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, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF1934**

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, Ontario, Canada	**L3R 5H6**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(289) 800-9600**

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

Title of each class	**Trading Symbol**	**Name of 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 12, 2021, the registrant had 13,255,559 common shares issued and outstanding.

Edesa Biotech, Inc.
Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2021

Table of Contents

[PART I — FINANCIAL INFORMATION]

Item 1.	Financial Statements (Unaudited).	3
	Condensed Interim Consolidated Balance Sheets – June 30, 2021 and September 30, 2020.	3
	Condensed Interim Consolidated Statements of Operations – Three and Nine Months Ended June 30, 2021 and 2020.	4
	Condensed Interim Consolidated Statements of Cash Flows – Nine Months Ended June 30, 2021 and 2020.	5
	Condensed Interim Consolidated Statements of Changes in Shareholders' Equity – Three and Nine Months Ended June 30, 2021 and 2020.	6
	Notes to Condensed Interim Consolidated Financial Statements.	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations.	18
Item 3.	Quantitative and Qualitative Disclosures About Market Risk.	22
Item 4.	Controls and Procedures.	22
PART II — OTHER INFORMATION		
Item 1.	Legal Proceedings.	23
Item 1A.	Risk Factors.	23
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds.	23
Item 3.	Defaults Upon Senior Securities.	23
Item 4.	Mine Safety Disclosures.	23
Item 5.	Other Information.	23
Item 6.	Exhibits.	24

Table of Contents

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

Edesa Biotech, Inc.
Condensed Interim Consolidated Balance Sheets

	June 30, 2021	September 30, 2020
Assets:		
Current assets:		
Cash and cash equivalents	**$ 8,052,574**	$ 7,213,695
Accounts and other receivable	**4,185,161**	87,446
Prepaid expenses and other current assets	**2,096,572**	802,877
Total current assets	**14,334,307**	8,104,018
Non-current assets:		
Property and equipment, net	**17,533**	14,815
Intangible asset, net	**2,407,657**	2,483,536
Operating lease right-of-use assets	**117,846**	160,006
Total assets	**$ 16,877,343**	$ 10,762,375
Liabilities, shareholders' equity and temporary equity:		
Current liabilities:		
Accounts payable and accrued liabilities	**$ 903,964**	$ 1,460,127
Short-term operating lease liabilities	**79,503**	69,730
Total current liabilities	**983,467**	1,529,857
Non-current liabilities:		
Long-term payables	**48,396**	29,928

Long-term operating lease liabilities	**41,725**	94,460
Total liabilities	**1,073,588**	1,654,245
Commitments *(Note 6)*		
Temporary equity:		
Convertible preferred shares	-	2,476,955
Shareholders' equity:		
Capital shares		
Authorized unlimited common and preferred shares without par value		
Issued and outstanding:		
13,255,559 common shares (September 30, 2020 - 9,615,119)	**34,627,125**	18,500,853
Additional paid-in capital	**4,006,347**	1,550,480
Accumulated other comprehensive loss	**(20,129)**	(287,204)
Accumulated deficit	**(22,809,588)**	(13,132,954)
Total shareholders' equity	**15,803,755**	6,631,175
Total liabilities, shareholders' equity and temporary equity	**$ 16,877,343**	$ 10,762,375

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

Table of Contents

Edesa Biotech, Inc.
Condensed Interim Consolidated Statements of Operations

	Three Months Ended		Nine Months Ended	
	June 30, 2021	**June 30, 2020**	**June 30, 2021**	**June 30, 2020**
Revenues:				
Product sales	**$ -**	$ 109,985	**$ -**	$ 328,301
Expenses:				
Cost of sales	-	1,472	-	15,287
Research and development	**4,464,347**	1,143,868	**13,819,305**	2,174,680
General and administrative	**1,608,232**	733,079	**4,377,507**	2,528,702
	6,072,579	1,878,419	**18,196,812**	4,718,669
Loss from Operations	**(6,072,579)**	(1,768,434)	**(18,196,812)**	(4,390,368)
Other Income (Loss):				
Reimbursement grant income	**1,306,796**	-	**8,477,261**	-
Interest income	**2,610**	3,799	**4,279**	36,762
Foreign exchange gain (loss)	**3,663**	(692)	**58,963**	5,110
Loss on disposition of property and equipment	-	(436)	-	(436)
	1,313,069	2,671	**8,540,503**	41,436
Loss before income taxes	**(4,759,510)**	(1,765,763)	**(9,656,309)**	(4,348,932)
Income tax expense	-	-	**800**	800
Net Loss	**(4,759,510)**	(1,765,763)	**(9,657,109)**	(4,349,732)
Exchange differences on translation	**174,128**	68,972	**267,075**	47,178
Net Comprehensive Loss	**$ (4,585,382)**	$ (1,696,791)	**$ (9,390,034)**	$ (4,302,554)
Weighted average number of common shares	**13,251,999**	8,859,520	**11,680,294**	8,364,866
Loss per common share - basic and diluted	**$ (0.36)**	$ (0.20)	**$ (0.83)**	$ (0.52)

