

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 March 31, 2023

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:

Title of each class	Trading Symbol	Name of each exchange on which registered
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 May 10, 2023, the registrant had 20,587,717 common shares issued and outstanding.

EDESA BIOTECH, INC.
QUARTERLY REPORT ON FORM 10-Q
Quarter Ended March 31, 2023

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PART 1 – FINANCIAL INFORMATION

Item 1. Financial Statements

Edesa Biotech, Inc.
Condensed Interim Consolidated Balance Sheets

	<u>March 31,</u> <u>2023</u>	<u>September 30,</u> <u>2022</u>
Assets:		
Current assets:		
Cash and cash equivalents	\$ 7,471,252	\$ 7,090,919
Accounts and other receivable	50,233	1,255,451
Prepaid expenses and other current assets	<u>608,109</u>	<u>745,543</u>
Total current assets	8,129,594	9,091,913
Non-current assets:		
Property and equipment, net	10,769	12,694
Long-term deposits	174,126	171,464
Intangible asset, net	2,230,606	2,281,192
Right-of-use assets	<u>128,390</u>	<u>18,465</u>
Total assets	<u>\$ 10,673,485</u>	<u>\$ 11,575,728</u>
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 1,499,380	\$ 2,121,802
Short-term right-of-use lease liabilities	<u>65,406</u>	<u>18,975</u>
Total current liabilities	1,564,786	2,140,777
Non-current liabilities:		
Long-term payables	44,340	43,662
Long-term right-of-use lease liabilities	<u>64,422</u>	<u>-</u>
Total liabilities	1,673,548	2,184,439
Commitments (Note 5)		
Shareholders' equity:		
Capital shares		
Authorized unlimited common and preferred shares without par value		
Issued and outstanding:		
20,058,665 common shares (September 30, 2022 - 16,662,014)	45,453,733	42,473,099
Additional paid-in capital	12,489,949	11,176,345
Accumulated other comprehensive loss	(230,026)	(213,602)
Accumulated deficit	<u>(48,713,719)</u>	<u>(44,044,553)</u>
Total shareholders' equity	8,999,937	9,391,289
Total liabilities and shareholders' equity	<u>\$ 10,673,485</u>	<u>\$ 11,575,728</u>

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

Edesa Biotech, Inc.
Condensed Interim Consolidated Statements of Operations

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>March 31,</u> <u>2023</u>	<u>March 31,</u> <u>2022</u>	<u>March 31,</u> <u>2023</u>	<u>March 31,</u> <u>2022</u>
Expenses:				
Research and development	\$ 1,458,190	\$ 3,042,815	\$ 2,815,528	\$ 6,993,861
General and administrative	952,391	1,532,416	1,973,358	2,743,093
Loss from operations	(2,410,581)	(4,575,231)	(4,788,886)	(9,736,954)
Other income (loss):				
Reimbursement grant income	-	-	-	780,257
Interest income	85,718	3,748	135,147	9,868
Foreign exchange gain (loss)	(8,686)	2,967	(14,627)	(364)
	<u>77,032</u>	<u>6,715</u>	<u>120,520</u>	<u>789,761</u>
Loss before income taxes	(2,333,549)	(4,568,516)	(4,668,366)	(8,947,193)
Income tax expense	800	800	800	800
Net loss	(2,334,349)	(4,569,316)	(4,669,166)	(8,947,993)
Exchange differences on translation	8,643	13,066	(16,424)	44,915
Net comprehensive loss	\$ (2,325,706)	\$ (4,556,250)	\$ (4,685,590)	\$ (8,903,078)
Weighted average number of common shares	19,973,319	13,867,345	19,171,939	13,610,164
Loss per common share - basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.33)</u>	<u>\$ (0.24)</u>	<u>\$ (0.66)</u>

