase warrants to purchase an aggregate of up to 2,739,727 common shares. After deducting the placement agent fees and offering expenses, net proceeds to the Company were approximately \$9.01 million.

On November 22, 2021, we entered into an equity distribution agreement with RBC Capital Markets, LLC (RBCCM), as sales agent. Pursuant to the terms of the agreement, as amended March 4, 2022, the Company could offer and sell, from time to time, common shares through an at-the-market offering program for up to \$15.4 million in gross cash proceeds. From November 22, 2021 to March 21, 2022, we sold a total of 626,884 common shares pursuant to the agreement. After deducting commissions and direct costs, net proceeds totaled approximately \$2.62 million. On March 21, 2022, the Company and RBCCM entered into an agreement terminating the agreement effective March 21, 2022.

Under our contribution agreement with the Canadian government's Strategic Innovation Fund (SIF), we are eligible to receive cash reimbursements up to C\$14.05 million (approximately \$11 million USD) in the aggregate for certain research and development expenses related to our EB05 clinical development program. For the year ended September 30, 2021, we recorded \$10.34 million in grant income, and for the nine months ended June 30, 2022, we recorded \$0.78 million in grant income.

On March 2, 2021, we completed a registered public offering of an aggregate of 1,562,500 common shares, no par value, of the Company at an offering price of \$6.40 per share for net proceeds of \$8.89 million, after deducting underwriter fees and related offering expenses.

For the year ended September 30, 2021, the exercise of warrants and options as well as sales under an equity distribution agreement with RBCCM resulted in the issuance of 987,859 common shares and net cash proceeds to the Company of \$5.12 million.

At June 30, 2022, we had cash and cash equivalents of \$12.81 million, working capital of \$9.52 million, shareholders' equity of \$11.84 million and an accumulated deficit of \$41.23 million. We plan to finance company operations over the course of the next twelve months with cash and cash equivalents on hand and reimbursements of eligible research and development expenses under our contribution agreement with the Canadian government. Management has flexibility to adjust this timeline by making changes to planned expenditures related to, among other factors, the size and timing of clinical trial expenditures, staffing levels, and the acquisition or in-licensing of new product candidates. To help fund our operations and meet our obligations in the future, we are planning to seek additional financing through government grants, equity sales, debt financings or other capital sources, including potential future licensing, collaboration or similar arrangements with third parties or other strategic transactions. If we determine it is advisable to raise additional funds, there is no assurance that adequate funding will be available to us or, if available, that such funding will be available on terms that we or our shareholders view as favorable. Market volatility, inflation and concerns related to the COVID-19 pandemic may have a significant impact on the availability of funding sources and the terms at which any funding may be available.

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**Research and Development**

Our primary business is the development of innovative therapeutics for inflammatory and immune-related diseases with clear unmet medical needs. We focus our resources on research and development activities, including the conduct of clinical studies and product development, and expense such costs as they are incurred. Our research and development expenses have primarily consisted of employee-related expenses, including salaries, benefits, taxes, travel, and share-based compensation expense for personnel in research and development functions; expenses related to process development and production of product candidates paid to contract manufacturing organizations, including the cost of acquiring, developing, and manufacturing research material; costs associated with clinical activities, including expenses for contract research organizations; and clinical trials and activities related to regulatory filings for our product candidates, including regulatory consultants.

Research and development expenses, which have historically varied based on the level of activity in our clinical programs, are significantly influenced by study initiation expenses and patient recruitment rates, and as a result are expected to continue to fluctuate, sometimes substantially. Our research and development costs were \$11.54 million and \$13.82 million for the nine months ended June 30, 2022 and 2021, respectively. The decrease was due primarily to decreased milestone and bulk drug substance payments and lower license fees, which were partially offset by higher external research expenses related to the ongoing Phase 2/Phase 3 clinical study of our EB05 drug candidate, higher manufacturing expenses and increased salary and related personnel expenses.

**Off Balance Sheet Arrangements**

We do not have any off balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company and are not required to provide disclosure under this item.

**Item 4. Controls and Procedures.**

*Disclosure Controls and Procedures*

Our management is responsible for establishing and maintaining disclosure controls and procedures to provide reasonable assurance that material information related to our Company, including our consolidated subsidiaries, is made known to senior management, including our Chief Executive Officer and Chief Financial Officer, by others within those entities on a timely basis so that appropriate decisions can be made regarding public disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and our Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Securities and Exchange Act of 1934, as amended) as of June 30, 2022. Our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures, as of June 30, 2022, were effective.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II — OTHER INFORMATION**

**Item 1. Legal Proceedings.**

From time to time, we may be involved in legal proceedings, claims and litigation arising in the ordinary course of business. We are not currently a party to any material legal proceedings or claims outside the ordinary course of business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**Item 1A. Risk Factors.**

There have been no material changes to the risk factors discussed in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended September 30, 2021, filed with the Securities and Exchange Commission on December 28, 2021.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

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**Item 6. Exhibits****EXHIBIT INDEX****Exhibit No. Description**

<a href="#">31.1</a>	<a href="#">Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
<a href="#">31.2</a>	<a href="#">Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
<a href="#">32.1*</a>	<a href="#">Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
<a href="#">32.2*</a>	<a href="#">Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

\* The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of Edesa Biotech, Inc. under the Securities Act of 1933, as amended, or the Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 12, 2022

**EDESA BIOTECH, INC.**

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



**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

I, Pardeep Nijhawan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Edesa Biotech, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2022.

By: /s/ Pardeep Nijhawan  
Pardeep Nijhawan  
Director, Chief Executive Officer and Corporate  
Secretary  
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

I, Kathi Niffenegger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Edesa Biotech, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2022.

By: /s/ Kathi Niffenegger

Kathi Niffenegger  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. 1350, AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Edesa Biotech, Inc. (the Company) on Form 10-Q for the quarter ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Pardeep Nijhawan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2022.

By: /s/ Pardeep Nijhawan

Pardeep Nijhawan  
Director, Chief Executive Officer and Corporate  
Secretary  
(Principal Executive Officer)

**CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. 1350, AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Edesa Biotech, Inc. (the Company) on Form 10-Q for the quarter ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Kathi Niffenegger, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2022.

By: /s/ Kathi Niffenegger

Kathi Niffenegger  
Chief Financial Officer  
(Principal Financial Officer)