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

Table of Contents

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

	Nine Months Ended	
	June 30, 2021	**June 30, 2020**
Cash Flows from Operating Activities:		
Net loss	**$ (9,657,109)**	$ (4,349,732)
Adjustments for:		
Depreciation and amortization	**89,853**	28,543
Loss on disposition of property and equipment	**-**	436
Share-based compensation	**2,290,794**	511,966
Changes in working capital items:		
Accounts and other receivable	**(4,008,512)**	156,361
Prepaid expenses and other current assets	**(1,389,083)**	(134,665)
Accounts payable and accrued liabilities	**(635,554)**	473,688
Net cash used in operating activities	**(13,309,611)**	(3,313,403)
Cash Flows from Investing Activities:		
Proceeds on sales of property and equipment	**-**	45,840
Purchase of property and equipment	**(7,610)**	(825)
Purchase of intangible assets	**-**	(29,483)
Purchase of short-term investments	**-**	(500,000)
Proceeds from maturities of short-term investments	**-**	500,000
Net cash provided by (used in) investing activities	**(7,610)**	15,532
Cash Flows from Financing Activities:		
Proceeds from issuance of common shares and warrants	**12,793,591**	4,360,500
Proceeds from exercise of warrants	**1,467,536**	-
Proceeds from exercise of share options	**41,985**	-
Payments for issuance costs of common shares	**(349,408)**	(468,699)
Payments for issuance costs of convertible preferred shares	**-**	(57,154)
Proceeds from borrowings	**-**	29,660
Net cash provided by financing activities	**13,953,704**	3,864,307
Effect of exchange rate changes on cash and cash equivalents	**202,396**	43,676
Net change in cash and cash equivalents	**838,879**	610,112
Cash and cash equivalents, beginning of period	**7,213,695**	5,030,583
Cash and cash equivalents, end of period	**$ 8,052,574**	$ 5,640,695
Supplemental Disclosure of Noncash Financing Activities:		
Preferred shares converted from temporary equity to common shares	**$ 2,496,480**	-
Issuance costs withheld from gross proceeds from issuance of common shares	**955,950**	-
Fair value of compensation warrants to underwriter	**407,023**	-
Issuance of convertible preferred shares to acquire license	**-**	2,500,000
Fair value of placement agent warrants	**-**	18,051

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

Table of Contents

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, 2021						
Balance - March 31, 2021	**13,246,559**	**$34,602,637**	**$2,914,482**	**$ (194,257)**	**$ (18,050,078)**	**$ 19,272,784**
Issuance of common shares upon exercise of share options	9,000	24,488	(8,585)	-	-	15,903
Share-based compensation	-	-	1,100,450	-	-	1,100,450
Net loss and comprehensive loss	-	-	-	174,128	(4,759,510)	(4,585,382)

Balance - June 30, 2021	**13,255,559**	**$34,627,125**	**$4,006,347**	**$ (20,129)**	**$ (22,809,588)**	**$ 15,803,755**
Three Months Ended June 30, 2020						
Balance - March 31, 2020	**8,859,159**	**$14,732,674**	**$1,880,721**	**$ (363,868)**	**$ (9,318,584)**	**$ 6,930,943**
Issuance of common shares upon exercise of warrants	2,736	52,229	(52,229)	-	-	-
Preferred return on convertible preferred shares	-	-	-	-	(15,205)	(15,205)
Share-based compensation	-	-	123,191	-	-	123,191
Net loss and comprehensive loss	-	-	-	68,972	(1,765,763)	(1,696,791)
Balance - June 30, 2020	**8,861,895**	**$14,784,903**	**$1,951,683**	**$ (294,896)**	**$ (11,099,552)**	**$ 5,342,138**
Nine Months Ended June 30, 2021						
Balance - September 30, 2020	**9,615,119**	**$18,500,853**	**$1,550,480**	**$ (287,204)**	**$ (13,132,954)**	**$ 6,631,175**
Issuance of common shares in equity offerings	2,148,963	13,749,541	-	-	-	13,749,541
Issuance costs including fair value of underwriter warrants	-	(1,871,220)	407,023	-	-	(1,464,197)
Issuance of common shares upon exercise of warrants	341,806	1,681,936	(214,400)	-	-	1,467,536
Issuance of common shares upon exercise of share options	19,746	69,535	(27,550)	-	-	41,985
Preferred return on convertible preferred shares	-	-	-	-	(19,525)	(19,525)
Conversion of convertible preferred shares	1,129,925	2,496,480	-	-	-	2,496,480
Share-based compensation	-	-	2,290,794	-	-	2,290,794
Net loss and comprehensive loss	-	-	-	267,075	(9,657,109)	(9,390,034)
Balance - June 30, 2021	**13,255,559**	**$34,627,125**	**$4,006,347**	**$ (20,129)**	**$ (22,809,588)**	**$ 15,803,755**
Nine Months Ended June 30, 2020						
Balance - September 30, 2019	**7,504,468**	**$12,005,051**	**$ 327,768**	**$ (342,074)**	**$ (6,734,615)**	**$ 5,256,130**
Issuance of common shares and warrants in equity offering	1,354,691	3,070,358	1,290,142	-	-	4,360,500
Issuance of common shares upon exercise of warrants	2,736	52,229	(52,229)	-	-	-
Preferred return on convertible preferred shares	-	-	-	-	(15,205)	(15,205)
Issuance costs	-	(342,735)	(125,964)	-	-	(468,699)
Share-based compensation	-	-	511,966	-	-	511,966
Net loss and comprehensive loss	-	-	-	47,178	(4,349,732)	(4,302,554)
Balance - June 30, 2020	**8,861,895**	**$14,784,903**	**$1,951,683**	**$ (294,896)**	**$ (11,099,552)**	**$ 5,342,138**

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

Table of Contents

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

1. Nature of Operations

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

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

Impact of COVID-19

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

2. Basis of Presentation

The accompanying unaudited condensed interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q. They do not include all information

and footnotes necessary for a fair presentation of financial position, results of operations and cash flows in conformity with U.S. GAAP for complete financial statements. These 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, 2020, which were filed with the Securities and Exchange Commission (SEC) on December 7, 2020.

