

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

Form 10-Q

(Mark One)

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

For the quarterly period ended **February 28, 2019**

or

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

For the transition period from _____ to _____

Commission File Number **333-199213**

ARTELO BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

33-1220924

(IRS Employer Identification No.)

888 Prospect Street, Suite 210, La Jolla CA

(Address of principal executive offices)

92037

(Zip Code)

(760) 943-1689

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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 and posted 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, or a small reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 Exchange Act) YES NO

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY
PROCEEDINGS DURING THE PRECEDING FIVE YEARS

Check whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court. YES NO

APPLICABLE ONLY TO CORPORATE ISSUERS

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

As of April 12, 2019, 15,879,489 shares of the registrant's common stock were issued and outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

**ARTELO BIOSCIENCES, INC.
Consolidated Balance Sheets
(Unaudited)**

	<u>February 28, 2019</u>	<u>August 31, 2018</u>
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 457,328	\$ 337,424
Prepaid expenses and deposits	17,589	36,884
Other receivables	8,951	22,127
Total Current Assets	483,868	396,435
Equipment, net of accumulated depreciation of \$415 and \$282, respectively	414	563
TOTAL ASSETS	<u>484,282</u>	<u>396,998</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 586,002	\$ 529,272
Due to related party	5,534	2,700
Derivative liability	584,920	-
Total Current Liabilities	1,176,456	531,972
STOCKHOLDERS' DEFICIT		

Preferred Stock, par value \$0.001, 50,000,000 shares authorized, 0 and 0 shares issued and outstanding as of February 28, 2019 and August 31, 2018, respectively	-	-
Common Stock, par value \$0.001, 150,000,000 shares authorized, 15,679,489 and 14,002,293 shares issued and outstanding as of February 28, 2019 and August 31, 2018, respectively	15,679	14,002
Additional paid-in capital	2,923,417	2,501,884
Accumulated deficit	(3,620,272)	(2,638,580)
Accumulated other comprehensive loss	(10,998)	(12,280)
Total Stockholders' Deficit	<u>(692,174)</u>	<u>(134,974)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$ 484,282</u>	<u>\$ 396,998</u>

The accompanying notes are an integral part of these unaudited financial statements.

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ARTELO BIOSCIENCES, INC.
Consolidated Statements of Operations
(Unaudited)

	Three months ended		Six months ended	
	February 28,		February 28,	
	2019	2018	2019	2018
OPERATING EXPENSES				
General and administrative	\$ 57,922	\$ 30,924	\$ 263,423	\$ 167,488
Professional fees	209,946	119,999	377,239	227,344
Research and development	489,981	647,467	674,020	680,543

Depreciation	70	74	140	146
Total Operating Expenses	<u>757,919</u>	<u>798,464</u>	<u>1,314,822</u>	<u>1,075,521</u>
Loss from Operations	(757,919)	(798,464)	(1,314,822)	(1,075,521)
OTHER EXPENSE				
Change in fair value of derivative liabilities	<u>333,130</u>	<u>-</u>	<u>333,130</u>	<u>-</u>
Total other expense	<u>333,130</u>	<u>-</u>	<u>333,130</u>	<u>-</u>
NET LOSS	<u>\$ (424,789)</u>	<u>\$ (798,464)</u>	<u>\$ (981,692)</u>	<u>\$ (1,075,521)</u>
OTHER COMPREHENSIVE LOSS				
Foreign currency translation adjustments	<u>(3,606)</u>	<u>(1,254)</u>	<u>1,282</u>	<u>(2,279)</u>
Total Other Comprehensive Income Loss	<u>(3,606)</u>	<u>(1,254)</u>	<u>1,282</u>	<u>(2,279)</u>
TOTAL COMPREHENSIVE LOSS	<u>\$ (428,395)</u>	<u>\$ (799,718)</u>	<u>\$ (980,410)</u>	<u>\$ (1,077,800)</u>
Basic Loss per Common Share	<u>\$ (0.03)</u>	<u>\$ (0.07)</u>	<u>\$ (0.07)</u>	<u>\$ (0.10)</u>
Diluted Loss per Common Share	<u>\$ (0.05)</u>	<u>\$ (0.07)</u>	<u>\$ (0.09)</u>	<u>\$ (0.10)</u>
Basic and Diluted Weighted Average Common Shares Outstanding	15,342,620	11,677,909	14,684,419	11,555,105

The accompanying notes are an integral part of these unaudited financial statements.

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ARTELO BIOSCIENCES, INC.
Consolidated Statements of Stockholders' Equity (Deficit)
(Unaudited)

	<u>Common stock</u>		<u>Additional paid-in capital (deficiency)</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>				
Balance, August 31, 2018	14,002,293	\$ 14,002	\$ 2,501,884	\$ (12,280)	\$ (2,638,580)	\$ (134,974)
Common shares issued for cash	227,727	228	170,546	-	-	170,774
Common shares issued for services - officers	-	-	13,000	-	-	13,000
Stock option granted for services	-	-	28,051	-	-	28,051
Net loss for the period	-	-	-	-	(556,903)	(556,903)
Other comprehensive gain	-	-	-	4,888	-	4,888
Balance, November 30, 2018	14,230,020	14,230	2,713,481	(7,392)	(3,195,483)	(475,164)
Common shares issued for cash	1,449,469	1,449	1,085,682	-	-	1,087,131
Common shares issued for services - officers	-	-	13,000	-	-	13,000
Reclass of warrant derivative liability from equity	-	-	(918,050)	-	-	(918,050)
Stock option granted for services	-	-	29,304	-	-	29,304

Net loss for the period	-	-	-	(424,789)	(424,789)
Other comprehensive loss	-	-	(3,606)	-	(3,606)
Balance, February 28, 2019	<u>15,679,489</u>	<u>\$ 15,679</u>	<u>\$ 2,923,417</u>	<u>\$ (10,998)</u>	<u>\$ (3,620,272)</u>

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<u>Common stock</u>	Additional paid-in	Accumulated Other Comprehensive	Accumulated
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	<u>Shares</u>	<u>Amount</u>	<u>capital</u>	<u>Income</u>	<u>Deficit</u>	<u>Total</u>
Balance, August 31, 2017	11,327,302	\$ 11,327	\$ 827,942	\$ 657	\$ (295,089)	\$ 544,837
Common shares issued for cash	25,000	25	9,975	-	-	10,000
Common shares issued for services - officers	-	-	17,251	-	-	17,251
Net loss for the period	-	-	-	-	(277,057)	(277,057)
Other comprehensive gain	-	-	-	(1,025)	-	(1,025)
Balance, November 30, 2017	11,352,302	11,352	855,168	(368)	(572,146)	294,006
Common shares issued for cash	895,587	896	581,241	-	-	582,137
Common shares issued for services - officers	-	-	12,750	-	-	12,750
Common shares issued for services	120,000	120	125,880	-	-	126,000
Net loss for the period	-	-	-	-	(798,464)	(798,464)
Other comprehensive gain	-	-	-	(1,254)	-	(1,254)
Balance, February 28, 2018	12,367,889	\$ 12,368	\$ 1,575,039	\$ (1,622)	\$ (1,370,610)	\$ 215,175

The accompanying notes are an integral part of these unaudited financial statements.

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ARTELO BIOSCIENCES, INC.
Consolidated Statements of Cash Flows
(Unaudited)

	Six months ended	
	February 28,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (981,692)	\$ (1,075,521)
Stock based compensation	83,355	156,001
Depreciation	140	146
Change in fair value of derivative	(333,130)	-
Changes in operating assets and liabilities:		
Prepaid expenses	19,295	(12,423)
Other receivables	13,176	(1,327)
Accounts payable and accrued liabilities	56,730	295,745
Net cash used in operating activities	(1,142,126)	(637,379)

CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of equipment	-	(887)
Net cash used in investing activities	-	(887)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common shares	1,257,905	592,137
Advance from related party	8,075	16,583
Repayment to related party	(5,221)	(15,843)
Net cash provided by financing activities	1,260,759	592,877
Effects on changes in foreign exchange rate	1,271	(2,279)
Net decrease in cash and cash equivalents	119,904	(47,668)
Cash and cash equivalents - beginning of period	337,424	572,775
Cash and cash equivalents - end of period	<u>\$ 457,328</u>	<u>\$ 525,107</u>
Supplemental cash flow		
Cash paid for interest	<u>\$ -</u>	<u>\$ -</u>
Cash paid for income taxes	<u>\$ -</u>	<u>\$ -</u>
Non-cash financing and investing activities:		
Reclass of warrant derivative liability from equity	<u>\$ 918,050</u>	<u>\$ -</u>

The accompanying notes are an integral part of these unaudited financial statements.

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ARTELO BIOSCIENCES, INC.
Notes to the Unaudited Consolidated Financial Statements
For the Six Months Ended February 28, 2019

NOTE 1 - ORGANIZATION AND DESCRIPTION OF BUSINESS

ARTELO BIOSCIENCES, INC. (the "Company") is a Nevada corporation incorporated on May 2, 2011. It is based in San Diego County, California. The accounting and reporting policies of the Company conform to accounting principles generally accepted in the United States of America ("GAAP"), and the Company's fiscal year end is August 31st.

Effective on February 10, 2017, the Company changed its name from "KNIGHT KNOX DEVELOPMENT CORP.," to "REACTIVE MEDICAL INC.," On April 14, 2017, the Company changed its name from "REACTIVE MEDICAL INC." to "ARTELO BIOSCIENCES, INC."

The Company registered fully owned subsidiaries in Ireland, Trinity Reliant Ventures Limited, on November 11, 2016 and in the UK, Trinity Research & Development Limited, on June 2, 2017. Operations in the subsidiaries have been consolidated in the financial statements.

