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, 2024

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	**N/A**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
100 Spy Court, Markham, ON, Canada L3R 5H6	**(289)800-9600**
(Address of principal executive offices and zip code)	(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 9, 2024, the registrant had 3,247,389 common shares issued and outstanding.

EDESA BIOTECH, INC.
QUARTERLY REPORT ON FORM 10-Q
Quarter Ended June 30, 2024

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PART 1 – FINANCIAL INFORMATION

Item 1. Financial Statements

Edesa Biotech, Inc.
Condensed Interim Consolidated Balance Sheets

	June 30, 2024	September 30, 2023
Assets:		
Current assets:		
Cash and cash equivalents	**$** 2,040,884	$ 5,361,397
Accounts and other receivable	551,064	626,543
Prepaid expenses and other current assets	454,686	448,912
Total current assets	3,046,634	6,436,852
Non-current assets:		
Property and equipment, net	-	8,702
Long-term deposits	40,661	173,490
Intangible asset, net	2,104,141	2,180,020
Right-of-use assets	36,286	91,373
Total assets	**$** 5,227,722	$ 8,890,437
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable and accrued liabilities	**$** 2,321,810	$ 1,747,150
Short-term right-of-use lease liabilities	38,817	74,714
Total current liabilities	2,360,627	1,821,864
Non-current liabilities:		
Long-term right-of-use lease liabilities	-	19,773
Total liabilities	2,360,627	1,841,637
Commitments *(Note 5)*		
Shareholders' equity:		
Capital shares		
Authorized unlimited common and preferred shares without par value		
Issued and outstanding:		
3,247,389 common shares (September 30, 2023 - 3,075,473)	47,236,024	46,643,151
Additional paid-in capital	13,482,824	13,039,265
Accumulated other comprehensive loss	(224,791)	(214,648)
Accumulated deficit	(57,626,962)	(52,418,968)
Total shareholders' equity	2,867,095	7,048,800
Total liabilities and shareholders' equity	**$** 5,227,722	$ 8,890,437

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

Edesa Biotech, Inc.
Condensed Interim Consolidated Statements of Operations

	Three Months Ended		Nine Months Ended	
	June 30, 2024	**June 30, 2023**	**June 30, 2024**	**June 30, 2023**
Expenses:				
Research and development	**$** 897,305	$ 1,025,622	**$** 2,778,100	$ 3,841,150
General and administrative	**$** 1,035,140	$ 1,038,587	**$** 3,232,248	3,011,945
Loss from operations	(1,932,445)	(2,064,209)	(6,010,348)	(6,853,095)
Other income (loss):				
Reimbursement grant income	236,226	-	661,062	-
Interest income	32,848	82,754	137,007	217,901
Misc other income	-	-	14,766	-
Foreign exchange loss	(4,841)	(3,451)	(9,681)	(18,078)
	264,233	79,303	803,154	199,823
Loss before income taxes	(1,668,212)	(1,984,906)	(5,207,194)	(6,653,272)
Income tax expense	-	-	800	800
Net loss	(1,668,212)	(1,984,906)	(5,207,994)	(6,654,072)
Exchange differences on translation	1,612	39,839	(10,143)	23,415
Net comprehensive loss	**$** (1,666,600)	$ (1,945,067)	**$** (5,218,137)	$ (6,630,657)
Weighted average number of common shares	3,221,806	2,930,681	3,180,647	2,802,793
Loss per common share - basic and diluted	**$** (0.52)	$ (0.68)	**$** (1.64)	$ (2.37)

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

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

	Nine Months Ended	
	June 30, 2024	**June 30, 2023**
Cash flows from operating activities:		
Net loss	**$** (5,207,994)	$ (6,654,072)
Adjustments for:		
Depreciation and amortization	141,843	137,501
Share-based compensation	443,559	729,380
Gain on payable forgiveness	(14,766)	-
Changes in working capital items:		
Accounts and other receivable	71,501	1,149,129
Prepaid expenses and other current assets	109,647	339,031
Accounts payable and accrued liabilities	533,044	(869,430)
Net cash used in operating activities	(3,923,166)	(5,168,461)
Cash flows from financing activities:		
Proceeds from issuance of common shares and warrants	729,387	3,861,245
Proceeds from exercise of warrants	-	770,531
Payments for issuance costs of common shares and warrants	(76,389)	(214,130)
Repayment of debt	(29,532)	-
Net cash provided by financing activities	623,466	4,417,646
Effect of exchange rate changes on cash and cash equivalents	(20,813)	117,066
Net change in cash and cash equivalents	(3,320,513)	(633,749)
Cash and cash equivalents, beginning of period	5,361,397	7,090,919
Cash and cash equivalents, end of period	**$** 2,040,884	$ 6,457,170