The accompanying condensed interim consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Edesa Biotech Research, Inc., an Ontario corporation, and Edesa Biotech USA, Inc., a California corporation in the U.S. All intercompany balances and transactions have been eliminated in 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 nine months ended June 30, 2021 are not necessarily indicative of the results that may be expected for other interim periods or the fiscal year ending September 30, 2021.

Use of estimates

The preparation of the unaudited condensed interim 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 unaudited condensed interim consolidated financial statements and the reported amounts of revenue and expenses during the period. 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; classification of convertible preferred shares as liability or equity; 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 assign value to underwriter warrants; and forecasting future cash flows for assessing the going concern assumption.

Functional and reporting currencies

The condensed interim 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.

Future accounting pronouncements

In June 2016, the FASB issued *ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which includes provisions that require the measurement of an estimate of all current expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. Financial assets measured at amortized cost basis are to be presented at the net amount expected to be collected and credit losses relating to available-for-sale debt securities are to be recorded through an allowance for credit losses. The guidance is effective for public entities for fiscal years beginning after December 15, 2019, including interim periods within those years, with early adoption permitted for fiscal years beginning after December 15, 2018, however the effective date is delayed by one year for smaller reporting companies as defined by the SEC. These standards are effective for the Company during the fiscal year ending September 30, 2022. Management expects that ASU 2016-13, as updated, will not have a significant impact on the Company's consolidated financial statements.

3. Property and Equipment

Property and equipment, net consisted of the following:

	June 30, 2021	September 30, 2020
Computer equipment	$ 43,339	$ 34,651
Furniture and equipment	6,138	5,694
	49,477	40,345
Less: accumulated depreciation	(31,944)	(25,530)
Total property and equipment, net	$ 17,533	$ 14,815

Depreciation expense amounted to $2,481 and $1,992 for the three months ended June 30, 2021 and 2020, respectively, and $6,414 and $7,046 for the nine months ended June 30, 2021 and 2020, respectively.

4. 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 quarterly.

The required upfront license payment of $2.5 million was paid by the issuance of Series A-1 Convertible Preferred Shares. The value of the license includes acquisition legal costs. The license agreement requires certain development, approval and commercialization milestone payments contingent on certain future events. The Company also has a commitment to pay royalties based on any net sales of licensed products and a percentage of any sublicensing revenue. See Note 6 for license commitments and Note 7 for convertible preferred shares in temporary equity.

Intangible assets, net consisted of the following:

	June 30, 2021	September 30, 2020
The Constructs	$ 2,529,483	$ 2,529,483
Less: accumulated amortization	(121,826)	(45,947)
Total intangible assets, net	$ 2,407,657	$ 2,483,536

Amortization expense amounted to $25,293 and $20,654 for the three months ended June 30, 2021 and 2020, respectively, and $75,879 and $20,654 for the nine months ended June 30, 2021 and 2020, respectively.

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

Year Ending	
September 30, 2021	$ 25,293
September 30, 2022	101,172
September 30, 2023	101,172
September 30, 2024	101,172
September 30, 2025	101,172
Thereafter	1,977,676
	$ 2,407,657

5. Leases

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

The gross amounts of assets and liabilities related to operating leases on the Balance Sheets were as follows:

	June 30, 2021	September 30, 2020
Assets:		
Operating lease right-of-use assets	$ 117,846	$ 160,006
Liabilities:		
Current:		
Short-term operating lease liabilities	$ 79,503	$ 69,730
Long-term:		
Long-term operating lease liabilities	41,725	94,460
Total lease liabilities	$ 121,228	$ 164,190

The components of lease cost were as follows:

	Three Months Ended		Nine Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Operating lease cost, included in general and administrative on the Statements of Operations	$ 20,887	$ 18,508	$ 60,828	$ 57,079

Lease terms and discount rates were as follows:

	June 30, 2021	September 30, 2020
Remaining lease term (months):	18	27
Estimated incremental borrowing rate:	6.5%	6.5%

The approximate future minimum lease payments under operating leases at June 30, 2021 were as follows:

Year Ending	
September 30, 2021	$ 21,260
September 30, 2022	85,041
September 30, 2023	21,260
Total lease payment	127,561
Less imputed interest	6,333
Present value of lease liabilities	121,228
Less current installments	79,503
Long-term lease liabilities excluding current installments	$ 41,725

Cash flow information was as follows:

	Nine Months Ended June 30, 2021	Nine Months Ended June 30, 2020
Cash paid for amounts included in the measurement of lease liabilities, included in accounts payable and accrued liabilities on the Statements of Cash Flows	$ 60,830	$ 57,081

The Company leased facilities through its California subsidiary under two operating leases that expired in September 2020. Total rent under these leases included in general and administrative expenses was $55,068 and $164,915 for the three and nine months ended June 30, 2020, respectively. There was no rent under these leases during the three and nine months ended June 30, 2021.