The Company intends to license, develop and commercialize novel therapeutic treatments targeting the endocannabinoid system. To date, the Company's activities have primarily been limited to its formation, business development activities, sponsored research, and the raising of equity capital.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company prepares its financial statements in accordance with rules and regulations of the Securities and Exchange Commission (the "SEC") and GAAP in the United States of America. The accompanying interim financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information in accordance with Article 8 of Regulation S-X. Accordingly, they do not include all of the

information and footnotes required by GAAP for complete financial statements. In the Company's opinion, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the six months ended February 28, 2019 are not necessarily indicative of the results for the full year. While management of the Company believes that the disclosures presented herein are adequate and not misleading, these interim financial statements should be read in conjunction with the audited financial statements and the footnotes thereto for the year ended August 31, 2018 contained in the Company's Form 10-K filed on November 29, 2018.

Basis of Consolidation

The financial statements have been prepared on a consolidated basis, with the Company's fully owned subsidiaries Trinity Reliant Ventures Limited and Trinity Research & Development Limited. All intercompany balances and transactions have been eliminated.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, the Company used a Monte Carlo valuation model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date.

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NOTE 3 - GOING CONCERN

The Company's financial statements are prepared using GAAP applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has not established an ongoing source of revenues sufficient to cover its operating cost and requires additional capital to commence its operating plan. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. These factors raise substantial doubt about its ability to continue as a going concern.

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management's plan to obtain such resources for the Company includes: sales of equity instruments; traditional financing, such as loans; and obtaining capital from management and significant stockholders sufficient to meet its minimal operating expenses. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

There is no assurance that the Company will be able to obtain sufficient additional funds when needed or that such funds, if available, will be obtainable on terms satisfactory to the Company. In addition, profitability will ultimately depend upon the level of revenues received from business operations. However, there is no assurance that the Company will attain profitability. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the liquidation of liabilities in the normal course of business. During the six months ended February 28, 2019, the Company had a net loss of \$981,692. As of February 28, 2019, the Company had an accumulated deficit of \$3,620,272 and has earned no revenues. The Company intends

to fund operations through equity financing arrangements, which may be insufficient to fund its capital expenditures, working capital and other cash requirements for future periods.

NOTE 4 - RELATED PARTY TRANSACTIONS

During the six months ended February 28, 2019, the president of the Company incurred \$600 of expenses on behalf of the Company. The amounts owed to the related party as of February 28, 2019 and August 31, 2018 are \$2,802 and \$2,202, respectively. The amounts are non-interest bearing and have no terms of repayment.

During the six months ended February 28, 2019, the former President, and current Senior Vice President, European Operations, who is a major stockholder of the Company, paid for expenses on behalf of the Company for a total of \$7,475. The amount of \$5,221 was repaid during the six months ended February 28, 2019. The amounts owed to the related party as of February 28, 2019 and August 31, 2018 are \$2,732 and \$498, respectively. The amounts are non-interest bearing, and have no terms of repayment.

During the six months ended February 28, 2019, an entity owned by the Senior Vice President, European Operations, who is a major stockholder of the Company, provided \$18,000 worth of consulting services to the Company. As of February 28, 2019, there is \$4,000 outstanding.

NOTE 5 - EQUITY

Preferred shares

The Company has authorized 50,000,000 shares of preferred stock with a par value of \$0.001.

During the six months ended February 28, 2019, there were no issuances of preferred stock

Common Shares

The Company has authorized 150,000,000 shares of common stock with a par value of \$0.001 per share. Each share of common stock entitles the holder to one vote, in person or proxy, on any matter on which an action of the stockholders of the Company is sought.

During the six months ended February 28, 2019, the Company received cash of \$1,257,905 for 1,677,196 units at a price of \$0.75 per unit (a "Series D Unit") pursuant to the Company's Series D offering. Each Series D Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series D Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$1.75 per share, for a period of 5 years from the issue date.

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Warrants

In connection with the common stock sold pursuant to subscription agreements in fiscal year 2019, 2018 and 2017, each individual investor received warrants to purchase additional shares of the stock.

For each unit purchased in the Company's Series A offering, Series B offering, Series C offering and Series D offering, each investor will receive one Series A, Series B, Series C or Series D Common Stock Purchase Warrant, respectively, to purchase one share of the Company's common stock for a period of five years from the date of the subscription agreement at a price per share from \$1.00 to \$1.75, depending on the subscription round.

Under the terms of the subscription agreements for the Company's private placement offerings, following the closing date of such private offering until the earlier of (i) the date that the registration statement of the shares issued in such offering is declared effective by the SEC, or (ii) the date the shares otherwise become freely tradable, if the Company issues any common stock or common stock equivalent entitling the new investor to acquire common stock at a price below the purchase price for that particular prior subscription agreement, the Company will be required to issue the prior investor additional units, each consisting of one share of common stock and a warrant to purchase one share of common stock, equal to the difference between the units actually issued at such closing to the new investor, and the number of units we would have issued to the prior investor had the offering been completed at this new, lower price per share. Management reviewed the terms of the agreements and determined that in accordance with ASC 815, these cash subscription agreements entered into by the Company contain derivative features. As of February 28, 2019, a derivative liability of \$584,920 has been recorded.

A summary of activity during the six months ended February 28, 2019 follows:

	Number of shares	Weighted Average Exercise Price	Weighted Average Life (years)
Outstanding, August 31, 2018	3,962,293	\$ 1.30	4.23
Granted	1,677,196	1.75	5
Forfeited	-	-	-
Exercised	-	-	-
Outstanding, February 28, 2019	5,639,489	\$ 1.43	4.04

The intrinsic value of the warrants as of February 28, 2019 is \$390,422.

Stock Options

On August 17, 2018, the Company granted options to consultants to purchase an aggregate of 400,000 shares of the Company's common stock at a price of \$1.35 per share with various vesting schedules. The options expire on August 17, 2028, unless such consultant ceases his or her service as a consultant prior the exercise or expiration of the option. One consultant also serves as a director.

During the six months ended February 28, 2019, \$57,355 was expensed, and as of February 28, 2019, \$372,164 remains unamortized. The intrinsic value of the 400,000 options as of February 28, 2019 is \$0, and the weighted average value of the remaining life of the options is \$9.47.

During the six months ended February 28, 2019, the Company recorded \$26,000 of stock compensation expense for five members of the Company's Board of Directors.

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The following is a summary of stock option activity during the six months ended February 28, 2019:

	Options Outstanding		Fair Value on Grant Date
	Number of Options	Weighted Average Exercise Price	
Outstanding, August 31, 2018	400,000	\$ 1.35	\$ 536,688
Granted	-	-	-
Exercised	-	-	-

Forfeited/canceled	-	-	-
Outstanding, February 28, 2019	400,000	\$ 1.35	\$ 536,688

The following table summarizes information relating to exercisable stock options as of February 28, 2019:

Options Outstanding			Options Exercisable	
Number of Options	Weighted Average Remaining Contractual life (in years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
400,000	9.47	\$ 1.35	108,560	\$ 1.35

NOTE 6 – COMMITMENTS AND CONTINGENCIES

The Company has certain financial commitments in relation to Research and Development contracts. As of February 28, 2019:

- The Company is obligated to make one payment of \$77,760 on March 1, 2019 for research and development.
- The Company is obligated to make two semi-annual payments totaling 115,000 GBP over the next year. A payment of \$57,500 GBP is due on October 5, 2018, and April 5, 2019, respectively. The October 5, 2018 payment has not yet been paid by the Company.
- The Company is invoiced monthly and quarterly in relation to several Research and Development contracts.
- The Company may be obligated to make additional payments related to Research and Development contracts entered into, dependent on the progress and milestones achieved through the programs.

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NOTE 7 – DERIVATIVE LIABILITY AND FAIR VALUE MEASUREMENTS

The Company recognized a derivative liability related to the purchase price protection clause associated with equity offerings for Series D offering (Note 5). Additional units would be issued to the unit holder if the Company should issue common stock or the equivalent at a share price less than \$0.75 per share. In accordance with ASC 815-10- *Derivatives and Hedging* we measured the derivative liability using a Monte Carlo pricing model. Accordingly, at the end of each quarterly reporting date, the derivative fair market value is re-measured and adjusted to current market value.

Changes in the fair value of the warrant liability were as follows:

Fair value – August 31, 2018	\$	-
Reclass of warrant derivative liability from equity		(918,050)
Change in fair value for the period of warrant derivative liability		333,130
Fair value – February 28, 2019		584,920

The Monte Carlo pricing model was used to estimate the fair value of the derivative liability and reflected the following assumptions:

<u>Assumptions for Pricing Model:</u>	<u>February 28, 2019</u>	<u>August 31, 2018</u>
Expected term in years	0.25 – 0.33	—
Volatility	146%	—
Risk-free interest rate	2.45% - 2.52%	—
Expected annual dividends	0%	—

NOTE 8 – SUBSEQUENT EVENTS

Subsequent to February 28, 2019, the Company received cash of \$143,932 for 151,507 units at a price of \$0.95 per unit (a “Series E Unit”) pursuant to the Company’s Series E Offering. Each Series E Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series E Stock Purchase Warrant to purchase one-half (1/2) share of common stock at a price of \$2.00 per share for a period of 3 years from the issue date. The Series E Offering is currently open. No common shares, units, or warrants have been issued.

On March 15, 2019, the Board approved the issuance of 200,000 shares of our Common Stock to Blackrock Ventures, Ltd., a Company owned by a former director, in exchange for its prior services to the Company.