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

Edesa Biotech, Inc.
Condensed Interim Consolidated Statements of Cash Flows

	Six Months Ended	
	March 31, 2023	March 31, 2022
Cash flows from operating activities:		
Net loss	\$ (4,669,166)	\$ (8,947,993)
Adjustments for:		
Depreciation and amortization	54,502	59,633
Share-based compensation	621,221	1,239,286
Changes in working capital items:		
Accounts and other receivable	1,137,833	2,068,473
Prepaid expenses and other current assets	140,852	97,209
Accounts payable and accrued liabilities	(648,482)	1,859,124
Net cash used in operating activities	<u>(3,363,240)</u>	<u>(3,624,268)</u>
Cash flows from investing activities:		
Purchase of property and equipment	-	(4,339)
Net cash used in investing activities	<u>-</u>	<u>(4,339)</u>
Cash flows from financing activities:		
Proceeds from issuance of common shares and warrants	3,027,496	11,957,567
Proceeds from exercise of warrants	770,531	-
Payments for issuance costs of common shares and warrants	(121,612)	(327,653)
Net cash provided by financing activities	<u>3,676,415</u>	<u>11,629,914</u>
Effect of exchange rate changes on cash and cash equivalents	<u>67,158</u>	<u>46,633</u>
Net change in cash and cash equivalents	<u>380,333</u>	<u>8,047,940</u>
Cash and cash equivalents, beginning of period	<u>7,090,919</u>	<u>7,839,259</u>
Cash and cash equivalents, end of period	<u>\$ 7,471,252</u>	<u>\$ 15,887,199</u>
Supplemental Disclosure of Noncash Financing Activities:		
Issuance costs withheld from gross proceeds from issuance of common shares and warrants	\$ -	\$ 393,461
Fair value of placement agent warrants	-	408,059

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

Edesa Biotech, Inc.
Condensed Interim Consolidated Statements of Changes in Shareholders' Equity

	Shares	Common Shares	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Three Months Ended March 31, 2023						
Balance - December 31, 2022	19,353,351	\$ 44,473,823	\$ 12,417,672	\$ (238,669)	\$ (46,379,370)	\$ 10,273,456
Issuance of common shares upon exercise of warrants	705,314	994,618	(224,087)	-	-	770,531
Issuance costs	-	(14,708)	8,817	-	-	(5,891)
Share-based compensation	-	-	287,547	-	-	287,547
Net loss and comprehensive loss	-	-	-	8,643	(2,334,349)	(2,325,706)
Balance - March 31, 2023	20,058,665	\$ 45,453,733	\$ 12,489,949	\$ (230,026)	\$ (48,713,719)	\$ 8,999,937
Three Months Ended March 31, 2022						
Balance - December 31, 2021	13,518,799	\$ 36,116,225	\$ 5,480,739	\$ (173,413)	\$ (30,874,306)	\$ 10,549,245
Issuance of common shares and warrants in equity offering	1,943,488	4,952,013	6,702,293	-	-	11,654,306
Issuance costs including fair value of placement agent warrants	-	(804,158)	(448,738)	-	-	(1,252,896)
Share-based compensation	-	-	630,008	-	-	630,008
Net loss and comprehensive loss	-	-	-	13,066	(4,569,316)	(4,556,250)
Balance - March 31, 2022	15,462,287	\$ 40,264,080	\$ 12,364,302	\$ (160,347)	\$ (35,443,622)	\$ 17,024,413
Six Months Ended March 31, 2023						
Balance - September 30, 2022	16,662,014	\$ 42,473,099	\$ 11,176,345	\$ (213,602)	\$ (44,044,553)	\$ 9,391,289
Issuance of common shares and warrants in equity offering	2,691,337	2,082,669	944,827	-	-	3,027,496
Issuance of common shares upon exercise of warrants	705,314	994,618	(224,087)	-	-	770,531
Issuance costs	-	(96,653)	(28,357)	-	-	(125,010)
Share-based compensation	-	-	621,221	-	-	621,221
Net loss and comprehensive loss	-	-	-	(16,424)	(4,669,166)	(4,685,590)
Balance - March 31, 2023	20,058,665	\$ 45,453,733	\$ 12,489,949	\$ (230,026)	\$ (48,713,719)	\$ 8,999,937
Six Months Ended March 31, 2022						
Balance - September 30, 2021	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	-	-	1,239,286	-	-	1,239,286
Net loss and comprehensive loss	-	-	-	44,915	(8,947,993)	(8,903,078)
Balance - March 31, 2022	15,462,287	\$ 40,264,080	\$ 12,364,302	\$ (160,347)	\$ (35,443,622)	\$ 17,024,413