6. Commitments

Research and other commitments

The Company has commitments for contracted research organizations who perform clinical trials for the Company's ongoing clinical studies, other service providers and the drug substance acquired in connection with a license agreement. Aggregate future contractual payments at June 30, 2021 are as follows:

Year Ending	
September 30, 2021	$ 1,026,000
September 30, 2022	3,039,000
September 30, 2023	157,000
September 30, 2024	63,000
	$ 4,285,000

License 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 4 for intangible asset. Under the license agreement, the Company recorded an expense of $3.5 million as a result of meeting a milestone during the nine months ended June 30, 2021 and is committed to remaining payments of up to an aggregate amount of $352.5 million contingent upon meeting certain milestones outlined in the license agreement, primarily relating to future potential commercial approval and sales milestones. The Company also has a commitment to pay royalties based on any net sales of the products in the countries where the Company directly commercializes the products containing the Constructs and a percentage of any sublicensing revenue received by the Company and its affiliates in the countries where it does not directly commercialize the products containing the Constructs. No royalty or sublicensing payments were made to the third party during the nine months ended June 30, 2021 and 2020.

In connection with this license agreement and pursuant to a purchase agreement entered into in April 2020, the Company acquired drug substance of one of the Constructs for an aggregate purchase price of $5.0 million, payable in two future installments, the first when the Company is ready to initiate a Phase 2 trial and the second when the Company is ready to initiate a Phase 3 trial. A payment of $2.5 million was made for the drug substance during the nine months ended June 30, 2021. The remaining purchase commitment is included in the table above for the year ending September 30, 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 $18.6 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. No license or royalty payments were made to the third party during the nine months ended June 30, 2021 and 2020.

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. For the nine months ended June 30, 2021, the Company recorded an expense of $106,000 as a result of meeting a milestone outlined in the 2021 license agreement. The Company is committed to remaining payments of up to an aggregate amount of $69.1 million, primarily relating to future potential commercial approval and sales milestones. In addition, if the Company fails to file an investigational new drug application or foreign equivalent (“IND”) for the product within a certain period of time following the date of the agreement, the Company is required to remit to the inventor a fixed license fee annually as long as the requirement to file an IND remains unfulfilled.

Related party patent royalty commitments

In August 2002, through its California subsidiary, the Company entered into a patent royalty agreement with a director of the Company, whereby he would receive royalty payments in exchange for assignment of his patent rights to the Company. The royalty is 5% of gross receipts in excess of $500,000 annually from legacy products using this invention. There were no royalty expenses during the three and nine months ended June 30, 2021 and 2020.

Retirement savings plan 401(k) contributions

Executive officers and employees of the California subsidiary are eligible to receive the Company’s non-elective safe harbor employer contribution of 3% of eligible compensation under a 401(k) plan to provide retirement benefits. Employees are 100% vested in employer contributions and in any voluntary employee contributions. Contributions to the 401(k) plan were $4,552 and $3,461 during the three months ended June 30, 2021 and 2020, respectively and $19,181 and $7,996 during the nine months ended June 30, 2021 and 2020, respectively.

7. Temporary Equity

Series A-1 Convertible Preferred Shares

As described in Notes 4 and 6, in April 2020, the Company issued 250 convertible preferred shares valued at $2.5 million designated as Series A-1 Convertible Preferred Shares (the “Series A-1 Shares). The Series A-1 Shares had no par value, a stated value of $10,000 per share and ranked, with respect to redemption payments, rights upon liquidation, dissolution or winding-up of the Company, or otherwise, senior in preference and priority to the Company’s common shares.

Subject to certain exceptions and adjustments for share splits, each Series A-1 Share was convertible six months after its date of issuance into a number of the Company’s common shares calculated by dividing (i) the sum of the stated value of such Series A-1 Share plus a return equal to 3% of the stated value of such Series A-1 Share per annum (collectively, the “Preferred Amount”) by (ii) a fixed conversion price of $2.26.

Because the convertible preferred shares were redeemable outside the control of the Company, they were presented as temporary equity rather than permanent shareholders’ equity until they were converted or redeemed. At June 30, 2021 all 250 Series A-1 Shares have been converted to common shares.

Issued and outstanding Series A-1 Convertible Preferred Shares:

	Series A-1 Convertible Preferred Shares (#)	Series A-1 Convertible Preferred Shares
Balance September 30, 2019	-	$ -
Issuance of convertible preferred shares	250	2,500,000
Convertible preferred share issuance costs	-	(57,154)
Preferred return on convertible preferred shares	-	34,109
Balance September 30, 2020	250	$ 2,476,955

Preferred return on convertible preferred shares	-	19,525
Conversion to common shares	(250)	(2,496,480)
Balance June 30, 2021	-	$ -

8. Capital Shares

Equity Offerings

On March 2, 2021, the Company closed an underwritten offering of 1,562,500 common shares, no par value, at a price to the public of $6.40 per share less underwriting discounts and commissions. Gross proceeds from the offering amounted to $10,000,000. The Company granted to the underwriters a 30-day option to purchase up to an additional 234,375 common shares. The underwriters option expired subsequent to March 31, 2021 with no further shares issued. On the closing date the Company issued Underwriter Warrants to purchase an aggregate of up to 109,375 common shares at an exercise price of $8.00 per share, expiring on February 26, 2026.