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Item 2. Management's Discussion and Analysis of Financial Condition or Plan of Operation

This quarterly report contains forward-looking statements. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential” or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Our unaudited financial statements are stated in United States Dollars (US\$) and are prepared in accordance accounting principles generally accepted in the United States of America (“GAAP”). The following discussion should be read in conjunction with our financial statements and the related notes that appear elsewhere in this quarterly report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below and elsewhere in this quarterly report.

In this quarterly report, unless otherwise specified, all dollar amounts are expressed in United States dollars and all references to “common shares” refer to the common shares in our capital stock.

As used in this quarterly report, the terms “we”, “us”, “our” and “our company” mean Artelo Biosciences, Inc., and our wholly owned subsidiaries, Trinity Reliant Ventures Limited, in Ireland, and Trinity Research & Development Limited, in England and Wales unless otherwise indicated.

Overview

We were incorporated under the laws of the State of Nevada on May 2, 2011 under the name Knight Knox Development Corp. Our principal address is 888 Prospect Street, Suite 210, La Jolla, California, USA and our European office is located at 29 Fitzwilliam Street, Upper, Dublin 2 Ireland. Our telephone number in North America is 760-943-1689 and our European office number is +353 (1) 443 4604. Our corporate website is www.artelobio.com.

From inception to January 2017 our business plan was that of a development stage e-commerce company with the intention of operating a fully functional auction site where customers would register for an account and sell and purchase goods and services. Beginning in April 2017, we changed our business plan and we are now focused on becoming a specialty biopharmaceutical company that intends to license, develop and commercialize novel cannabinoid therapeutic treatments, although we have licensed one provisional patent pertaining to a novel cannabinoid-based drug combination to date, we are not yet developing any such treatments.

On January 19, 2017, a majority of our stockholders and our board of directors approved a name change from Knight Knox Development Corp. to Reactive Medical Inc., to better reflect a change of direction of our business. In addition, the majority stockholder and our board of directors approved an increase to our authorized capital from 75,000,000 shares of common stock, par value \$0.001 to 150,000,000 shares of common stock, par value \$0.001 and authorize the creation of 50,000,000 shares of preferred stock, par value \$0.001. The change of name became effective with the OTC Markets at the opening of trading on February 10, 2017 under the symbol “RMED”.

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On April 3, 2017, Mr. Peter O'Brien resigned from his positions as President, Chief Executive Officer, Chief Financial Officer, Secretary and Treasurer of the Company and was appointed Senior Vice President of European Operations. On April 3, 2017, Mr. Gregory Gorgas was appointed President, Chief Executive Officer, Chief Financial Officer, Secretary, Treasurer and a member of our board of directors. On that date, the Company entered into an employment contract with Mr. Gorgas, which commits the Company and Mr. Gorgas to specific rights and responsibilities, customary to industry standards. For example, upon fulfilling certain obligations, including raising capital in excess of \$5,000,000. Mr. Gorgas will then be paid an annual salary of \$250,000 and be eligible for additional compensation in the form of bonus, equity, and benefits, commensurate with industry standards. Per the terms of the employment agreement, that any investment in, or appointment to or continuing service on a board of directors or similar body of, any corporation or entity, must be approved in writing by the Company. The agreement includes non-competition terms. The employment agreement can only be terminated in accordance with the Term of Employment specified in the agreement.

Simultaneously, on April 3, 2017, Mr. Gorgas entered into a stock purchase agreement to purchase 1,760,000 common shares for a purchase price of \$1,760.

On April 14, 2017, with the approval of our board of directors and stockholders owning a majority of our Company's issued and outstanding shares by written consent in lieu of a meeting, we filed a Certificate of Change with the Secretary of State of Nevada, changing our name to Artelo Biosciences, Inc., effective as of April 28, 2017. The change of name became effective on the OTC Markets on May 2, 2017 under the symbol "ARTL".

On December 20, 2017, we entered into the Material and Data Transfer, Option and License Agreement with NEOMED (the "NEOMED Agreement"). The NEOMED Agreement, which has an effective date of January 2, 2018, provides our Company with up to twelve months from the date of receipt by our Company of the required materials to conduct certain non-clinical research studies, diligence and technical analyses with the Compound and an option for an exclusive worldwide license to develop and commercialize products comprising or containing the Compound. Pursuant to the terms of the NEOMED Agreement, within 30 days after the effective date of the NEOMED Agreement, NEOMED, without additional consideration and at its sole cost, delivered to our Company certain technology transfer materials and the quantity of the Compound substance specified in a research plan, both as set out under the NEOMED Agreement. We will have one year from the date of receipt by our Company of the required materials to exercise the option. Upon exercise of the option, NEOMED will provide our Company with an exclusive worldwide license under all of NEOMED's intellectual property rights covering the Compound ("Licensed IP Rights") to research, develop, make, have made, use, offer for sale, sell, have sold and import products containing the Compound and otherwise exploit the Licensed IP Rights in all fields.

On January 18, 2018, we entered into a license agreement with the Research Foundation (the "Foundation") at Stony Brook University (the "Stony Brook Agreement") which became effective on that same date. The Stony Brook Agreement provides us with an exclusive license under certain licensed patents

of the Foundation (the "Patent Rights") to develop, make, manufacture, have made, use, sell, have sold, import, export, and offer for sale Patent Product(s) (as defined in the Stony Brook Agreement) and Other Product(s) (as defined in the Stony Brook Agreement) worldwide in all fields, including without limitation the field of human therapeutics. The Agreement has an effective date of January 18, 2018 (the "Effective Date").

Pursuant to the Stony Brook Agreement, we will pay to the Foundation an upfront fee and annual license maintenance fees, beginning on the first anniversary of the Effective Date and annually thereafter on each anniversary of the Effective Date.

We will be required to pay a low-single digit royalty on net sales on any patent products (the "Royalties"). The Stony Brook Agreement provides for a reduction of the Royalties in certain cases.

Pursuant to the Stony Brook Agreement, we will also pay to the Foundation, beginning in the first calendar year of the first commercial sales, an annual minimum royalty fee (the "Annual Minimum Royalty"). The Annual Minimum Royalty will be credited against the total Royalties due for the calendar year in which the Annual Minimum Royalty.

We have never declared bankruptcy, been in receivership, or involved in any kind of legal proceeding.

Our Current Business

We are a clinical stage biopharmaceutical company focused on developing and commercializing treatments intended to modulate the endocannabinoid system (the "ECS"), including a solid-state composition of cannabidiol ("CBD co-crystal"), with improved pharmaceutical-like properties which could have a meaningful impact on cannabinoid-based drug development. Our management team is highly experienced and has a successful history of development, regulatory approval and commercialization of pharmaceuticals.

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Our pipeline broadly leverages leading scientific methodologies to ECS modulation, balances risk across mechanism of action and stages of development, and represents a comprehensive approach in utilizing the power of the ECS to develop pharmaceuticals for patients with unmet healthcare needs. In addition to our cocrystal program, we are currently evaluating ART27.13, which is entering a Phase 1b/2a trial for cancer related anorexia, and ART26.12, which is being studied as an endocannabinoid modulator and cancer therapeutic and is in the late pre-clinical stage.

The crystal structure of cannabidiol (“CBD”) is known to exhibit polymorphism, or the ability to manifest in different forms. Polymorphism can adversely affect stability, dissolution, and bioavailability of a drug product and thus affect its quality, safety, and efficacy. We have developed a proprietary cocrystal composition of CBD, which we have designated as ART12.11. We believe our cocrystal exists as a single crystal form and as such is anticipated to have advantages over other forms of CBD that exhibit polymorphism. Anticipated advantages of this single crystal structure include improved stability, solubility, and a more consistent absorption profile. We believe these features will result in more consistent bioavailability and may lead to improved safety and efficacy.

Patent applications including broad claims to our novel cocrystal composition of CBD were filed in late 2018. Composition claims are generally known in the pharmaceutical industry as the most desired type of intellectual property and, if issued, should provide for long lasting market exclusivity for our CBD cocrystal drug product candidate. In addition, due to the reasons outlined above, we believe that our CBD cocrystal will have superior pharmaceutical properties compared to non-cocrystal CBD products under development at other competing companies.

In addition to our own internal discovery research, we are currently developing two patent protected product candidates that we obtained through our licensing activities. Our first program is a synthetic cannabinoid product candidate, ART27.13, being developed for cancer-related anorexia. ART27.13 is a peripherally-restricted high-potency dual CB₁ and CB₂ receptor agonist which was originally developed at AstraZeneca plc (“AstraZeneca”), and which

we received through the NEOMED Institute, a Canadian not-for-profit corporation (“NEOMED”). In Phase 1 single dose studies in healthy volunteers and a multiple ascending dose study in otherwise healthy patients with back pain conducted by AstraZeneca, ART27.13 exhibited an attractive pharmacokinetic and absorption, distribution, metabolism, and excretion (“ADME”) profile and was well tolerated within the target exposure range. It also exhibited dose-dependent and potentially clinically meaningful increases in body weight. Importantly, the changes in body weight were not associated with fluid retention or other adverse effects and occurred at exposures without CNS side effects. Preliminary discussions with U.S. and Canadian regulators suggest there is a potential pathway for development of ART27.13 for the treatment of cancer-related anorexia, which affects approximately 60% of advanced stage cancer patients. We are planning to initiate a Phase 1b/2a clinical study of cancer-related anorexia with ART27.13 in late 2019.