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

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. It operates under its wholly owned subsidiaries, Edesa Biotech Research, Inc., an Ontario, Canada corporation, and Edesa Biotech USA, Inc., a California, USA corporation.

The Company's common shares trade on The Nasdaq Capital Market in the United States under the symbol "EDSA".

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, 2022, which was filed with the Securities and Exchange Commission (SEC) on December 16, 2022.

The accompanying unaudited condensed interim consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. 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 six months ended March 31, 2023 are not necessarily indicative of the results that may be expected for other interim periods or the fiscal year ending September 30, 2023.

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; operating lease 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

The consolidated financial statements of the Company are presented in U.S. dollars, unless otherwise stated, which is the Company's and its wholly owned subsidiary's, Edesa Biotech USA, Inc., functional currency. The functional currency of the Company's wholly owned subsidiary, Edesa Biotech Research, Inc., as determined by management, is Canadian dollars.

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 have been fully 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>March 31, 2023</u>	<u>September 30, 2022</u>
The Constructs	\$ 2,529,483	\$ 2,529,483
Less: accumulated amortization	<u>(298,877)</u>	<u>(248,291)</u>
Total intangible assets, net	<u>\$ 2,230,606</u>	<u>\$ 2,281,192</u>

Amortization expense amounted to \$0.03 million for each of the three months ended March 31, 2023 and 2022 and \$0.05 million for each of the six months ended March 31, 2023 and 2022 .

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

Year Ending	
September 30, 2023	\$ 50,586
September 30, 2024	101,172
September 30, 2025	101,172
September 30, 2026	101,172
September 30, 2027	101,172
Thereafter	<u>1,775,332</u>
	<u>\$ 2,230,606</u>

4. Right-of-Use Lease with Related Party

The Company leases a facility used for executive offices from a related company. The original lease expired in December 2022, and the Company executed a two-year extension through December 2024.

The components of right-of-use lease cost were as follows:

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>March 31, 2023</u>	<u>March 31, 2022</u>	<u>March 31, 2023</u>	<u>March 31, 2022</u>
Right-of-use lease cost, included in general and administrative on the Statements of Operations	<u>\$ 21,443</u>	<u>\$ 20,255</u>	<u>\$ 40,342</u>	<u>\$ 40,608</u>

Lease terms and discount rates were as follows:

	<u>March 31, 2023</u>	<u>September 30, 2022</u>
Remaining lease term (months):	21	3
Estimated incremental borrowing rate:	9.2%	6.5%

The future minimum lease payments under right-of-use leases at March 31, 2023 were as follows:

Year Ending	
September 30, 2023	\$ 39,995
September 30, 2024	79,989
September 30, 2025	<u>19,997</u>
Total lease payments	139,981
Less imputed interest	<u>10,153</u>
Present value of right-of-use lease liabilities	129,828
Present value included in current liabilities	<u>65,406</u>
Present value included in long-term liabilities	<u>\$ 64,422</u>

Cash flow information was as follows:

	Six Months Ended	
	March 31, 2023	March 31, 2022
Cash paid for amounts included in the measurement of right-of-use lease liabilities, included in accounts payable and accrued liabilities on the Statements of Cash Flow.	<u>\$ 38,907</u>	<u>\$ 40,610</u>