The direct costs related to the issuance of the common shares were $1,145,010. These direct costs were recorded as an offset against gross proceeds. The Company also recorded the fair value of underwriter warrants in the amount of $407,023 as share-based compensation to nonemployees under additional paid-in capital and an offset against gross proceeds.

On January 8, 2020, the Company closed a registered direct offering of 1,354,691 common shares, no par value and a concurrent private placement of Class A Purchase Warrants to purchase an aggregate of up to 1,016,036 common shares and Class B Purchase Warrants to purchase an aggregate of up to 677,358 common shares. Gross proceeds from the offering amounted to $4,360,500.

The Class A Purchase Warrants were exercisable on or after July 8, 2020, at an exercise price of $4.80 per share and will expire on July 8, 2023. The Class B Purchase Warrants were exercisable on or after July 8, 2020, at an exercise price of $4.00 per share and expired on November 8, 2020. In connection with the offering, the Company also issued warrants to purchase an aggregate of 12,364 common shares to certain affiliated designees of the placement agent as part of the placement agent's compensation. The placement agent warrants were exercisable on or after July 6, 2020, at an exercise price of $3.20 per share, and will expire on January 6, 2025.

The warrants are considered contracts on the Company's own shares and are classified as equity. The Company allocated gross proceeds with $3,070,358 as the value of common shares and $1,008,743 as the value of Class A Purchase Warrants and $281,399 as the value of Class B Purchase Warrants under additional paid-in capital in the condensed interim consolidated statements of changes in shareholders' equity on a relative fair value basis.

The direct costs related to the issuance of the common shares and warrants were $468,699. These direct costs were recorded as an offset against gross proceeds with $330,025 being recorded under common shares and $138,674 being recorded under additional paid-in capital on a relative fair value basis. The Company also recorded the fair value of placement agent warrants in the amount of $18,051 as share-based compensation to nonemployees under additional paid-in capital and an offset against gross proceeds with $12,710 being recorded under common shares and $5,341 being recorded under additional paid-in capital on a relative fair value basis.

Equity Distribution Agreement

In September 2020, the Company entered into an Equity Distribution Agreement with RBC Capital Markets, LLC ("RBCCM"), as sales agent, pursuant to which the Company could offer and sell, from time to time, common shares through an at-the-market equity offering program for up to $9.2 million in gross cash proceeds. The agreement was terminated on February 25, 2021. During the nine months ended June 30, 2021, 586,463 shares were sold under the distribution agreement, resulting in $13,749,541 in gross proceeds. The commissions and direct costs of the offering program totaled $319,188 and were recorded as an offset against gross proceeds.

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
Balance September 30, 2019	48,914	$ 11.19
Issued	1,705,758	4.47

Exercised	(761,951)	4.31
Balance September 30, 2020	992,721	$ 4.92
Issued	109,375	8.00
Exercised	(341,806)	4.29
Balance June 30, 2021	760,290	$ 5.65

The following table summarizes information about the warrants outstanding at June 30, 2021:

Number of Warrants (#)	Exercise Prices	Expiry Dates
28,124	$ 15.90	May 2023
603,529	$ 4.80	July 2023
7,484	$ 4.81	June 2024
11,778	$ 3.20	January 2025
109,375	$ 8.00	February 2025
760,290		

The weighted average contractual life remaining on the outstanding warrants at June 30, 2021 is 27 months.

The fair value of warrants issued during the nine months ended June 30, 2021 and 2020 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Nine Months Ended June 30, 2021	Nine Months Ended June 30, 2020		
	Underwriter Warrants	Class A Warrants	Class B Warrants	Placement Agent Warrants
Risk free interest rate	0.67%	1.61%	1.55%	1.61%
Expected life	5 years	3.5 years	0.83 years	5 years
Expected share price volatility	94.20%	103.81%	134.15%	101.89%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

Share Options

The Company adopted an Equity Incentive Compensation Plan in 2019 (the 2019 Plan) administered by the Board of Directors. Options, restricted shares and restricted share units are eligible for grant under the 2019 Plan. The number of shares available for issuance under the 2019 Plan at June 30, 2021 was 2,625,951, including shares available for the exercise of outstanding options.

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 and vesting 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
Balance – September 30, 2019	319,645	$ 3.39
Granted	366,365	3.35
Exercised	(4,450)	2.60
Forfeited	(5,790)	2.73
Expired	(333)	145.20
Balance – September 30, 2020	675,437	$ 3.30
Granted	1,138,000	6.21
Exercised	(19,746)	2.12
Forfeited	(19,066)	6.07
Expired	(1,906)	102.49
Balance – June 30, 2021	1,772,719	$ 5.07

The following table summarizes information about the options under the 2019 Plan outstanding and exercisable at June 30, 2021:

Number of Options (#)	Exercisable at June 30, 2021 (#)		Range of Exercise Prices	Expiry Dates
214	214	$	638.40	Nov 2021
238	238	$	304.08	Dec 2022
3,499	3,499	$	35.28- 93.24	Sep 2023-Mar 2025
296,403	293,163	$	2.16	Aug 2027-Dec 2028
335,365	210,525	$	3.16	Feb 2030
429,000	106,892	$	7.44- 8.07	Sep 2030-Oct 2030
708,000	72,203	$	5.25- 5.65	Jan 2031-April 2031
1,772,719	686,734			

The weighted average contractual life remaining on the outstanding options at June 30, 2021 is 101 months.