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 Shareholders' Equity
Three Months Ended June 30, 2024						
Balance - March 31, 2024	3,215,968	$ 47,136,168	$ 13,373,318	$ (226,403)	$ (55,958,750)	$ 4,324,333
Issuance of common shares	31,421	138,421	-	-	-	138,421
Issuance costs	-	(38,565)	-	-	-	(38,565)
Share-based compensation	-	-	109,506	-	-	109,506
Net loss and comprehensive loss	-	-	-	1,612	(1,668,212)	(1,666,600)
Balance - June 30, 2024	3,247,389	$ 47,236,024	$ 13,482,824	$ (224,791)	$ (57,626,962)	$ 2,867,095
Three Months Ended June 30, 2023						
Balance - March 31, 2023	2,865,517	$ 45,453,733	$ 12,489,949	$ (230,026)	$ (48,713,719)	$ 8,999,937
Issuance of common shares upon exercise of warrants	115,441	833,749	-	-	-	833,749
Issuance costs	-	(146,295)	-	-	-	(146,295)
Share-based compensation	-	-	108,159	-	-	108,159
Net loss and comprehensive loss	-	-	-	39,839	(1,984,906)	(1,945,067)
Balance - June 30, 2023	2,980,958	$ 46,141,187	$ 12,598,108	$ (190,187)	$ (50,698,625)	$ 7,850,483
Nine Months Ended June 30, 2024						
Balance - September 30, 2023	3,075,473	$ 46,643,151	$ 13,039,265	$ (214,648)	$ (52,418,968)	$ 7,048,800
Issuance of common shares	171,916	729,387	-	-	-	729,387
Issuance costs	-	(136,514)	-	-	-	(136,514)
Share-based compensation	-	-	443,559	-	-	443,559
Net loss and comprehensive loss	-	-	-	(10,143)	(5,207,994)	(5,218,137)
Balance - June 30, 2024	3,247,389	$ 47,236,024	$ 13,482,824	$ (224,791)	$ (57,626,962)	$ 2,867,095
Nine Months Ended June 30, 2023						
Balance - September 30, 2022	2,380,280	$ 42,473,099	$ 11,176,345	$ (213,602)	$ (44,044,553)	$ 9,391,289
Issuance of common shares and warrants in equity offering	499,918	2,916,418	944,827	-	-	3,861,245
Issuance of common shares upon exercise of warrants	100,760	994,618	(224,087)	-	-	770,531
Issuance costs	-	(242,948)	(28,357)	-	-	(271,305)
Share-based compensation	-	-	729,380	-	-	729,380
Net loss and comprehensive loss	-	-	-	23,415	(6,654,072)	(6,630,657)
Balance - June 30, 2023	2,980,958	$ 46,141,187	$ 12,598,108	$ (190,187)	$ (50,698,625)	$ 7,850,483

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

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, 2023, which was filed with the Securities and Exchange Commission (SEC) on December 15, 2023.

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 nine months ended June 30, 2024 are not necessarily indicative of the results that may be expected for other interim periods or the fiscal year ending September 30, 2024.

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

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:

	June 30, 2024	September 30, 2023
The Constructs	$ 2,529,483	$ 2,529,483
Less: accumulated amortization	(425,342)	(349,463)
Total intangible assets, net	$ 2,104,141	$ 2,180,020

Amortization expense amounted to $0.03 million for each of the three months ended June 30, 2024 and 2023 and $0.08 million for each of the nine months ended June 30, 2024 and 2023.

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

Year Ending	
September 30, 2024	25,293
September 30, 2025	101,172
September 30, 2026	101,172
September 30, 2027	101,172
September 30, 2028	101,172
Thereafter	1,674,160
	$ 2,104,141

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:

	Three Months Ended		Nine Months Ended	
	June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Right-of-use lease cost, included in general and administrative on the Statements of Operations	$ 19,299	$ 21,188	$ 59,208	$ 61,530

Lease terms and discount rates were as follows:

	June 30, 2024	September 30,2023
Remaining lease term (months):	6	15
Estimated incremental borrowing rate:	9.2%	9.2%

The future minimum lease payments under right-of-use leases at June 30, 2024 were as follows:

Year Ending	
September 30, 2024	$ 19,781
September 30, 2025	19,781
Total lease payments	39,562
Less imputed interest	745
Present value of right-of-use lease liabilities	38,817
Present value included in current liabilities	38,817
Present value included in long-term liabilities	$ -

Cash flow information was as follows:

	Nine Months Ended	
	June 30, 2024	June 30, 2023
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.	$ 59,732	$ 59,045

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 June 30, 2024 are as follows:

Year Ending	
September 30, 2024	$ 301,000
September 30, 2025	49,000
September 30, 2026	36,000
September 30, 2027	42,000
September 30, 2028	-
	$ 428,000

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 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 nine months ended June 30, 2024 and 2023.