5. Commitments

Research and other commitments

The Company has commitments for contracted research organizations who perform clinical trials for the Company's ongoing clinical studies and other service providers. Approximate aggregate future contractual payments at March 31, 2023 are as follows:

Year Ending	
September 30, 2023	\$ 1,670,600
September 30, 2024	400,000
September 30, 2025	48,000
September 30, 2026	35,000
September 30, 2027	<u>11,000</u>
	<u>\$ 2,164,600</u>

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 is committed to payments of up to an aggregate amount of \$356 million contingent upon meeting certain milestones outlined in the license agreement, primarily relating to future potential commercial approval and sales milestones. 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 milestone, royalty or sublicensing payments were made to the third party during the three and six months ended March 31, 2023 and 2022.

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 \$18.4 million after deducting \$0.08 million that is included in the commitments table above for the year ending September 30, 2023. 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. Milestone payments totaling \$0.06 million and \$0.12 million were made to the third party during the three and six months ended March 31, 2023, respectively. No milestones were met during the three and six months ended March 31, 2022. No royalty or sublicensing payments were made to the third party during the three and six months ended March 31, 2023 and 2022.

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. Milestone payments of \$0.03 million were made under the 2021 agreement during the six months ended March 31, 2022. No milestones were met during the three and six months ended March 31, 2023 or the three months ended March 31, 2022. The Company is committed to remaining milestone 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 or prorated license fee annually as long as the requirement to file an IND remains unfulfilled.

6. Capital Shares

Equity Distribution Agreements

On March 27, 2023, the Company entered into an equity distribution agreement with Canaccord Genuity LLC (Canaccord), as sales agent, pursuant to which the Company may offer and sell, from time to time, common shares through an at-the-market equity offering program for up to \$20 million in gross proceeds, subject to certain offering limitations that currently allow the Company to offer and sell common shares having an aggregate gross sales price of up to \$8.37 million. The Company has no obligation to sell any of the common shares and may at any time suspend sales or terminate the equity distribution agreement in accordance with its terms. During the three months ended March 31, 2023, there were no sales under the equity distribution agreement.

From November 22, 2021 until terminated March 21, 2022, the Company had an equity distribution agreement for an at-the-market equity offering program with another sales agent. During the six months ended March 31, 2022, the Company sold a total of 626,884 common shares pursuant to the agreement for net proceeds of \$2.62 million.

Equity offerings

On November 2, 2022, the Company completed a private placement of units consisting of 2,691,337 common shares, Class A warrants to purchase up to an aggregate of 1,345,665 common shares and Class B warrants to purchase up to an aggregate of 1,345,665 common shares. Net proceeds from the offering were \$2.91 million, which were allocated between the relative fair values of the common shares (using a fair value of \$2.69 million) and the common share purchase warrants (using a total fair value of \$1.22 million). The warrants became exercisable December 23, 2022. The Class A warrants have an exercise price of \$1.50 per share and will expire on December 23, 2025. The Class B warrants have an exercise price of \$1.00 per share and will expire on December 23, 2023. The warrants are considered contracts on the Company's own shares and are classified as equity.

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. Net proceeds from the offering were \$9.01 million, which were allocated between the relative fair values of the common shares and pre-funded warrants (using a total fair value of \$5.87 million) and the common share purchase warrants (using a total fair value of \$4.13 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. The warrants are considered contracts on the Company's own shares and are classified as equity. In connection with the offering, the Company 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 with a fair value of \$0.41 million.

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:

	Number of Warrant Shares (#)	Weighted Average Exercise Price
Six Months Ended March 31, 2023		
Balance - September 30, 2022	3,651,953	\$ 4.00
Issued	2,691,330	1.25
Exercised	(705,314)	1.09
Balance - March 31, 2023	5,637,969	\$ 3.05
Six Months Ended March 31, 2022		
Balance - September 30, 2021	720,446	\$ 5.69
Issued	2,931,507	3.59
Balance - March 31, 2022	3,651,953	\$ 4.00

The weighted average contractual life remaining on the outstanding warrants at March 31, 2023 is 37 months.