Our second in-licensed program is a platform of small-molecule inhibitors for fatty acid binding protein 5, or FABP5, based upon scientific developments achieved at Stony Brook University (“SBU”) which we have designated ART26.12. To date, SBU has received nearly \$4 million in funding from the National Institutes of Health (the “NIH”) to begin developing these candidates. Fatty acid binding proteins (“FABPs”) are attractive therapeutic targets, however, their high degree of similarity among the various types has proven challenging to the creation of drugs targeting specific FABPs. Fatty acid binding protein 5 (“FABP5”) is believed to specifically target and regulate one of the body’s endogenous cannabinoids, anandamide (“AEA”). While searching for a FABP5 inhibitor to regulate AEA, we believe researchers at SBU discovered the chemistry for creating a highly specific and potent small molecule inhibitor for FABP5. In addition to its potential as an endocannabinoid modulator, FABP5 is also an attractive target for cancer drug development. Large amounts of human clinical epidemiological and animal model data support FABP5 as a well validated oncology therapeutic target, especially for triple negative breast cancer and castration-resistant prostate cancer. We licensed exclusive world-wide rights to these inhibitors from SBU. The program is in the final stages of lead optimization, and we plan to initiate Investigational New Drug (“IND”) enabling studies thereafter. We anticipate clinical studies in cancer can begin in 2020.

We are developing our product candidates in accordance with traditional drug development standards and plan to make them available to the general public via prescription or physician orders only after obtaining marketing authorization from a regulatory authority, such as the U.S. Food and Drug Administration (the “FDA”). Our management team has experience developing and commercializing ethical pharmaceutical products, including several first-in-class therapeutics. Based upon our current management’s capabilities and the future talent we may attract, we expect to retain rights to internally develop and commercialize products, however, we may seek collaborations with partners in the biopharmaceutical industry when that strategy serves to maximize value for our stockholders.

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Background

The ECS is composed of cannabinoid receptors, endogenous receptor ligands (“endocannabinoids”) and their associated transporter mechanisms, as well as enzymes responsible for the synthesis and degradation of endocannabinoids, and has emerged as a considerable target for pharmacotherapy approaches of numerous human diseases. As a widespread modulatory system, the ECS plays important roles in the central nervous system (the “CNS”), development, synaptic plasticity, and the response to endogenous and environmental factors.

The modulation of the ECS can be effected by using selective or non-selective agonists, partial agonists, inverse agonists, and antagonists of the cannabinoid receptors, CB₁ and CB₂. The CB₁ receptor is distributed in brain areas associated with motor control, emotional responses, motivated behavior and energy homeostasis. In the periphery, CB₁ is ubiquitously expressed in the adipose tissue, pancreas, liver, gastrointestinal tract, skeletal muscles, heart and the reproductive system. The CB₂ receptor is mainly expressed in the immune system regulating its functions, and is upregulated in response to tissue stress or damage in most cell types. The ECS is therefore involved in pathophysiological conditions in both the central and peripheral tissues.

The actions of endogenous ligands can be enhanced or attenuated by targeting mechanisms that are associated with their transport within the cellular and extra cellular matrix as well as their synthesis and breakdown. Small molecule chemical modulators of the ECS can either be derived from the cannabis plant (“phytocannabinoids”) or can be semi-synthetic derivatives of phytocannabinoids or endocannabinoids, or completely synthetic new chemical entities. We plan to develop approaches within our portfolio that address receptor binding and endocannabinoid transport modulation using both synthetic cannabinoids and new chemical entity approaches. Future approaches may also involve targeting synthesis or breakdown enzymes.

ECS targeting cannabinoid-based medicines are already approved and used to treat numerous medical conditions. The ECS is further implicated in many disease states within the peer reviewed literature including conditions which involve the regulation of food intake, central nervous system, pain, cardiovascular, gastrointestinal, immune and inflammation, behavioral, antiproliferative and reproductive functions. These areas of ECS pathophysiology are aligned with our therapeutic areas of focus: pain, inflammation, anorexia, cardiovascular, and cancer.

Results of Operations

The following summary of our results of operations, for the six months ended February 28, 2019 and 2018, should be read in conjunction with our interim financial statements, as included in this Form 10-Q and our audited financial statements for the year ended August 31, 2018, as included in Form 10-K filed with the SEC on November 29, 2018.

Our financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation. We expect we will require additional capital to meet our long term operating requirements. We expect to raise additional capital through, among other things, the sale of equity or debt securities, but we cannot guarantee that we will be able to achieve same.

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The following table provides selected financial data about the Company as of February 28, 2019 and August 31, 2018.

Balance Sheet Data

	February 28, 2019	August 31, 2018
Cash	\$ 457,328	\$ 337,424
Total Assets	\$ 484,282	\$ 396,998

Total Liabilities	\$ 1,176,456	\$ 531,972
Stockholders' Deficit	\$ (692,174)	\$ (134,974)

We have not generated any revenues since inception through February 28, 2019. The increase in cash was primarily due to an issuance of common shares.

For the Three Months Ended February 29, 2018 Compared to the Three Months Ended February 28, 2018

	Three months ended	
	February 28,	
	2019	2018
Operating Expenses		
General and administrative	\$ 57,922	\$ 30,924
Professional fees	209,946	119,999
Research and development	489,981	647,467
Depreciation	70	74
Total Operating Expenses	<u>757,919</u>	<u>798,464</u>
Loss from Operations	(757,919)	(798,464)
Change in fair value of derivative liabilities	333,130	-
Net Loss	<u>\$ (424,789)</u>	<u>\$ (798,464)</u>

Our operating expenses, for the three months ended February 28, 2019 were \$757,919 compared to \$798,464 for the same period in 2018. The Company's operating expenses were primarily related to professional fees for ongoing regulatory requirements, research and development and general and administrative expenses.

For the Six Months Ended February 28, 2019 Compared to the Six Months Ended February 28, 2018

	Six months ended	
	February 28,	
	2019	2018
Operating Expenses		
General and administrative	\$ 263,423	\$ 167,488
Professional fees	377,239	227,344
Research and development	674,020	680,543
Depreciation	140	146
Total Operating Expenses	<u>1,314,822</u>	<u>1,075,521</u>
Loss from Operations	(1,314,822)	(1,075,521)
Change in fair value of derivative liabilities	333,130	-
Net Loss	<u>\$ (981,692)</u>	<u>\$ (1,075,521)</u>

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Our operating expenses, for the six months ended February 28, 2019 were \$1,314,822 compared to \$1,075,521 for the same period in 2018. The higher operating expenses during the six months ended February 28, 2019 were primarily related to professional fees for ongoing regulatory requirements, research and development and general and administrative expenses.

Liquidity and Capital Resources

Working Capital

	February 28, 2019	August 31, 2018
Current Assets	\$ 483,868	\$ 396,435
Current Liabilities	1,176,456	531,972
Working Capital Deficiency	<u>\$ (692,588)</u>	<u>\$ (135,537)</u>

Cash Flows

	Six months ended February 28,	
	2018	2017
Cash Flows used in operating activities	\$ (1,142,126)	\$ (637,379)
Cash Flows used in investing activities	-	(887)
Cash Flows provided by financing activities	1,260,759	592,877
Effects on changes in foreign exchange rate	1,271	(2,279)
Net change in cash during period	<u>\$ 119,904</u>	<u>\$ (47,668)</u>

Cash Flow from Operating Activities

During the six months ended February 28, 2019, cash used in operating activities was \$1,142,126 compared to cash used in operating activities of \$637,379 during the period ended February 28, 2018. The cash used from operating activities was primarily attributed to net loss of \$981,692 and change in fair value of derivative of \$333,130, offset by stock-based compensation of \$89,235, and an increase in accounts payable and accrued liabilities of \$56,730.

Cash Flow from Investing Activities

The Company did not use any funds for investing activities in the six months ended February 28, 2019. The Company used \$887 for purchase of equipment for the six months ended February 28, 2018.

Cash Flow from Financing Activities

During the six months ended February 28, 2019, the company received \$1,260,759. During the six months ended February 28, 2018, the company received \$592,877.

Going Concern

Our financial statements are prepared using GAAP applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has not established an ongoing source of revenues sufficient to cover its operating cost and requires additional capital to commence its operating plan. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. These factors raise substantial doubt about its ability to continue as a going concern.

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In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management's plan to obtain such resources for the Company include: sales of equity instruments; traditional financing, such as loans; and obtaining capital from management and significant stockholders sufficient to meet its minimal operating expenses. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

Off Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not have any undisclosed borrowings or debt, and we have not entered into any synthetic leases. We are, therefore, not

materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in such relationships.

Critical Accounting Policies and Estimates

We prepare our financial statements in conformity with GAAP, which requires management to make certain estimates and apply judgments. We base our estimates and judgments on historical experience, current trends and other factors that management believes to be important at the time the financial statements are prepared. On a regular basis, we review our accounting policies and how they are applied and disclosed in our financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a “smaller reporting company,” we are not required to provide the information required by this Item.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (our principal executive officer, principal financial officer and principal accounting officer), has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a- 15(e) and 15d- 15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer has concluded that as of such date, our disclosure controls and procedures were not effective such that the information relating to us required to be disclosed in our Securities and Exchange Commission (“SEC”) reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

During the period covered by this report there were no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising out of its operations in the normal course of business. We are not involved in any pending legal proceeding or litigation and, to the best of our knowledge, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject, which would reasonably be likely to have a material adverse effect on us.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as other information included in our 2018 Annual Report on Form 10-K, including our financial statements and the related notes, and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," any of which may be relevant to decisions regarding an investment in or ownership of our stock. The occurrence of any of these risks could have a significant adverse effect on our reputation, business, financial condition, results of operations, growth and ability to accomplish our strategic objectives. We have organized the description of these risks into groupings in an effort to enhance readability, but many of the risks interrelate or could be grouped or ordered in other ways, so no special significance should be attributed to the groupings or order below.

RISKS RELATED TO OUR BUSINESS AND PRODUCT CANDIDATES

Our ability to continue our operations requires that we raise additional capital and our operations could be curtailed if we are unable to obtain the additional funding as or when needed.