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. Upon divestiture of substantially all of the assets of the Company, the Company shall 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. A milestone payment of $0.04 million and $0.16 million were to the third party during the three and nine months ended June 30, 2023 and no milestone payments were made during the three and nine months ended June 30, 2024.

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 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 quarterly as long as the requirement to file an IND remains unfulfilled. For the three and nine months ended June 30, 2024, the Company recorded an expense of $25,000 and $75,000 as a result of meeting milestones outlined in the 2021 license agreement. There were no milestones achieved in the three and nine months ended June 30, 2023 and no expenses were incurred.

In June 2024, the Company's drug candidate, EB05, was selected by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, for evaluation in a U.S. government-funded clinical study. The Phase 2 platform trial will be a randomized, double-blinded, placebo-controlled, multi-center U.S. clinical trial to investigate novel threat-agnostic host-directed therapeutics, including EB05, in hospitalized adult patients with ARDS due to a variety of causes. For the EB05 cohort of the study, patients will be randomized one-to-one to either EB05 plus Standard of Care (SOC) or to a placebo plus SOC control arm. The Company plans to provide drug product for the study as well as technical support. The Company is responsible for providing drug product and placebo for the Phase 2 platform trial.

6. Capital Shares

Equity offerings

On November 2, 2022, the Company completed a private placement of units consisting of 384,475 common shares, Class A warrants to purchase up to an aggregate of 192,248 common shares and Class B warrants to purchase up to an aggregate of 192,248 common shares. Net proceeds from the offering were $2.9 million, which were allocated between the relative fair values of the common shares (using a fair value of $2.7 million) and the common share purchase warrants (using a total fair value of $1.2 million). The warrants became exercisable December 23, 2022. The Class A warrants have an exercise price of $10.50 per share and will expire on December 23, 2025. The Class B warrants have an exercise price of $7.00 per share and expired on December 23, 2023. The warrants are considered contracts on the Company's own shares and are classified as equity.

Equity distribution agreement

On March 27, 2023, the Company entered into an equity distribution agreement with Canaccord, 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 $8.4 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 nine months ended June 30, 2024, the Company sold a total of 171,916 common shares pursuant to the agreement for net proceeds of approximately $0.6 million after deducting commissions and direct costs.

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 warrant activity is as follows:

	Number of Warrant Shares (#)	Weighted Average Exercise Price
Nine Months Ended June 30, 2024		
Balance - September 30, 2023	720,909	$ 19.51
Expired	(111,192)	7.26
Balance - June 30, 2024	609,717	$ 21.74
Nine Months Ended June 30, 2023		
Balance - September 30, 2022	521,718	$ 28.00
Issued	384,496	8.75
Exercised	(100,760)	7.63
Expired	(4,018)	111.30
Balance - June 30, 2023	801,436	$ 20.93

The weighted average contractual life remaining on the outstanding warrants at June 30, 2024 is 32 months.

The following table summarizes information about the warrants outstanding at June 30, 2024:

Number of Warrants (#)	Exercise Prices	Expiry Dates
1,687	$ 22.40	January 2025
173,614	$ 10.50	December 2025
15,627	$ 56.00	February 2026
27,399	$ 31.94	March 2027
391,390	$ 24.64	September 2027
609,717		

The fair value of warrants granted during the nine months ended June 30, 2023 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Nine Months Ended June 30, 2023	
	Class A Warrants	Class B Warrants
Risk free interest rate	4.54%	4.76%
Expected life (years)	3.14	1.14
Expected share price volatility	90.73%	89.70%
Expected dividend yield	0.00%	0.00%

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. The total number of shares available for issuance under the terms of the 2019 Plan is 642,737. The remaining number of shares available to grant at June 30, 2024 is 156,679.