Table of Contents

During the nine months ended June 30, 2021, the independent directors of the Board of Directors granted a total of 105,000 options to new employees of the Company pursuant to the 2019 Plan. The options have a term of 10 years with monthly vesting in equal proportions over 36 months beginning on the monthly anniversary of the grant date following 90 days of employment, and an exercise price equal to the Nasdaq closing price on the grant dates.

In October 2020 and April 2021, the independent directors of the Board of Directors granted a total of 430,000 and 603,000 options, respectively, to directors, officers and employees of the Company pursuant to the 2019 Plan. The options have a term of 10 years and an exercise price equal to the Nasdaq closing price on the grant dates. Options for directors have monthly vesting in equal proportions over 12 months beginning on the grant date and options for officers and current employees have monthly vesting in equal proportions over 36 months beginning on the grant date.

The fair value of options granted during the nine months ended June 30, 2021 and 2020 was estimated using the Black-Scholes option valuation model using the following assumptions:

	Nine Months Ended June 30, 2021	Nine Months Ended June 30, 2020
Risk free interest rate	0.31%-0.90%	1.45%
Expected life	5 years	5 years
Expected share price volatility	94.00%-97.28%	104.14%
Expected dividend yield	0.00%	0.00%

The Company recorded $1,100,450 and $123,191 of share-based compensation expenses for the three months ended June 30, 2021 and 2020, respectively and $2,290,794 and $511,966 of share-based compensation expenses for the nine months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, the Company had approximately $2.74 million of unrecognized share-based compensation expense, which is expected to be recognized over a period of 36 months.

Issued and outstanding common shares

	Number of Common Shares (#)		Common Shares
Balance September 30, 2019	7,504,468	$	12,005,051
Common shares issued in equity offering	1,354,691		3,070,358
Common shares issued upon exercise of warrants	751,510		3,754,265
Common shares issued upon exercise of share options	4,450		20,935
Share issuance costs	-		(349,756)
Balance September 30, 2020	9,615,119	$	18,500,853
Common shares issued in equity offerings	2,148,963		13,749,541
Common shares issued upon exercise of warrants	341,806		1,681,936
Common shares issued upon exercise of share options	19,746		69,535
Common shares issued upon conversion of preferred shares	1,129,925		2,496,480
Share issuance costs	-		(1,871,220)
Balance June 30, 2021	13,255,559	$	34,627,125

9. 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. Claims during the nine months ended June 30, 2021 included reimbursement of eligible costs from the eligibility date in the SIF contribution agreement to June 30, 2021. At June 30, 2021, grant reimbursements receivable of $3,991,683 were included in accounts and other receivable.

10. Financial Instruments

(a) Fair values

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

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

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

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, U.S. banks believed to be credit worthy, U.S. Treasury Bills and money market mutual funds of U.S. government securities. The Company’s cash is not subject to any external restrictions. The Company assesses the collectability of accounts receivable through a review of the current aging, as well as an analysis of historical collection rates, general economic conditions and credit status of customers. Credit risk for HST refunds receivable and reimbursement grant receivable is not considered significant since amounts are due from the Canada Revenue Agency and Canadian Strategic Innovation Fund.

(c) Foreign exchange risk

The Company’s subsidiary has 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, 2021, the Company’s Ontario subsidiary had assets of C$11.1 million and the U.S. dollar was equal to 1.2398 Canadian dollars. Based on the exposure at June 30, 2021, a 10% annual change in the Canadian/U.S. exchange rate would impact the Company’s loss and other comprehensive loss by approximately $0.89 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.

11. Segmented Information

The Company's operations comprise a single reportable segment engaged in the research and development, manufacturing and commercialization of innovative pharmaceutical products. As the operations comprise a single reportable segment, amounts disclosed in the financial statements for loss for the period, depreciation and total assets also represent segmented amounts.

12. 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.

13. Related Party Transactions

During the periods presented, the Company was party to the following related party transactions:

- During the three months ended June 30, 2021 and 2020, the Company incurred rent expense of $20,887 and $18,508, respectively, from a company controlled by the Company's CEO and $60,828 and $57,079 for the nine months ended June 30, 2021 and 2020, respectively. 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.

- During the nine months ended June 30, 2020, accounts payable and accrued liabilities of $23,457 at September 30, 2019 was paid to a director for royalties on product sales by the California subsidiary during 2019. No royalty expenses were incurred since 2019.

14. Subsequent Events

In July and August 2021, through its Ontario subsidiary, the Company entered into license agreements with a third party to obtain world-wide rights to intellectual property and manufacturing systems related to two of the Company's product candidates. The license agreements require future milestone payments, sublicensing fees and royalties contingent upon certain future events.

Table of Contents

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, 2021 and our audited consolidated financial statements for the year ended September 30, 2020 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on December 7, 2020.