Upon the completion of our financial statements for the period ended February 28, 2019, and management's assessment of our ability to continue as a going concern, we concluded there was substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year-ended August 31, 2018, noting the existence of substantial doubt about our ability to continue as a going concern. As of February 28, 2019, there have been no changes to management's conclusion that there remains substantial doubt about our ability to continue as a going concern.

Our existing cash and cash equivalents will not be sufficient to fund our operating expenses throughout our fiscal year ending August 31, 2019. To continue to fund operations, we will need to secure additional funding. We may obtain additional financing in the future through the issuance of our Common Stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all. Further, any failure to raise capital as and when needed could compromise our ability to execute on our business plan, and we may be forced to liquidate our assets. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

We face many of the risks and difficulties frequently encountered by relatively new companies with respect to our operations.

Our business objective is to pursue the licensing, development and commercialization of therapeutic treatments that are associated with modulation of the endocannabinoid system. We have limited operating history as a medical research company engaged in biopharmaceutical research upon which an evaluation of our Company and our prospects could be based. There can be no assurance that our management will be successful in being able to commercially exploit the results, if any, from our product development research projects or that we will be able to develop products and treatments that will enable us to generate sufficient revenues to meet our expenses or to achieve and/or maintain profitability.

If we are unable to raise sufficient capital as needed, we may be required to reduce the scope of our planned research and development activities, which could harm our business plans, financial condition and operating results, or cease our operations entirely, in which case, you will lose all your investment.

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We do not have any therapeutic products that are approved for commercial sale. Our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors.

We currently do not have any therapeutic products that are approved for commercial sale. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates if approved. To obtain revenues from sales of our product candidates that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing therapies with commercial potential. Our ability to generate revenue and achieve profitability depends significantly on our success in many areas, including:

- our research and development efforts, including preclinical studies and clinical trials of our product candidates;
- developing sustainable, scalable, reliable and cost-effective manufacturing and distribution processes for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own current good manufacturing processes (“cGMPs”), manufacturing facilities and processes;
- addressing any competing technological and industry developments;
- identifying, assessing, acquiring and/or developing new technology platforms and product candidates across numerous therapeutic areas;

- obtaining regulatory approvals and marketing authorizations for product candidates;
- launching and commercializing any approved products, either directly or with a collaborator or distributor;
- obtaining market acceptance of and acceptable reimbursement for any approved products;
- completing collaborations, licenses and other strategic transactions on favorable terms, if at all;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and we may not generate significant revenue from sales of such products, resulting in limited or no profitability in the future. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital for the foreseeable future. Any failure to become and remain profitable may adversely affect the market price of our securities, our ability to raise capital and our future viability.

We have no mature product candidates and may not be successful in licensing any.

One of the key elements of our business strategy is to license technologies or compounds from companies and/or research institutions. We may not be able to identify technologies or compounds that are commercially viable, or that are available for licensure under acceptable terms. If we are able to identify suitable technologies or compounds, we may be unable to successfully negotiate a license, or maintain the licensing and collaboration arrangements necessary to develop and commercialize any product candidates. We may be unable to compete with companies that are more established than us and have greater financial resources than us for licenses to available technologies and compounds. Even if we are successful in licensing programs, we may not be able to satisfy development requirements should we be unable to raise additional funding.

Any failure to establish or maintain licensing or collaboration arrangements on favorable terms could adversely affect our ability to develop and commercialize product candidates, which can adversely affect our business prospects and financial condition.

Even if we are successful in licensing lead product candidates, resource limitations may limit our ability to successfully develop them.

Pharmaceutical development requires substantial capital, skilled personnel and infrastructure to successfully develop products for the market. The success of our business is highly dependent on our ability to successfully develop, obtain regulatory approval for and commercialize products. We do not currently have the financial resources to fund the development of any lead product candidate, and there is no assurance that we can raise enough capital to fund product development. If we are unable to raise additional capital, we will not be able to pursue the development of any products and may have to relinquish rights to any products we may have licensed.

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We will need to raise additional financing to support our business objectives. We cannot be sure we will be able to obtain additional financing on terms favorable to us when needed, or at all. If we are unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially in the foreseeable future. Developing our product candidates and conducting clinical trials in the future will require substantial amounts of capital. We will also require a significant additional amount of capital to commercialize any products that are approved in the future.

We will need to raise significant additional capital in the future to pursue our business objectives. Our current financial resources are limited. We will need to raise additional funds in the near future in order to satisfy our working capital and capital expenditure requirements. We may raise additional funds through public or private equity offerings, debt financings, strategic partnerships or alliances, receivables or royalty financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be diluted and the terms of such financings may include liquidation or other preferences that adversely affect the rights of existing stockholders. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. These restrictions could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. Debt financings may also be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates. In addition, if we raise additional funds through corporate collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to products or product candidates, or grant licenses on terms that are not favorable to us. Our future capital requirements may depend on a wide range of factors, including, but not limited to:

- the costs related to initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- any change in the clinical development plans for these product candidates;
- the number and characteristics of product candidates that we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the events related to the outcome, timing and cost of meeting regulatory requirements established by the DEA, the FDA or other comparable foreign regulatory authorities;
- the potential costs of filing, prosecuting, defending and enforcing our patent claims and other intellectual property;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;

- the cost of defending intellectual property disputes; and
- the cost of marketing and generating revenues for any of our product candidates.

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If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts, or other aspects of our business plan. We also may be

required to relinquish, license or otherwise dispose of rights to products or product candidates that we would otherwise seek to commercialize or develop ourselves on terms that are less favorable than might otherwise be available. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

We have very limited operating history and capabilities.

Although our business was formed in 2011, we have had very limited operations in our current field of interest. We do not currently have the ability to perform the functions necessary to develop any product candidates. The successful development of any product candidates will require us to perform a variety of functions including, but not limited to:

- Identifying, licensing and obtaining development programs and lead candidates
- Conducting initial research required to identify a lead candidate as the result of intellectual property we have licensed
- Initiating preclinical, clinical or other required studies for future product candidates
- Adding manufacturers and suppliers required to advance our programs
- Obtaining regulatory and marketing approvals for our product candidates that successfully complete clinical studies
- Making milestone or other payments under any license agreements
- Expanding, maintaining and protecting our intellectual property portfolio
- Attracting and retaining skilled personnel
- Creating and maintaining an infrastructure required to support our operations as a public company

Our operations continue to be focused on acquiring, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

We may not be able to file Investigational New Drug applications to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed in a timely manner, or at all.

Prior to commencing clinical trials in the United States for any of our product candidates, we may be required to have an Investigational New Drug application (“IND”) for each product candidate. Submission of an IND may not result in the FDA allowing clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, these regulatory authorities may change their requirements in the future. The fact that we are pursuing novel technologies may also exacerbate these risks with respect to our product candidates, and as a result we may not meet our anticipated clinical development timelines.

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Use of our product candidates could be associated with side effects or adverse events.

As with most biopharmaceutical products, use of our product candidates could be associated with side effects or adverse events which can vary in severity and frequency. Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval or market our product candidates. Side effects such as toxicity or other safety issues associated with the use of our product candidates could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business. We may be required by regulatory agencies to conduct additional preclinical or clinical trials regarding the safety and efficacy of our product candidates which we have not planned or anticipated. We cannot assure you that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition. We may also inadvertently fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and clinical trials may not be predictive of future clinical trial results, and our clinical trials may fail to adequately demonstrate substantial evidence of safety and efficacy of our product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to support obtaining regulatory approval for our product candidates.

We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated by us, regulatory authorities, clinical trial investigators, and ethics committees for a variety of reasons, including failure to:

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on clinical trial design, to commence a clinical trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective clinical research organizations (“CROs”) and clinical trial sites;
- obtain and maintain institutional review board (“IRB”), approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a clinical trial;
- have a sufficient number of patients complete a clinical trial or return for post-treatment follow-up;

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- ensure clinical investigators observe clinical trial protocol or continue to participate in a clinical trial;

- address any patient safety concerns that arise during the course of a clinical trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- timely manufacture sufficient quantities of a product candidate for use in clinical trials; or
- raise sufficient capital to fund a clinical trial.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such clinical trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such clinical trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including good clinical practices ("GCPs"), or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates for any reason, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Due to our limited resources, we may be forced to focus on a limited number of development candidates which may force us to pass on opportunities that could have a greater chance of clinical success.

Due to our limited resources and capabilities, we will have to decide to focus on developing a limited number of product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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We will need to rely on third parties to conduct our preclinical research and clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such research or trials.

We plan to rely on third-party CROs, to conduct the majority of our preclinical research studies and our clinical trials. In addition, we plan to rely on other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. There is no assurance we can obtain the services we need at commercially reasonable prices or within the timeframes we desire. Even though we will enter into agreements governing their activities, we will have limited influence over their actual performance and we will control only certain aspects of their activities. Further, agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the CROs. If there is any dispute or disruption in our relationship with our contractors or if we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on third parties for research and development activities will reduce our control over these activities, and will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely affected. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CRO fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, our clinical trials may be delayed or we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or if the quality of the clinical data they obtain is compromised due to the failure to conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience as a company in marketing products. If we develop internal sales, marketing and distribution organization, this would require significant capital expenditures, management resources and time, and we would have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we expect to pursue collaborative arrangements regarding the sales, marketing and distribution of our products. However, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, their sales forces may not be successful in marketing our products. Any revenue we receive would depend upon the efforts of such

third parties, which may not be successful. We may have little or no control over the sales, marketing and distribution efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales, marketing and distribution efforts of our product candidates. There can be no assurance that we will be able to develop internal sales, marketing distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

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If any of our offices become damaged or inoperable, or we are required to vacate our facilities, our ability to pursue our research and development efforts may be jeopardized.