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 Grant Date Fair Value
Nine Months Ended June 30, 2024			
Balance - September 30, 2023	420,615	$ 25.60	$ 18.84
Granted	500	4.10	3.10
Forfeited	(2,401)	15.00	10.70
Expired	(35,674)	33.18	24.63
Balance - June 30, 2024	383,040	$ 24.93	$ 18.33
Nine Months Ended June 30, 2023			
Balance - September 30, 2022	314,853	$ 32.62	$ 23.94
Granted	47,571	10.01	7.49
Forfeited	(12,779)	22.96	16.38
Expired	(34)	2,129	2,129
Balance - June 30, 2023	349,611	$ 29.61	$ 21.77

During the three and nine months ended June 30, 2024, the independent members of the Board of Directors granted 500 employee options and no director options. During the three and nine months ended June 30, 2024 and 2023, there were no employee or director options granted. 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 June 30, 2024 is 83 months.

The following table summarizes information about the options under the 2019 Plan outstanding and exercisable at June 30, 2024:

Number of Options (#)	Exercisable at June 30, 2024 (#)	Range of Exercise Prices	Expiry Dates
374	374	$ 246.96 - 596.82	June 2024 - Mar 2025
37,719	37,719	C$ 15.12	May 2024 - Dec 2028
43,031	43,031	$ 22.12	May 2024 - Feb 2030
51,006	51,006	$ 52.08 - 56.49	May 2024 - Oct 2030
81,041	80,971	$ 36.75 - 40.18	Apr 2024 - Sep 2031
58,753	48,610	$ 25.97	Apr 2024 - Feb 2032
111,116	54,551	$ 4.10 - 10.01	Apr 2024 - Oct 2033
383,040	316,262		

The options exercisable at June 30, 2024 had a weighted average exercise price of $28.05, $22.00 intrinsic value and a weighted average remaining life of 78 months. There were 66,778 options at June 30, 2024 that had not vested with a weighted average exercise price of $10.15, $68.00 intrinsic value and a weighted average remaining life of 104 months.

The fair value of options granted during the nine months ended June 30, 2024 and 2023 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Nine Months Ended June 30, 2024	Nine Months Ended June 30, 2023
Risk free interest rate	4.92%	3.62% - 4.18%
Expected life (years)	5	5
Expected share price volatility	97.26%	95.3% - 97.34%
Expected dividend yield	0.00%	0.00%

The Company recorded $0.1 million and $0.1 million of share-based compensation expenses for the three months ended June 30, 2024 and 2023, respectively and $0.4 million and $0.7 million for the nine months ended June30, 2024 and 2023.

As of June 30, 2024, the Company had approximately $0.1 million of unrecognized share-based compensation expense, which is expected to be recognized over a period of 27 months.

Restricted share units (RSU)

The Company's 2019 Plan allows restricted share units (RSUs) to be granted to directors, officers, employees and certain external consultants and advisers. Under the 2019 Plan, the RSU term is not to exceed 10 years. The fair value is based on the 5-day VWAP of the Company's common shares up to the date of grant. The initial grant of RSUs was in August 2023. There were no RSUs granted in the comparative period.

The following is a summary of changes in the status of RSUs from October 1, 2023 through June 30, 2024:

	Number of RSU (#)	Weighted Average Grant Date Fair Value
Nine Months Ended June 30, 2024		
Balance - September 30, 2023	33,045	$ 5.60
Granted	19,772	4.52
Balance - June 30, 2024	52,817	$ 5.20

The following table summarizes information about the RSUs under the 2019 Plan outstanding and exercisable at June 30, 2024:

	Number of RSU (#)	Expiry Date
Fully-vested RSUs	52,817	August 2033 - June 2034

All RSUs that were granted vested immediately upon the grant date. The outstanding RSUs can be converted to common shares by the holder at any time prior to the expiry date. There is no future unrecorded compensation expense for the RSUs.

7. Government Contributions

Reimbursement grant income for the Company's federal grant with the Canadian government's SIF is recorded based on the claim period of eligible costs.

In February 2021, the Company entered into a multi-year contribution agreement (the 2021 SIF Agreement) with the Canadian Government's Strategic Innovation Fund. Under the 2021 SIF Agreement, the Government of Canada committed up to C$14.1 million in nonrepayable funding which was intended to support research and development related to our EB05 clinical program. No further funding will be received from the 2021 SIF Agreement.

In October 2023, the Company entered into a multi-year contribution agreement (the 2023 SIF Agreement) with the Canadian Government's Strategic Innovation Fund. Under the 2023 SIF Agreement, the Government of Canada committed up to C$23 million in partially repayable funding toward (i) conducting and completing the Company's Phase 3 clinical study of its experimental drug EB05 in critical-care patients with Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19 or other infectious agents, (ii) submitting EB05 for governmental approvals and manufacturing scale-up, following, and subject to, completing the Phase 3 study and (iii) conducting two non-clinical safety studies to assess the potential long-term impact of EB05 exposure (the Project). Of the C$23 million committed by SIF, up to C$5.8 million is not repayable by the Company. The remaining C$17.2 million is conditionally repayable starting in 2029 only if and when the Company earns gross revenue. The repayable portion would be payable over fifteen (15) years based on a percentage rate of the Company's annual revenue growth. The maximum amount repayable under the Agreement is 1.4 times the original repayable amount. In addition, the Company is entitled to partial reimbursement of certain eligible expenses under the Agreement.