The following table summarizes information about the warrants outstanding at March 31, 2023:

Number of Warrants (#)	Exercise Prices	Expiry Dates
28,124	\$ 15.90	May 2023
563,685	\$ 4.80	July 2023
770,786	\$ 1.00	December 2023
7,484	\$ 4.81	June 2024
11,778	\$ 3.20	January 2025
1,215,230	\$ 1.50	December 2025
109,375	\$ 8.00	February 2026
191,780	\$ 4.56	March 2027
2,739,727	\$ 3.52	September 2027
5,637,969		

The fair value of warrants granted during the six months ended March 31, 2023 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Six Months Ended March 31, 2023		Six Months Ended March 31, 2022	
	Class A Warrants	Class B Warrants	Class A Warrants	Class B Warrants
Risk free interest rate	4.54%	4.76%	2.37%	2.37%
Expected life	3.14 years	1.14 years	5.5 years	5 years
Expected share price volatility	90.73%	89.70%	87.09%	87.09%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

Pre-funded Warrants

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

	Number of Pre-funded Warrant Shares (#)
Six Months Ended March 31, 2022	
Balance - September 30, 2021	-
Issued	1,199,727
Balance - March 31, 2022	1,199,727

There were no pre-funded warrants during the six months ended March 31, 2023.

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 prior plans. Options, restricted shares and restricted share units are eligible for grant under the 2019 Plan. At March 31, 2023, the total number of shares available for issuance is 2,625,951 including shares available for the exercise of outstanding options under the 2019 Plan. The remaining number of options available for grant at March 31, 2023 is 89,540.

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 granted for directors normally have monthly vesting in equal proportions over 12 months beginning on the grant date. Options granted for employees normally have monthly vesting in equal proportions over 36 months beginning on the grant date. Options granted for new employees normally have monthly vesting in equal proportions over 36 months beginning on the monthly anniversary of the grant date following 90 days of employment.

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 Grant Date Fair Value
Six Months Ended March 31, 2023			
Balance - September 30, 2022	2,203,699	\$ 4.66	\$ 3.42
Granted	332,950	1.43	1.07
Expired	(238)	304.08	304.08
Balance - March 31, 2023	<u>2,536,411</u>	<u>\$ 4.20</u>	<u>\$ 3.09</u>
Six Months Ended March 31, 2022			
Balance - September 30, 2021	1,776,219	\$ 5.06	\$ 3.79
Granted	500,083	3.66	2.48
Forfeited	(14,754)	6.48	5.06
Expired	(214)	502.68	477.65
Balance - March 31, 2022	<u>2,261,334</u>	<u>\$ 4.70</u>	<u>\$ 3.45</u>

During the six months ended March 31, 2023, the independent members of the Board of Directors granted 332,950 employee and new employee options pursuant to the 2019 Plan. During the six months ended March 31, 2022, the independent members of the Board of Directors granted 415,083 employee options and 85,000 director options. The options have a term of 10 years and an exercise price equal to the Nasdaq closing price on the grant date.

The weighted average contractual life remaining on the outstanding options at March 31, 2023 is 94 months.

The following table summarizes information about the options under the 2019 Plan outstanding and exercisable at March 31, 2023:

Number of Options (#)	Exercisable at March 31, 2023 (#)	Range of Exercise Prices	Expiry Dates
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	323,976	\$ 3.16	Feb 2030
397,000	330,736	\$ 7.44 - 8.07	Sep 2030 - Oct 2030
682,500	480,624	\$ 5.25 - 5.65	Jan 2031 - Sep 2031
500,083	246,378	\$ 2.94 - 3.71	Feb 2032 - Mar 2032
332,950	9,539	\$ 0.96 - 1.43	Dec 2032 - Feb 2033
<u>2,536,411</u>	<u>1,691,155</u>		