We currently do not have any manufacturing facilities. We also do not own any properties, laboratories, or manufacturing facilities. However, we have offices in La Jolla, California, and Dublin, Ireland. Our facilities could be harmed or rendered inoperable by natural or man-made disasters,

including earthquakes, fires, power shortages, telecommunications failures, water shortages, famines, pestilence, floods, hurricanes, typhoons, tornadoes, extreme weather conditions, medical epidemics, cyber warfare, international conflict, climate change, and other natural or man-made disasters or other business interruptions, for which we are predominantly self-insured. Any of these may render it difficult or impossible for us to continue company operations. If any of our facilities is inoperable for even a short period of time, the interruption in research and development may result in harm to our reputation and increased costs, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work.

If we fail to comply with our obligations to our licensor in our intellectual property license, we could lose license rights that are important to our business.

We are a party to the Material and Data Transfer, Option and License Agreement with NEOMED (the “NEOMED Agreement”) and a license agreement with the Research Foundation (the “Foundation”) at Stony Brook University (the “Stony Brook Agreement”), and we may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that any future license agreements will impose, various diligence, product payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product candidate that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The occurrence of such events could have a material adverse effect on our business, financial condition and results of operations.

Even if we are successful in licensing or developing research programs and/or product candidates, we or our licensors must maintain the intellectual property.

Our commercial success is significantly dependent on intellectual property related to any product candidates and technologies we may either acquire, license or develop internally. We are currently the licensee of multiple issued patents and pending patent applications, and we intend to license additional technologies from pharmaceutical and biotechnology companies, and research institutions. In addition, based upon our own discovery research initiatives, we filed two patent applications on December 10, 2018 on novel chemistry related to a solid-state CBD composition.

Our success depends in large part on our and our licensor’s ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and product candidates. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensor’s patent rights are highly uncertain. Our and our licensor’s pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensor were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. We may become involved in opposition or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our product candidates without infringing third-party patent rights.

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Even if any owned and/or licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The costs and other requirements associated with filing new patent applications, and the ongoing cost of prosecuting pending patent applications and maintenance of issued patents are material to us. Bearing these costs and complying with these requirements are essential to procurement and maintenance of patents integral to our product candidates.

Legal, filing costs, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will come due for payment periodically throughout the lifecycle of patent applications and issued patents. In order to help ensure that we comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents for which we are an assignee or co-assignee, we employ legal help and related professionals as needed to comply with those requirements. Failure to meet a required fee payment, document production or procedural requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances, the defect can be cured through late compliance, but there are situations where the failure to meet the required deadline cannot be cured. Such an occurrence could compromise the intellectual property protection around a preclinical or clinical product candidate and possibly weaken or eliminate our ability to protect our eventual market share for that product candidate.

Our ability to research, develop and commercialize any product candidates is dependent on our ability to acquire, maintain or utilize third party contract research facilities that possess licenses relating to the cultivation, possession and supply of controlled substances.

In the United States, the U.S. Drug Enforcement Agency (“DEA”) regulates the cultivation, possession and supply of cannabis for medical research and/or commercial development, including the requirement of annual registrations to manufacture or distribute pharmaceutical products derived from cannabis extracts. We do not currently conduct manufacturing or repackaging/relabeling of any product candidates in the United States, however we intend to conduct research on compounds that may be derived from cannabis, including naturally-occurring cannabinoids, currently considered a Schedule 1 controlled substance. We plan to obtain the required licenses regulating the possession and supply of cannabinoids and to utilize third party contractors to conduct research who have the required registrations, however there is no assurance that we will be successful in obtaining the required licenses or that we will be successful identifying or engaging third party contractors who have the required registrations.

We plan to conduct a significant portion of our research in the United Kingdom, where licenses to cultivate, possess and supply cannabinoids for medical research are granted by the Home Office on an annual basis. We do not currently possess the required licenses, so until we do so, our research must be conducted within research institutions that possess the required licenses. If we are unable to conduct research at institutions that possess the required licenses, or if those licenses are not renewed in the future, we may not be in a position to engage in or carry on research and development programs in the United Kingdom. In order to carry out research in countries other than the United States and the United Kingdom, similar licenses to those outlined above are required to be issued by the relevant authority in each country. In addition, we will be required to obtain licenses to export from the U.S. and to import into the recipient country. We may also conduct a portion of our research in Canada, where we currently collaborating on certain research, and Ireland, where we currently have an office.

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To date, we have not obtained import, export, or supply licenses within any countries. We do not have an established track record of obtaining such required licenses and there is no assurance we will be able to obtain or maintain such licenses in the future, which could restrict our ability to conduct the research required for development and commercialization of lead products.

Any product candidates we develop will be subject to U.S. controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition.

Some of our product candidates may contain controlled substances as defined in the federal Controlled Substances Act of 1970, or CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, no currently “accepted medical use” in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the United States which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While cannabis is a Schedule I controlled substance, products approved for medical use in the United States that contain cannabis or cannabis extracts will be placed in Schedules II-V, since approval by the FDA satisfies the “accepted medical use” requirement. If and when any of our product candidates receive FDA approval, the DEA will make a scheduling determination and place the product in a schedule other than Schedule I in order for it to be prescribed to patients in the U.S. Consequently, the manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to specific and potentially significant levels of regulation by the DEA. On November 25, 2015 the President of the United States signed a new law that (i) amends the CSA to require the DEA to issue an interim final scheduling rule within ninety days following FDA approval and the Secretary of Health and Human Services recommending that the Attorney General control the drug in Schedule II, III, IV or V, and (ii) amends the FDCA to ensure that companies do not lose exclusivity on newly approved drugs because of the DEA drug scheduling process. Furthermore, if the FDA, DEA, or any foreign regulatory authority determines that any approved cannabis derived products may have potential for abuse, it may require us to generate more clinical or other data than we customary to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of that product.

DEA registration and inspection of facilities. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining the necessary registrations may result in delay of the importation, manufacturing or distribution of any cannabinoid derived products we may develop. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

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State-controlled substances laws. Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Clinical trials. It is possible some compounds we develop may contain cannabis extracts, which are Schedule I substances, therefore to conduct clinical trials in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our lead products (as applicable) and to obtain the product from our importer. If the DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import. We do not currently conduct any clinical trials, manufacturing or repackaging/relabeling in the U.S.

Importation. If one of our product candidates is approved and classified as a Schedule II or III substance, an importer can import for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect product availability and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third party comments to be submitted. It is always possible a competitor could take this opportunity to make adverse comments that delay the grant of an importer registration.

If one of our product candidates is approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If a product is listed as a Schedule II substance, we will not be allowed to import that drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. It is always possible the DEA could find that the active substance in a product, even if it is a plant derived substance, could be manufactured in the US. Moreover, Schedule I controlled substances, including BDSS, have never been registered with the DEA for importation commercial purposes, only for scientific and research needs. Therefore, if any of our future products could not be imported, that product would have to be wholly manufactured in the United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.

Manufacture in the United States. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of any future product candidates, cannabis comprising the active ingredient in the final dosage form is currently Schedule I controlled substances and would be subject to such quotas as these substances could remain listed on Schedule I. The annual quota allocated to us or our contract manufacturers for the active ingredients in our products may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and operations.

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Distribution in the United States. If any of our product candidates is scheduled as Schedule II or III, we would also need to identify wholesale distributors with the appropriate DEA and state registrations and authority to distribute the product to pharmacies and other health care providers. We would need to identify distributors to distribute the product to pharmacies; these distributors would need to obtain Schedule II or III distribution registrations. The failure to obtain, or delay in obtaining, or the loss any of those registrations could result in increased costs to us. If any of our product candidates is a Schedule II drug, pharmacies would have to maintain enhanced security with alarms and monitoring systems and they must adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying either or both of these products. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

Our product development projects, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue.

Even when and if product development is successful and regulatory approval has been obtained, our ability to generate significant revenue depends on the acceptance of our product candidates by physicians and patients. We cannot assure you that any of our product candidates will achieve the expected market acceptance and revenue, if and when we obtain the regulatory approvals. The market acceptance of any of our potential products depends on a number of factors, including the indication statement and warnings approved by regulatory authorities in the drug label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payers such as government health care systems and insurance companies, the price of the product, the nature of any post-approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. Any factors preventing or limiting the market acceptance of our products could have a material adverse effect on our business, results of operations and financial condition.

Results of preclinical studies and earlier clinical trials are not necessarily predictive indicators of future results.

Any positive results from future preclinical testing of our product candidates and potential clinical trials may not necessarily be predictive of the results from Phase 1, Phase 2 or Phase 3 clinical trials. In addition, our interpretation of results derived from clinical data or our conclusions based on our preclinical data may prove inaccurate. Frequently, pharmaceutical and biotechnology companies have suffered significant setbacks in clinical trials after achieving positive results in preclinical testing and early clinical trials, and we cannot be certain that we will not face similar setbacks. These setbacks may be caused by the fact that preclinical and clinical data can be susceptible to varying interpretations and analyses. Furthermore, certain product candidates performed satisfactorily in preclinical studies and clinical trials, but nonetheless failed to obtain FDA approval or a marketing authorization granted by the European Commission. If we fail to produce positive results in our clinical trials for our product candidates, the development timeline and regulatory approval and commercialization prospects for them and as a result our business and financial prospects, would be materially adversely affected.

Clinical trials of cannabinoid-based product candidates are novel with very limited or non-existing history; we face a significant risk that the trials will not result in commercially viable products and treatments.