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

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

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

Under the 2023 SIF Agreement the Company recorded grant income of $0.2 million and $0.6 million for the three and nine months ended June 30, 2024. No grant income was recorded under the 2023 SIF Agreement for the three and nine months ended June 30, 2023.

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.

(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 and a 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 reimbursement grant and HST refunds receivable are not considered significant since amounts are due from the Canadian government's 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, 2024, the Company and its Canadian subsidiary had assets denominated in Canadian dollars of approximately C$1.0 million and the U.S. dollar exchange rate at this date was equal to 1.3680 Canadian dollars. Based on the exposure at June 30, 2024, a 10% annual change in the Canadian/U.S. exchange rate would impact the Company's loss and other comprehensive loss by approximately $0.1 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 earnings per share 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 the three and nine months ended June 30, 2024 and 2023, the Company paid cash of $20,000 and $60,000, respectively, for a ROU 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. Rent of approximately $7,000 was payable at June 30, 2024. There was no rent payable at June 30, 2023.

In October 2023, we entered into $10.0 million revolving credit agreement with Pardeep Nijhawan Medicine Professional Corporation, an entity controlled by Dr. Pardeep Nijhawan, MD, our Chief Executive Officer and Secretary and member of our board of directors (Credit Agreement), providing an unsecured revolving credit facility, with a credit limit of $3.5 million (Credit Limit) which was available immediately. The line of credit bears interest at the Canadian Imperial Bank of Commerce US Base-Interest Rate plus 3% per annum and has a maturity date of March 31, 2026, unless terminated earlier by either party with 90 days' notice. Advances under the line of credit are tied to a borrowing base (Borrowing Base) consisting of eligible grant receivables from SIF, future potential license fee receivables and any other accounts receivable. At no time shall the aggregate principal amount of all advances outstanding exceed the lesser of (i) the Credit Limit and (ii) an amount equal to 85% of the Borrowing Base. The Company has not drawn any funds from the Credit Agreement. During the three and nine months ended June 30, 2024 the Company incurred a standby charge of $13,000 and $38,000. There was no standby charge in the three and nine months ended June 30, 2023.

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, 2024 and our audited consolidated financial statements for the year ended September 30, 2023 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on December 15, 2023.

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, 2023 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 for the three months ended June 30, 2024 and 2023, and for the nine months ended June 30, 2024 and 2023 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.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions, and future performance, and involve known and unknown risks, uncertainties, and other factors, which may be beyond our control, and which may cause our actual results, performance, or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- *our ability to obtain funding for our operations;*
- *our estimates regarding our expenses, revenues, anticipated capital requirements and our needs for additional financing;*
- *the timing of the commencement, progress and receipt of data from any of our preclinical and clinical trials;*
- *the expected results of any preclinical or clinical trial and the impact on the likelihood or timing of any regulatory approval;*
- *the therapeutic benefits, effectiveness and safety of our product candidates;*
- *the timing or likelihood of regulatory filings and approvals;*
- *changes in our strategy or development plans;*
- *the volatility of our common share price;*
- *the rate and degree of market acceptance and clinical utility of any future products;*
- *the effect of competition;*
- *our ability to protect our intellectual property as well as comply with the terms of license agreements with third parties;*
- *our ability to identify, develop and commercialize additional products or product candidates;*
- *reliance on key personnel;*
- *general changes in economic or business conditions; and*
- *other risks and uncertainties, including those listed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended September 30, 2023*

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended September 30, 2023, filed with the SEC, on December 15, 2023, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We operate in an evolving environment and new risk factors and uncertainties may emerge from time to time. It is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should review the factors and risks and other information we describe in the reports we will file from time to time with the SEC.

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 in the fields of respiratory diseases and medical dermatology.