The fair value of options granted during the six months ended March 31, 2023 and 2022 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Six Months Ended	
	March 31, 2023	March 31, 2022
Risk free interest rate	3.62% - 4.18%	1.71% - 2.54%
Expected life	5 years	5 years
Expected share price volatility	95.3% - 97.34%	85.91% - 86.59%
Expected dividend yield	0.00%	0.00%

The Company recorded \$0.29 million and \$0.63 million of share-based compensation expenses for the three months ended March 31, 2023 and 2022, respectively and \$0.62 million and \$1.24 million for the six months ended March 31, 2023 and 2022, respectively.

As of March 31, 2023, the Company had \$0.77 million of unrecognized share-based compensation expense, which is expected to be recognized over a period of 35 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 March 31, 2023, the grant program is complete and all grant reimbursements have been received.

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.

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.

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 and terms, as well as an analysis of historical collection rates, general economic conditions and credit status of government agencies. Credit risk for the HST refunds receivable are not considered significant since amounts are due from 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 March 31, 2023, the Company and its Canadian subsidiary had assets denominated in Canadian dollars of approximately C\$5.2 million and the U.S. dollar exchange rate at this date was equal to 1.3532 Canadian dollars. Based on the exposure at March 31, 2023, a 10% annual change in the Canadian/U.S. exchange rate would impact the Company's loss and other comprehensive loss by approximately \$0.4 million.

(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

During each of three and six months ended March 31, 2023 and 2022, the Company paid cash of \$0.02 million and \$0.04 million, respectively, for a right of use lease 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. On December 31, 2022, the Company executed a two-year lease extension through December 31, 2024 in accordance with the terms of the original lease agreement.

11. Subsequent Events

Subsequent to March 31, 2023, equity sales under the Company's "at the market" offering program have resulted in the issuance of 562,052 common shares and receipt of net cash proceeds of \$0.60 million after deducting sales agent commissions.

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 March 31, 2023 and our audited consolidated financial statements for the year ended September 30, 2022 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on December 16, 2022.

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, 2022 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 March 31, 2023 and September 30, 2022, and for the three and six months ended March 31, 2023 and 2022 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 developing innovative ways to treat inflammatory and immune-related diseases.

Our approach is to acquire, develop and commercialize drug candidates based on mechanisms of action that have demonstrated proof-of-concept in human subjects. We prioritize our efforts on disease indications where there is compelling scientific rationale, no approved therapies or where there are unmet medical needs, and where there are large addressable market opportunities, among other factors. We have multiple late-stage product candidates in our development pipeline.

Our most advanced drug candidate is EB05 (paridiprubart), a monoclonal antibody developed for acute and chronic disease indications that involve dysregulated innate immunity responses. EB05 inhibits toll-like receptor 4 (TLR4), a key immune signaling protein and an important mediator of inflammation. We are currently evaluating EB05 as a potential treatment for Acute Respiratory Distress Syndrome (ARDS), a life-threatening form of respiratory failure. In September 2022, we reported final results from the Phase 2 part of a Phase 2/Phase 3 study of EB05 in ARDS patients who were hospitalized for Covid-19-related respiratory disease. Among the findings, EB05 demonstrated statistically significant mortality reductions in critically ill hospitalized patients treated with EB05 plus Standard of Care treatment (SOC). Based in part of these findings, the U.S. Food and Drug Administration (FDA) granted us Fast Track designation. We are currently enrolling patients in the Phase 3 part of the EB05 study.