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, 2020 and other reports we file with the Securities and Exchange Commission. Although we believe the expectations reflected in the forward-looking statements are reasonable, they relate only to events as of the date on which the statements are made. We do not intend to update any of the forward-looking statements after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed interim consolidated financial statements as of June 30, 2021 and September 30, 2020, and for the three and nine months ended June 30, 2021 and 2020 included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which we have prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Overview

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

EB05 is a monoclonal antibody therapy that we are developing as a treatment for Acute Respiratory Distress Syndrome (ARDS) in COVID-19 patients. ARDS is a life-threatening form of respiratory failure, and the leading cause of death among COVID-19 patients. ARDS can be also caused by bacterial pneumonia, sepsis, chest injury and other causes. Specifically, EB05 inhibits toll-like receptor 4 (TLR4), a key immune signaling protein and an important mediator of inflammation that has been shown to be activated by SARS-COV2 as well as other respiratory infections such as influenza. In multiple third-party studies, high serum levels of alarmins (damage signaling molecules) that bind to and activate TLR4 are associated with poor outcomes and disease progression in COVID-19 patients. Since EB05 has demonstrated the ability to block signaling irrespective of the presence or concentration of the various molecules that frequently bind with TLR4, we believe that EB05 could ameliorate TLR4-mediated inflammation cascades in ARDS patients, thereby reducing lung injury, ventilation rates and mortality. An international Phase 2/Phase 3 clinical study of EB05 is currently ongoing.

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

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

Table of Contents

Recent Developments

EB05 Clinical Study in Hospitalized COVID-19 Patients

In June 2021, a Data and Safety Monitoring Board (DSMB), composed of independent subject matter experts, conducted a pre-planned interim review of the first patient cohort participating in our EB05 clinical study. The DSMB assessed blinded comparative treatment data for safety and futility and, after completing their analysis, recommended that enrollment in the trial continue. The DSMB's recommendation is consistent with our expectation and the previous safety and tolerability profile of EB05. We plan to complete the end of Phase 2 (interim) analysis as early as third calendar quarter 2021.

We recently filed a trial amendment with the U.S. Food and Drug Administration to align the U.S. study protocol with other jurisdictions. Based on results from the upcoming interim analysis, we also plan to adjust the study's current patient segmentation and associated endpoints. Enrollment is ongoing.

EB01 Clinical Study in Allergic Contact Dermatitis Patients

In June 2021, an independent DSMB completed an interim review of blinded data from the first cohort of our Phase 2b study of EB01 and determined that our drug candidate met key interim study parameters. The DSMB assessed the blinded comparable data for safety as well as pre-assigned statistical thresholds used to determine the number of subjects for the final part of the Phase 2b study. The initial cohort analyzed consisted of a population of 46 subjects, of whom 36 completed the study follow-up and were used in the interim analysis. Based on the interim findings and the safety monitoring board's recommendations, we plan to enroll an additional cohort of at least 120 evaluable subjects, who will be provided with either EB01 topical treatment (at a 2.0%, 1.0% or 0.2% concentration) or a placebo cream. During the quarter, we added new investigational sites and expanded recruitment beyond the U.S. to Canada. We have also added a voluntary open-label extension for patients once they complete their treatment in the main study.

Reimbursement Grant

On February 2, 2021, our wholly owned subsidiary Edesa Biotech Research, Inc. entered into a multi-year contribution agreement with the Canadian government's Strategic Innovation Fund, or SIF (the "Agreement"). Under this Agreement, the Government of Canada committed up to C$14.05 million ($11 million) in nonrepayable funding toward (i) the Phase 2 portion of our ongoing Phase 2/3 study of our investigation therapy EB05 in hospitalized COVID-19 patients, and (ii) certain pre-clinical research intended to potentially broaden the application of our experimental therapy (collectively, the "Project"). Pursuant to the contribution agreement, Edesa will conduct work, incur expenses and fund all costs from our own cash resources. On a quarterly basis, we may submit claims to the SIF for 75% of eligible reimbursable expenses.

Under the Agreement, Edesa has agreed to certain obligations in relation to the completion of the Project. In the event that we breach our obligations under the Agreement, subject to applicable cure, the SIF may exercise a number of remedies, including suspending or terminating funding under the Agreement, demanding repayment of funding previously received and/or terminating the Agreement. The performance obligations of Edesa Biotech Research under the contribution agreement are guaranteed by the Company.

Significant Accounting Policies and Estimates

Edesa's significant accounting policies are described in Note 3 to our audited consolidated financial statements for the year ended September 30, 2020 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on December 7, 2020. There are no significant changes in those policies for the quarter ended June 30, 2021.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

There were no revenues for the three months ended June 30, 2021 compared to $0.11 million for the three months ended June 30, 2020, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

Table of Contents

Total operating expenses increased by $4.19 million to $6.07 million for the three months ended June 30, 2021 compared to $1.88 million for the same period last year:

- There was no cost of sales for the three months ended June 30, 2021 compared to less than $0.01 million for the three months ended June 30, 2020, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

- Research and development expenses increased by $3.32 million to $4.46 million for the three months ended June 30, 2021 compared to $1.14 million for the same period last year primarily due to increased external research expenses related to recruitment and enrollment in our ongoing clinical studies, increased investigational drug product expenses and an increase in noncash share-based compensation. Higher salary and related personnel expenses and patent fees also contributed to the increase.

- General and administrative expenses increased by $0.88 million to $1.61 million for the three months ended June 30, 2021 compared to $0.73 million for the same period last year primarily as a result of higher salary and related personnel expenses, noncash share-based compensation and increased headcount. Higher legal and other professional services also contributed to the increase.

Total other income increased by $1.31 million to $1.31 million for the three months ended June 30, 2021 compared to less than $0.01 million for the same period last year primarily due to increased grant income under our federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the three months ended June 30, 2021, Edesa reported a net loss of $4.76 million, or $0.36 per common share, compared to a net loss of $1.77 million, or $0.20 per common share, for the three months ended June 30, 2020.