Our most advanced drug candidate is EB05 (paridiprubart). EB05 represents a new class of therapies called Host-Directed Therapeutics (HDTs) that are designed to modulate the body's own immune response when confronted with infectious diseases or even chemical agents. Importantly, these therapies are designed to work across multiple infectious diseases and threats, and could be stockpiled preemptively ahead of outbreaks. Because they are threat agnostic, HDTs like paridiprubart have the potential to become standard of care in Intensive Care Units (ICUs) and critical countermeasures for both pandemic preparedness and biodefense. We are currently evaluating EB05 as a potential treatment for Acute Respiratory Distress Syndrome (ARDS), a life-threatening form of respiratory failure. Recruitment in a Phase 3 study is ongoing. EB05 has also been included in a U.S. government funded platform study of HDTs.

In addition to EB05, we are developing product candidates for a number of chronic inflammatory and dermatological conditions. We intend to file an investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for a future Phase 2 study of paridiprubart as a potential treatment for patients with progressive pulmonary fibrosis, a serious chronic disease that causes lung inflammation and scarring. For our EB06 monoclonal candidate, we have received regulatory approval by Health Canada to conduct a future Phase 2 study in patients with moderate to severe nonsegmental vitiligo, a common autoimmune disorder that causes skin to lose its color in patches. We plan to seek regulatory approval for this vitiligo study in the U.S. as well. In addition, we are developing an sPLA2 inhibitor, EB01 (daniluromer), as a topical treatment for chronic Allergic Contact Dermatitis (ACD), a common occupational skin condition. We intend to seek strategic arrangements to further develop and/or monetize this late-stage clinical asset, following favorable Phase 2b results of 1.0% EB01 cream.

Recent Developments

Government-Funded Platform Study in General ARDS

In June 2024, our drug candidate, EB05, was selected by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, for evaluation in a U.S. government-funded clinical study. The Phase 2 platform trial will be a randomized, double-blinded, placebo-controlled, multi-center U.S. clinical trial to investigate novel threat-agnostic host-directed therapeutics, including EB05, in hospitalized adult patients with ARDS due to a variety of causes. For the EB05 cohort of the study, patients will be randomized one-to-one to either EB05 plus Standard of Care (SOC) or to a placebo plus SOC control arm. Edesa plans to provide drug product for the study as well as technical support.

Given this opportunity, we are currently evaluating our broader development strategy for the development of EB05 to align our activities with sources of government funding and the greater market opportunity for general ARDS, including amending our Canadian government supported Phase 3 ARDS study, which is exclusively recruiting patients hospitalized with Covid-19. Potential options include, but are not limited to, expanding the enrollment criteria of the Phase 3 study, refocusing the project on manufacturing scale-up, extending the project timeline and/or pausing recruitment while awaiting results of the BARDA study. Should we decide to make changes to our ongoing Phase 3 trial and manufacturing plans, we may be required to renegotiate the terms of our 2023 SIF Agreement.

Significant Accounting Policies and Estimates

See Note 2 to our financial statements included in our Annual Report on Form 10-K for the year ended September 30, 2023 for a discussion of our significant accounting policies and estimates. There have been no material changes to such significant accounting policies or estimates.

Results of Operations

Comparison of the Three Months Ended June 30, 2024 and 2023

Total operating expenses decreased by $0.2 million to $1.9 million for the three months ended June 30, 2024 compared to $2.1 million for the same period last year:

- Research and development (R&D) expenses decreased by $0.1 million to $0.9 million for the three months ended June 30, 2024 compared to $1.0 million for the same period last year primarily due to decreased external research expenses related to our ongoing EB05 phase 3 clinical study and the completed EB01 phase 2 study, partially offset by an increase in expenses related to manufacturing of our investigational drug, paridiprubart. Our R&D expenses consist primarily of employee-related expenses, including salaries, benefits, taxes, travel, and share-based compensation expense for personnel in R&D 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.

- General and administrative (G&A) expenses were unchanged at $1.0 million for the three months ended June 30, 2024 and June 30, 2023. Our G&A expenses consist primarily of salaries and related costs for our employees in administrative, executive and finance functions. G&A expenses also include professional fees for legal, accounting, audit, tax and consulting services, insurance, office, and travel expenses.

Total other income increased by $185,000 to $264,000 for the three months ended June 30, 2024 compared to $79,000 for the same period last year and was composed of the following:

- Grant income increased by $0.2 million to $0.2 million for the three months ended June 30, 2024. There was no grant income in the comparative period. The increase is related to the grant income associated with the activities under the 2023 SIF Agreement.

- Interest income decreased by $50,000 to $33,000 for the three months ended June 30, 2024 compared to $83,000 for the same period last year primarily due to lower cash balances.

- Foreign exchange loss was $5,000 for the three months ended June 30, 2024 compared to a loss of $3,000 for the three months ended June 30, 2023.