In addition to EB05, we are developing product candidates for a number of chronic dermatological and inflammatory conditions. We recently reported preliminary, topline results from a Phase 2b clinical study evaluating multiple concentrations of our drug candidate, EB01, as a monotherapy for moderate-to-severe chronic Allergic Contact Dermatitis (ACD), a common occupational skin condition. Among the preliminary findings, 1.0% EB01 cream demonstrated statistically significant improvement over placebo for the primary endpoint and a key secondary endpoint. We are preparing for an End of Phase 2 meeting with FDA following full analysis. In January 2023, Health Canada approved our clinical trial application (CTA) for our EB06 monoclonal antibody candidate to conduct a future Phase 2 study in vitiligo, a common autoimmune disorder that causes skin to lose its color in patches. We are also preparing an investigational new drug application (IND) in the United States for our EB07 (paridiprubart) product candidate to conduct a future Phase 2 study in systemic sclerosis (SSc), an autoimmune rheumatic disorder that causes fibrosis (scarring/hardening) of skin and internal organs.

Recent Developments

EB05 (Paridiprubart) Clinical Study

In March 2023, we announced that the company and the FDA agreed on the primary endpoint and population for the Phase 3 part of a Phase 2/3 study evaluating our monoclonal antibody candidate, EB05, as a therapy for hospitalized Covid-19 patients with ARDS. Under the amended protocol design, Edesa will evaluate a single cohort of severely ill patients on invasive mechanical ventilation, both with and without additional organ support such as extracorporeal membrane oxygenation (ECMO). Edesa plans to enroll approximately 600 evaluable hospitalized subjects. The primary endpoint will be the mortality rate at 28 days. Last year, Canadian regulators approved a similar Phase 3 study of EB05 in Covid-19-induced ARDS among two separate cohorts of patients, and we are evaluating potential future harmonization of the Canadian protocol with the U.S. With recruitment now open in both the U.S. and Canada, we have discontinued recruitment at secondary sites, which were located in Poland and Colombia. In addition to Covid-19 induced ARDS, we are also exploring various approaches to evaluating EB05 in a general ARDS population.

In April 2023, we announced the World Health Organization and the United States Adopted Name (USAN) Council have adopted the international nonproprietary name "paridiprubart" for our anti-TLR4 monoclonal antibody candidate.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

Total operating expenses decreased by \$2.17 million to \$2.41 million for the three months ended March 31, 2023 compared to \$4.58 million for the same period last year:

- Research and development expenses decreased by \$1.58 million to \$1.46 million for the three months ended March 31, 2023 compared to \$3.04 million for the same period last year primarily due to decreased external research expenses related to our ongoing clinical studies and manufacturing of our investigational drugs.
- General and administrative expenses decreased by \$0.58 million to \$0.95 million for the three months ended March 31, 2023 compared to \$1.53 million for the same period last year primarily due to decreased personnel expenses and noncash share-based compensation.

Total other income increased by \$0.07 million to \$0.08 million for the three months ended March 31, 2023 compared to \$0.01 million for the same period last year primarily due to an increase in interest earned on cash balances.

For the three months ended March 31, 2023, our net loss was \$2.33 million, or \$0.12 per common share, compared to a net loss of \$4.57 million, or \$0.33 per common share, for the three months ended March 31, 2022.

Comparison of the Six Months Ended March 31, 2023 and 2022

Total operating expenses decreased by \$4.95 million to \$4.79 million for the six months ended March 31, 2023 compared to \$9.74 million for the same period last year:

- Research and development expenses decreased by \$4.17 million to \$2.82 million for the six months ended March 31, 2023 compared to \$6.99 million for the same period last year primarily due to decreased external research expenses related to our ongoing clinical studies and manufacturing of our investigational drugs.
- General and administrative expenses decreased by \$0.77 million to \$1.97 million for the six months ended March 31, 2023 compared to \$2.74 million for the same period last year primarily due to decreased personnel expenses and noncash share-based compensation.

Total other income decreased by \$0.67 million to \$0.12 million for the six months ended March 31, 2023 compared to \$0.79 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 six months ended March 31, 2023, our net loss was \$4.67 million, or \$0.24 per common share, compared to a net loss of \$8.95 million, or \$0.66 per common share, for the six months ended March 31, 2022.