At present, there is only a very limited documented clinical trial history from which we can derive any scientific conclusions, or prove that our present assumptions for the current and planned research are scientifically compelling. While we are encouraged by the limited results of clinical trials by others, there can be no assurance that any clinical trial will result in commercially viable products or treatments.

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Clinical trials are expensive, time consuming and difficult to design and implement. We, as well as the regulatory authorities may suspend, delay or terminate our clinical trials at any time, may require us, for various reasons, to conduct additional clinical trials, or may require a particular clinical trial to continue for a longer duration than originally planned, including, among others:

- lack of effectiveness of any formulation or delivery system during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- delays in obtaining regulatory authorization to commence a trial, including IRB approvals, licenses required for obtaining and using cannabis for research, either before or after a trial is commenced;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- patients or investigators failing to comply with study protocols;
- patients failing to return for post-treatment follow-up at the expected rate;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or act in ways inconsistent with the established investigator agreement, clinical study protocol, good clinical practices, and other IRB requirements;
- third-party entities do not perform data collection and analysis in a timely or accurate manner or at all; or
- regulatory inspections of our clinical studies require us to undertake corrective action or suspend or terminate our clinical studies.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

Changes in consumer preferences and acceptance of cannabinoid-derived products and any negative trends will adversely affect our business.

We are substantially dependent on initial and continued market acceptance and proliferation of cannabinoid-derived therapeutic treatments. We believe that as cannabinoid-derived products become more widely accepted by the medical and scientific communities and the public at large, the stigma associated with cannabinoid-derived products and treatments will moderate and, as a result, consumer demand will likely continue to grow. However, we cannot predict the future growth rate and size of the market, assuming that the regulatory framework is favorable of which there can be no assurance. Any negative outlook on cannabinoid-derived products and treatments could adversely affect our business prospects.

In addition, while some may believe that large, well-funded pharmaceutical and other related businesses and industries may have material

economic reasons to be in strong opposition to cannabinoid-based products, we do not believe that it is accurate. Despite the fact that several large pharmaceutical companies are already marketing FDA approved cannabinoid-based or ECS targeting therapies, it remains relatively uncommon among the global pharmaceutical giants. The pharmaceutical industry is also well-funded with a strong and experienced lobby presence at both the federal and state levels as well as internationally, that surpasses financial resources of the current group of research and development companies working on product candidates that modulate the endocannabinoid system. Any effort the pharmaceutical lobby could or might undertake to halt or delay the development of cannabinoid-based products could have a detrimental impact on our business.

These pressures could also limit or restrict the introduction and marketing of any such cannabinoid-derived product. Adverse publicity regarding cannabis misuse or adverse side effects from cannabis or other cannabinoid-derived products may adversely affect the commercial success or marketability. The nature of our business attracts and may be expected to continue to attract a high level of public and media interest and, in the event of any related adverse publicity, we may not succeed in monetizing our products and treatments.

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Our product candidates may contain controlled substances, the use of which may generate public controversy.

Since our product candidates may contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our product candidates. These pressures could also limit or restrict the introduction and marketing of our product candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid-derived products may adversely affect the commercial success or market penetration achievable by our product candidates. The nature of our business will likely attract a high-level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed.

The FDA has only approved one plant-derived drug a safe and effective treatment for indications related to epilepsy in children.

To date, the FDA has approved one plant-derived cannabinoid product as safe and effective for indications related to epilepsy in children. The

FDA is aware that there is considerable interest in the use of cannabinoids to attempt to treat a number of medical conditions. Before conducting testing in humans in the U.S. of a drug that has not been approved by the FDA, we will need to submit an IND application to the FDA. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications (“NDAs”), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Laws and regulations affecting therapeutic uses of cannabinoids are constantly evolving.

The constant evolution of laws and regulations affecting the research and development of cannabinoid-based pharmaceutical products and treatments could detrimentally affect our business. Laws and regulations related to the therapeutic uses of cannabinoids are subject to changing interpretations. These changes may require us to incur substantial costs associated with legal and compliance fees and ultimately require us to alter our business plan. Furthermore, violations or alleged violation of these laws could disrupt our business and result in a material adverse effect on our operations. In addition, we cannot predict the nature of any future laws, regulations, interpretations or applications of laws and regulations and it is possible that new laws and regulations may be enacted in the future that will be directly applicable to our business.

Research activities in the cannabis-pharma crossover industry may make it difficult to obtain insurance coverage.

In the event that we decide to commence research based on plant-derived cannabinoids in the U.S., obtaining and maintaining necessary insurance coverage, for such things as workers compensation, general liability, product liability and directors and officers insurance, may be more difficult and/or expensive for us to find because of our research directions utilizing synthetic and plant-derived cannabinoids. There can be no assurance that we will be able to find such insurance, if needed, or that the cost of coverage will be affordable or cost-effective. If, either because of unavailability or cost prohibitive reasons, we are compelled to operate without insurance coverage, we may be prevented from entering certain business sectors, experience inhibited growth potential and/or expose us to additional risks and financial liabilities.

We face a potentially highly competitive market.

Demand for medical cannabinoid-derived products is dependent on a number of social, political and economic factors that are beyond our control. While we believe that demand for such products will continue to grow, there is no assurance that such increase in demand will happen, that we will benefit from any demand increase or that our business, in fact, will ever become profitable.

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The emerging markets for cannabinoid-derived products and medical research and development are and will likely remain competitive. The development and commercialization of products is highly competitive. We compete with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as products and processes being developed by universities and other research institutions. Many of our competitors have developed, are developing, or will develop products and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that may enter the market. For some of our product development directions, other treatment options are currently available, under development, and may become commercially available in the future. If any of our product candidates is approved for the diseases and conditions we are currently pursuing, they may compete with a range of therapeutic treatments that are either in development or currently marketed.

Changes in legislation or regulation in the health care systems in the United States and foreign jurisdictions may affect us.

Our ability to successfully commercialize our products may depend on how the U.S. and other governments and/or health administrations provide coverage and/or reimbursements for our products. The ongoing efforts of governments, insurance companies, and other participants in the health care services industry to trim health care costs may adversely affect our ability to achieve profitability.

In certain foreign markets, including countries in the European Union, pricing of prescription pharmaceuticals is subject to governmental control. Price negotiations with governmental authorities may range from 6 to 12 months or longer after the receipt of regulatory marketing approval for a product. Our business could be detrimentally impacted if reimbursement of our products is unavailable or limited if pricing is set at unacceptable levels.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in our highly competitive industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our only employee, our Chief Executive Officer, Chief Financial Officer, President, Treasurer and Secretary, Gregory D. Gorgas. The loss of the services of Mr. Gorgas, and our inability to find a suitable replacement could result in delays in research and development and product development and harm our business.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable service providers to remain at our Company, in addition to salary and cash incentives, we have issued stock options and

restricted stock awards that vest over time. The value to service providers of stock options and restricted stock awards that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have an employment agreement with our sole employee, this employment agreement provides for at-will employment, which means that Mr. Gorgas could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the life of Mr. Gorgas. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations.

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We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

To effect our business plan, we will need to rapidly add other management, accounting, regulatory, and scientific staff. We currently have only one employee. We will need to attract, retain and motivate a significant number of new additional managerial, operational, sales, marketing, financial, and other personnel, as well as highly skilled scientific and medical personnel, and to expand our capabilities to successfully pursue our research, development, manufacturing and commercialization efforts and secure collaborations to market and distribute our products. This growth may strain our existing managerial, operational, financial and other resources. We also intend to add personnel in our research and development and regulatory departments as we expand our clinical trial and research capabilities. Moreover, we will need to hire additional accounting and other personnel and

augment our infrastructure as we continue to grow the Company. Any inability to attract and retain qualified employees to enable our planned growth and establish additional capabilities or our failure to manage our growth effectively could delay or curtail our product development and commercialization efforts and harm our business.

We are currently reliant on consultants to oversee critical activities and perform services on behalf of the Company.

Due to our limited financial resources, we have engaged consultants to work on a part-time basis to oversee critical activities and perform services on behalf of the Company. Even if we are successful in raising additional capital and require those activities and services be performed by full-time employees, there is no guarantee that we will be able to hire our current consultants or consultants with similar background and experience to oversee those functions or perform services on behalf of the Company. We are also at risk that the consultants we use may not be able to perform services on a timely basis for us as opposed to other companies who may offer greater compensation or more opportunity than we do, and that those consultants may eventually decide to accept full-time employment with other companies, some of which could be a direct competitor to us.

We have incurred losses since inception and cannot assure that we will ever achieve or sustain profitability.

We have incurred losses since inception. We expect to continue to incur significant expenses and increasing operating and net losses for the foreseeable future. To date, we have financed our operations primarily through the sale of equity securities. Though we closed four equity offerings between July 2017 and January 2019 we continue to have very limited resources. To date our primary activities have been limited to, and our limited resources have been dedicated to, raising capital, non-clinical research on our programs, recruiting service providers, negotiating with business partners and licensors of intellectual property, filing patent applications, and complying with public reporting requirements.

We have never been profitable and do not expect to be profitable in the foreseeable future. We expect our expenses to increase significantly as we pursue our objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, and we expect to continue to incur significant expenses and operating losses over the next several years. Our prior and continuing losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. We cannot assure that we will ever be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, license additional programs, establish or maintain development efforts, obtain regulatory approvals or continue operations.

Our employee or consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by our employee or consultants could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions, including civil, criminal or administrative.

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We may not successfully manage our growth.

Our success will depend upon the effective management of our growth, which will place a significant strain on our management and on administrative, operational and financial resources. To manage this growth, we will be required to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. Our inability to manage this growth could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to our product candidates, and our ability to successfully commercialize any product candidates we may develop, and our science may be adversely affected.