For the three months ended June 30, 2024, our net loss was $1.7 million, or $0.52 per common share, compared to a net loss of $2.0 million, or $0.68 per common share for the three months ended June 30, 2023.

Comparison of the Nine Months Ended June 30, 2024 and 2023

Total operating expenses decreased by $0.9 million to $6.0 million for the nine months ended June 30, 2024 compared to $6.9 million for the same period last year:

- R&D expenses decreased by $1.0 million to $2.8 million for the nine months ended June 30, 2024 compared to $3.8 million for the same period last year primarily due to decreased external research expenses related to our completed EB01 phase 2 study and a decrease in non-cash share-based compensation and labor costs, partially offset by an increase in expenses for our ongoing EB05 phase 3 clinical study and for manufacturing of our investigational drug, paridiprubart. Our R&D expenses consist primarily of employee-related expenses, including salaries, benefits, taxes, travel, and share-based compensation expense for personnel in R&D 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.

- G&A expenses increased by $0.2 million to $3.2 million for the nine months ended June 30, 2024 compared to $3.0 million for the same period last year primarily due to increased fees for professional services, partially offset by a decrease in non-cash share-based compensation. Our G&A expenses consist primarily of salaries and related costs for our employees in administrative, executive and finance functions. G&A expenses also include professional fees for legal, accounting, audit, tax and consulting services, insurance, office, and travel expenses.

Total other income increased by $0.6 million to $0.8 million for the nine months ended June 30, 2024 compared to $0.2 million for the same period last year and was composed of the following:

- Grant income increased by $0.6 million to $0.6 million for the nine months ended June 30, 2024. There was no grant income in the comparative period. The increase is related to the grant income associated with the activities under the 2023 SIF Agreement.

- Interest income decreased by $81,000 to $137,000 for the nine months ended June 30, 2024 compared to $218,000 for the same period last year primarily due to a decrease in cash balances.

- Miscellaneous other income was $15,000 for the nine months ended June 30, 2024 related to loan forgiveness on the CEBA loan that was repaid in the quarter.

- Foreign exchange loss was $9,700 for the nine months ended June 30, 2024 compared to a loss of $18,100 for the nine months ended June 30, 2023.

For the nine months ended June 30, 2024, our net loss was $5.2 million, or $1.64 per common share, compared to a net loss of $6.7 million, or $2.37 per common share for the nine months ended June 30, 2023.

Capital Expenditures

Our capital expenditures primarily consist of computer and office equipment. There were no significant capital expenditures for the three and nine months ended June 30, 2024 and 2023.

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.

Our primary use of cash is to fund our operating expenses, which consist of R&D and G&A expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in accounts payable and accrued expenses. Net cash used in operating activities was $3.9 million and $5.2 million for the nine months ended June 30, 2024 and 2023, respectively. We incurred net losses of $5.2 million and $6.7 million for the nine months ended June 30, 2024 and 2023.

In October 2023, we entered into the 2023 SIF Agreement with the Canadian Government's SIF. Under the 2023 SIF Agreement, the Government of Canada committed up to C$23 million in partially repayable funding. Of the C$23 million committed by SIF, up to C$5.8 million is not repayable by us. The remaining C$17.2 million is conditionally repayable starting in 2029 only if and when we earn gross revenue. In February 2021, we entered into the 2021 SIF Agreement, pursuant to which we were eligible to receive cash reimbursements up to C$14.1 million in the aggregate for certain R&D expenses related to our EB05 clinical development program. All potential funding available under the 2021 SIF Agreement has been received. For the three and nine months ended June 30, 2024 we recorded grant income of $0.2 million and $0.6 million respectively, related to the 2023 SIF Agreement. There was no grant income recognized in the comparative periods.

In October 2023, we entered into $10.0 million revolving credit agreement with Pardeep Nijhawan Medicine Professional Corporation, an entity controlled by Dr. Pardeep Nijhawan, MD, our Chief Executive Officer and Secretary and member of our board of directors (Credit Agreement), providing an unsecured revolving credit facility, with a credit limit of $3.5 million (Credit Limit) which was available immediately. The line of credit bears interest at the Canadian Imperial Bank of Commerce US Base-Interest Rate plus 3% per annum and has a maturity date of March 31, 2026, unless terminated earlier by either party with 90 days' notice. Advances under the line of credit are tied to a borrowing base (Borrowing Base) consisting of eligible grant receivables from SIF, future potential license fee receivables and any other accounts receivable. At no time shall the aggregate principal amount of all advances outstanding exceed the lesser of (i) the Credit Limit and (ii) an amount equal to 85% of the Borrowing Base. We have not drawn any funds from the Credit Agreement.