Comparison of the Nine Months Ended June 30, 2021 and 2020

There were no revenues for the nine months ended June 30, 2021 compared to $0.33 million for the nine months ended June 30, 2020, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

Total operating expenses increased by $13.48 million to $18.20 million for the nine months ended June 30, 2021 compared to $4.72 million for the same period last year:

- There was no cost of sales for the nine months ended June 30, 2021 compared to $0.02 million for the nine months ended June 30, 2020, reflecting the winddown and discontinuation of sales of product inventory from legacy operations.

- Research and development expenses increased by $11.65 million to $13.82 million for the nine months ended June 30, 2021 compared to $2.17 million for the same period last year primarily due to milestone payments related to advancement of our EB05 clinical program, increased external research expenses related to accelerated activity in our ongoing clinical studies, increased investigational drug product expenses and an increase in noncash share-based compensation. Higher salary and related personnel expenses and patent fees also contributed to the increase.

- General and administrative expenses increased by $1.85 million to $4.38 million for the nine months ended June 30, 2021 compared to $2.53 million for the same period last year primarily as a result of higher salary and related personnel expenses, noncash share-based compensation and increased headcount. Higher legal and other professional services also contributed to the increase.

Total other income increased by $8.50 million to $8.54 million for the nine months ended June 30, 2021 compared to $0.04 million for the same period last year primarily due to increased grant income under our federal reimbursement grant with the Canadian government's Strategic Innovation Fund.

For the nine months ended June 30, 2021, Edesa reported a net loss of $9.66 million, or $0.83 per common share, compared to a net loss of $4.35 million, or $0.52 per common share, for the nine months ended June 30, 2020.

Capital Expenditures

Our capital expenditures primarily consist of purchases of computer and office equipment. There were no significant capital expenditures for the nine months ended June 30, 2021 and 2020.

Table of Contents

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, convertible preferred shares, convertible loans, exercises of common share purchase warrants, government grants and tax incentives. For the nine-month periods ended June 30, 2021 and 2020, we reported net losses of $9.66 million and $4.35 million, respectively.

Under our contribution agreement with the Canadian government's Strategic Innovation Fund, we are eligible to receive cash reimbursements up to C$14.05 million ($11 million USD) in the aggregate for certain research and development expenses related to our EB05 clinical development program. During the nine-month period ended June 30, 2021, we recorded $8.48 million in grant income.

On March 2, 2021, we completed a registered public offering of an aggregate of 1,562,500 common shares, no par value, of the Company at an offering prices of $6.40 per share for net proceeds of $8.85 million, after deducting underwriter fees and related offering expenses.

For the nine months ended June 30, 2021, the exercise of warrants and options as well as sales under our equity distribution agreement with RBC Capital Markets, LLC resulted in the issuance of 948,015 common shares and net cash proceeds to the Company of $4.97 million.

At June 30, 2021, we had cash and cash equivalents of $8.05 million, working capital of $13.35 million, shareholders' equity of $15.80 million and an accumulated deficit of $22.81 million.

We plan to finance company operations over the course of the next twelve months with cash and cash equivalents on hand and reimbursements of eligible research and development expenses under our agreement with the Canadian government's SIF. Management has flexibility to adjust this timeline by a making changes to planned expenditures related to, among other factors, the size and timing of clinical trial expenditures, staffing levels, and the acquisition or in-licensing of new product candidates. To help fund our operations and meet our obligations, we may also 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 determine it is advisable to raise additional funds, there is no assurance that adequate funding will be available to us or, if available, that such funding will be available on terms that we or our shareholders view as favorable. Market volatility, inflation concerns and global disruptions related to the COVID-19 pandemic may have a significant impact on the availability of funding sources and the terms at which any funding may be available.

Research and Development

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

Research and development expenses, which have historically varied based on the level of activity in our clinical programs, are significantly influenced by study initiation expenses and patient recruitment rates, and as a result are expected to continue to fluctuate, sometimes substantially. Research and development expenses for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period. Our research and development costs were $13.82 million and $2.17 million for the nine months ended June 30, 2021 and 2020, respectively. The increase was primarily due to milestone payments related to advancement of our EB05 clinical program, increased external research expenses related to accelerated activity in our ongoing clinical studies, increased investigational drug product expenses and an increase in non-cash share-based compensation. Higher salary and related personnel expenses and patent fees also contributed to the increase.

Off-Balance Sheet Arrangements

We have no 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.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a “smaller reporting company,” as defined by Rule 12b-2 of the Exchange Act, and pursuant to Item 305 of Regulation S-K, we are not required to provide quantitative and qualitative disclosures about market risk.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

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

We carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and our Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Securities and Exchange Act of 1934, as amended) as of June 30, 2021. Our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures, as of June 30, 2021, 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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, 2020, filed with the Securities and Exchange Commission on December 7, 2020.

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.

Table of Contents

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1*	Certification of the Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of the Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.

Table of Contents

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 13, 2021

By: */s/ Kathi Niffenegger*
Kathi Niffenegger Chief Financial Officer
(Principal Financial Officer and Duly Authorized 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 13, 2021

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, Kathi Niffenegger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Edesa Biotech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2021

By: */s/ Kathi Niffenegger*
Kathi Niffenegger
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, 2021, 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 13, 2021

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, 2021, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Kathi Niffenegger, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2021

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