Capital Expenditures

Our capital expenditures primarily consist of computer and office equipment. There were no significant capital expenditures for the three and six months ended March 31, 2023 and 2022.

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 six-month periods ended March 31, 2023 and 2022, we reported net losses of \$4.67 million and \$8.95 million, respectively.

On March 27, 2023, we entered into an equity distribution agreement with Canaccord Genuity LLC (Canaccord), as sales agent, pursuant to which the Company may offer and sell, from time to time, common shares through an at-the-market equity offering program for up to \$20 million in gross cash proceeds, subject to certain offering limitations that currently allow the Company to offer and sell common shares having an aggregate gross sales price of up to \$8.37 million. Canaccord will use commercially reasonable efforts to sell the common shares from time to time, based upon our instructions. We have no obligation to sell any of the common shares and may at any time suspend sales under the equity distribution agreement or terminate the equity distribution agreement in accordance with its terms. The total amount of cash that may be generated under this equity distribution agreement is uncertain and depends on a variety of factors, including market conditions and the trading price of our common shares. There were no sales in the quarter ended March 31, 2023. Subsequent to the quarter end, sales under our equity distribution agreement with Canaccord have resulted in the issuance of 562,052 common shares and receipt of net cash proceeds of \$0.60 million after deducting sales agent commissions.

In November 2022, we completed a private placement of units consisting of 2,691,337 common shares, three-year warrants to purchase up to an aggregate of 1,345,665 common shares (Class A warrants) and twelve-month warrants to purchase up to an aggregate of 1,345,665 common shares (Class B warrants). The gross proceeds from this offering are approximately \$3.03 million, before offering expenses. During the six months ended March 31, 2023, 705,314 shares have been issued upon the exercise of Class A and Class B warrants, with proceeds to the Company of \$0.77 million.

In March 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.

From November 2021 to March 2022, we sold a total of 626,884 common shares under an “at-the-market” equity distribution program which resulted in net proceeds of \$2.62 million after deducting commissions and direct costs.

Under our contribution agreement with the Canadian government’s Strategic Innovation Fund (SIF), we were 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 years ended September 30, 2022 and 2021, we recorded grant income of \$0.78 million and \$10.34 million respectively. All grant reimbursements were received by December 31, 2022.

At March 31, 2023, we had cash and cash equivalents of \$7.47 million, working capital of \$6.56 million, shareholders’ equity of \$9.0 million and an accumulated deficit of \$48.71 million. We plan to finance company operations over the course of the next twelve months with cash and cash equivalents on hand and equity sales under the at-the-market offering program. 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 and manufacturing campaigns, 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 plan to seek additional financing through the sale of equity, government grants, debt financings or other capital sources, including potential future licensing, collaboration or similar arrangements with third parties or other strategic transactions. 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, interest rates, government policies and concerns related to the war in Ukraine and 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.

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 and contract testing 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 \$2.82 million and \$6.99 million for the six months ended March 31, 2023 and 2022, respectively. The decrease was due primarily to decreased external research expenses related to our ongoing clinical studies and manufacturing of our investigational drugs.

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 March 31, 2023. Our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures, as of March 31, 2023, 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 March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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, 2022, filed with the Securities and Exchange Commission on December 16, 2022.

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.

Item 6. Exhibits**EXHIBIT INDEX**

Exhibit No.	Description
31.1	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).
31.2	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).
32.1*	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).
32.2*	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).
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.

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: May 11, 2023

EDESA BIOTECH, INC.

/s/ Kathi Niffenegger

Kathi Niffenegger, Chief Financial Officer
*(Principal Financial Officer and Duly Authorized
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: May 11, 2023.

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: May 11, 2023.

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 March 31, 2023, 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: May 11, 2023.

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 March 31, 2023, 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: May 11, 2023.

By: /s/ Kathi Niffenegger
Kathi Niffenegger
Chief Financial Officer
(Principal Financial Officer)