In August 2022, we filed a $150.0 million shelf registration statement. In March 2023, we entered into an equity distribution agreement with Canaccord, as sales agent, pursuant to which we 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 us to offer and sell common shares having an aggregate gross sales price of up to $8.4 million (Canaccord ATM). There was approximately $6.3 million of available capacity on the Canaccord ATM as of June 30, 2024. We have 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. For the three months ended June 30, 2024, we sold a total of 31,421 common shares pursuant to the agreement for net proceeds of $0.1 million after deducting commissions and costs of $40,000. For the nine months ended June 30, 2024, we sold a total of 171,916 common shares pursuant to the agreement for net proceeds of $0.6 million after deducting commissions and costs of $140,000.

In November 2022, we completed a private placement of units consisting of 384,475 common shares, 12-month warrants to purchase up to an aggregate of 192,248 common shares and 3-year warrants to purchase up to an aggregate of 192,248 common shares. The gross proceeds from this offering were approximately $3.0 million, before offering expenses.

At June 30, 2024, we had an accumulated deficit of $57.6 million and working capital of $0.7 million, including $2.0 million in cash and cash equivalents. Subsequent to the quarter, we collected the receivable from 2023 SIF Agreement for $0.3 million from Canadian government. We plan to finance company operations over the course of the next twelve months with cash and cash equivalents on hand, including net proceeds from the Canaccord ATM, advances under the Credit Agreement and reimbursements of eligible R&D expenses under the 2023 SIF 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 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. If we raise additional funds by issuing equity securities, our shareholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing shareholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development of our product candidates.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company. To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, clinical trials of our product candidates, and other operations and potential product acquisitions and in licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in licensing or similar strategic business transaction.

Cash Flows

Net cash used in operating activities

Net cash used in operating activities was $3.9 million for the nine months ended June 30, 2024 compared to $5.2 million for the nine months ended June 30, 2023, primarily due to a decrease in R&D expenses of $1.0 million and an investment in working capital of $0.1 million, partially offset by a reduction in non-cash stock based compensation of $0.3 million.

Net cash used in investing activities

There was no cash used in investing activities for the nine months ended June 30, 2024 and 2023, respectively.

Net cash provided by financing activities

Net cash provided by financing activities was $0.6 million for the nine months ended June 30, 2024 as compared to $4.4 million for the nine months ended June 30, 2023. In the current period, we received proceeds of $0.7 million from the Canaccord ATM, partially offset by issuance costs of $76,000 and the repayment of debt of $29,500. In the comparative period, we received proceeds of $3.0 million from a private placement in November 2022, offset by issuance costs of $0.1 million for net proceeds of $2.9 million; we received $0.8 million in proceeds from the exercise of warrants and $0.7 million in net proceeds from the Canaccord ATM.

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 R&D activities, including the conduct of clinical studies and product development, and expense such costs as they are incurred. R&D 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 R&D expenses were $0.9 million and $2.8million for the three and nine months ended June 30, 2024 compared to $1.0 million and $3.8 million for the three and nine months ended June 30, 2023. The decrease was due primarily to lower external research expenses related to our ongoing clinical studies.

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 the 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 our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2024. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures as of June 30, 2024, 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, 2024 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, 2023, filed with the Securities and Exchange Commission on December 15, 2023.

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 of the Company's directors and officers adopted, modified, or terminated a Rule 10b-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the Company's fiscal quarter ended June 30, 2024 (each as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, as amended).

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
10.1^	Amendment No. 3 to Edesa Biotech, Inc. 2019 Equity Incentive Compensation Plan (included as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 30, 2024, and incorporated herein by reference).
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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* 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.

^ Management contract or compensatory plan or arrangement.

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.

EDESA BIOTECH, INC.

Date: August 9, 2024

/s/ Pardeep Nijhawan

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

Date: August 9, 2024

/s/ Stephen Lemieux

Stephen Lemieux, Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 31.1

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 9, 2024

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

EXHIBIT 31.2

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

I, Stephen Lemieux, 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 9, 2024

By: */s/ Stephen Lemieux*
Stephen Lemieux
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 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**

In connection with the Quarterly Report of Edesa Biotech, Inc. (the Company) on Form 10-Q for the quarter ended June 30, 2024, 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 9, 2024

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

EXHIBIT 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**

In connection with the Quarterly Report of Edesa Biotech, Inc. (the Company) on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Stephen Lemieux, 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 9, 2024

By: */s/ Stephen Lemieux*
Stephen Lemieux
Chief Financial Officer
(Principal Financial Officer)