As with our competitors, our ability to maintain and solidify a proprietary position for our product candidates will depend upon our success in obtaining effective patent claims that cover such product candidates, their manufacturing processes and their intended methods of use, and enforcing those claims once granted. Furthermore, in some cases, we may not be able to obtain issued claims covering our product candidates which are sufficient to prevent third parties, such as our competitors, from either utilizing our technology or designing around any patent claims to avoid infringing them. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, and results of operations.

Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. Additionally, we cannot predict whether the patent applications we or our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to file for or obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. If any licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised or even lost entirely. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be subject to challenges based on invalidity and/or unenforceability. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Patents also have a limited lifespan. In the United States, subject to certain extensions that may be obtained in some cases, the natural expiration of a utility patent is generally 20 years from its earliest effective filing date, and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced.

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Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the U.S. over the lifetime of our and our licensors' patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process and after patent issuance. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market in that jurisdiction with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship of inventions covered by our or our licensors' patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or rights or licenses to use, intellectual property that is important to our products. Even if we and our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, can be expensive or difficult to enforce, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar science or technology but that are not covered by the claims of the patents that we may own or license from our licensors or that incorporate certain research in our product candidates that is in the public domain;
- we, or our licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we or our licensors own now or in the future;
- we, or our licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our or our licensors' current or future pending patent applications will not lead to issued patents;
- issued patents that we or our licensors hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

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- our competitors or other third parties might conduct research and development activities in countries where we or our licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary product candidates that are patentable;
- the patents of others may harm our business if, for example, we or our licensors are found to have infringed those patents or if those patents serve as prior art to our or our licensors' patents which could potentially invalidate our or our licensors' patents; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property, which could ultimately result in public disclosure of the intellectual property if the third party's patent application is published or issues to a patent.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, and results of operations.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

There is a great deal of litigation concerning intellectual property in our industry, and we or our licensors could become involved in litigation. Even if resolved in our or our licensors' favor, litigation or other legal proceedings relating to intellectual property claims may cause us or our licensors to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct or defend against such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and ability to compete in the marketplace.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees and consultants were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATED TO OUR SECURITIES

Our executive officers and certain stockholders possess the majority of our voting power, and through this ownership, control the Company and our corporate actions.

Our current executive officers and certain large stockholders of the Company hold approximately 70.0% of the voting power of our outstanding shares. These officers and investors have a controlling influence in determining the outcome of any corporate transaction or other matters submitted to our stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets, election of directors, and other significant corporate actions. As such, our executive officers and these investors have the power to prevent or cause a change in control; therefore, without their consent we could be prevented from entering into transactions that could be beneficial to us. The interests of our executive officers may give rise to a conflict of interest with the Company and the Company's stockholders.

Shares of our common stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(i) which apply to a former “shell company.”

Our common stock is presently listed for trading on the OTC Market’s OTCQB service under the symbol “ARTL.” Our stock has limited trading volume and substantially all of our shares have been issued in unregistered offerings. Consequently, our securities will be subject to restrictions on transfer under the Securities Act and may not be transferred in the absence of registration or the availability of a resale exemption. In particular, in the absence of registration, such securities cannot be resold to the public until certain requirements under Rule 144 promulgated under the Securities Act have been satisfied, including certain holding period requirements and other requirements applicable to companies that have previously been a shell company. As a result, a purchaser of our securities may be unable to sell such securities at the time or at the price or upon such other terms and conditions as the purchaser desires, and the terms of such sale may be less favorable to the purchaser than might be obtainable because of a limited market, which may never develop.

Until December 2017, we were deemed a “shell company” under applicable SEC rules and regulations because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 promulgated under the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted (i) until at least 12 months have elapsed from the date on which our Current Report on Form 8-K reflecting our status as a non-shell company, was filed with the SEC; and (ii) unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months (or for such shorter period that we were required to file such reports and materials), other than Form 8-K reports. We are currently subject to the reporting rules under the Exchange Act, and after our fiscal year 2019 ends, we will not be subject to the reporting requirements under the Exchange Act unless we become listed on an exchange or we have a registration statement declared effective by the SEC in fiscal year 2020. Therefore, unless we register such shares of common stock for sale under the Securities Act, most of our stockholders will be forced to hold their shares of our common stock for at least that 12-month period before they are eligible to sell those shares, and even after that 12-month period, sales may not be made under Rule 144 unless we are in compliance with other requirements of Rule 144. Further, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend significant time and cash resources. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned). The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time than a non-former shell company could cause the market price of our securities to decline or make it difficult to establish a trading market in our shares.

Our common stock presently is listed for trading on the OTCQB which means you may not be able to resell shares of our common stock publicly, if at all, at times or prices you feel are fair and appropriate.

Our common stock presently is listed for trading on the OTC Market’s OTCQB service. A listing on the OTC Markets is generally understood to be a less active, and therefore less liquid, trading market than other types of markets such as a stock exchange. Compared to a listing on a stock exchange, a listing on the OTC Markets can be expected to have an adverse effect on the liquidity of our common stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts’ and the media’s coverage of us and our common stock. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock. In addition, we have had small trading volume in our common stock, which makes it difficult for our stockholders to sell their shares as and when they choose. Small trading volumes generally depress market prices. As a result, we believe that you may not be able to resell shares of our common stock publicly, if at all, at times or prices that you feel are fair or appropriate.

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Certain of the possible adjustments to the warrants may result in a deemed distribution from us to a beneficial owner of a warrant that will be taxable, even though the beneficial owner does not receive a corresponding distribution of cash.

The exercise terms of the warrants may be adjusted in certain circumstances. An adjustment to the number of shares of common stock that will be issued on the exercise of the warrants or an adjustment to the exercise price of the warrants (or, in certain circumstances, a failure to make adjustments) may be treated as a taxable deemed distribution to a holder of the warrants, even if such holder does not receive any cash or other property in connection with the adjustment. Holders of the warrants should consult their tax advisors regarding the proper treatment of any adjustments to the warrants.

Sales of our currently issued and outstanding stock may become freely tradable pursuant to Rule 144 and sales of such shares may have a depressive effect on the share price of our common stock.

Substantially all of the outstanding shares of common stock are “restricted securities” within the meaning of Rule 144. As restricted shares, these shares may be resold only pursuant to an effective registration statement or under the requirements of Rule 144 or other applicable exemptions from registration under the Securities Act and as required under applicable state securities laws. Rule 144 provides in essence that a non-affiliate who has held restricted securities for a period of at least six months may sell their shares of common stock. Under Rule 144, affiliates who have held restricted securities for a period of at least six months may, under certain conditions, sell every three months, in brokerage transactions, a number of shares that does not exceed the greater of 1% of a company’s outstanding shares of common stock or the average weekly trading volume during the four calendar weeks prior to the sale (the four-calendar week rule does not apply to companies quoted on the OTC Markets). A sale under Rule 144 or under any other exemption from the Securities Act, if available, or pursuant to subsequent registrations of our shares of common stock, may have a depressive effect upon the price of our shares of common stock in any active market that may develop.

“Penny Stock” rules may make buying or selling our securities difficult.

Trading in our securities is subject to the “penny stock” rules. The SEC has adopted regulations that generally define a penny stock to be any equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. These rules require that any broker-dealer that recommends our securities to persons other than prior customers and accredited investors, must, prior to the sale, make a special written suitability determination for the purchaser and receive the purchaser’s written agreement to execute the transaction. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated with trading in the penny stock market. In addition, broker-dealers must disclose commissions payable to both the broker-dealer and the registered representative and current quotations for the securities they offer. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit the market price and liquidity of our securities.

Our securities may be considered a “penny stock,” and thereby be subject to additional sale and trading regulations that may make it more difficult to sell.

The SEC, has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTCQB does not meet such requirements and if the price of our securities is less than \$5.00, our securities will be deemed penny stock. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser’s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement

to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our securities, and therefore stock holders may have difficulty selling their shares.

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We do not know whether an active, liquid and orderly trading market will develop for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of our securities.

There is a limited public market for shares of our securities. An active trading market for our shares may never develop or be sustained in the future. You may not be able to sell your shares quickly or at the market price if trading in shares of our securities is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our securities and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our securities as consideration, which could have a material adverse effect on our business, financial condition, and results of operations.

We do not plan to declare or pay any dividends to our stockholders in the near future.

We have not declared any dividends in the past, and we do not intend to distribute dividends in the near future. The declaration, payment and amount of any future dividends will be made at the discretion of our Board and will depend upon, among other things, the results of operations, cash flows and financial condition, operating and capital requirements, and other factors as our Board considers relevant. There is no assurance that future dividends will be paid, and if dividends are paid, there is no assurance with respect to the amount of any such dividend.

We incur significant costs as a result of operating as a public company and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, (“the Exchange Act”), which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and we will have until our fiscal year ending August 2020 to do so. We intend to continue to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than anticipated or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

Future changes in financial accounting standards or practices may cause adverse unexpected financial reporting fluctuations and affect reported results of operations.

A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct business.

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Our disclosure controls and procedures may not be effective to ensure that we make all required disclosures.

As a public reporting company, we are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Anti-takeover provisions in our amended and restated articles of incorporation and bylaws, as well as provisions in Nevada law, might discourage, delay or prevent a change of control of our company or changes in our management and, therefore, depress the trading price of our securities.

Our amended and restated articles of incorporation, bylaws and Nevada law contain provisions that could have the effect of rendering more difficult or discouraging an acquisition deemed undesirable by our Board. Our corporate governance documents include provisions:

- providing for a single class of directors where each member of the board shall serve for a one year term and may be elected to successive terms;
- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors, including provisions that require the company to advance payment for defending pending or threatened claims;
- limiting the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board;
- controlling the procedures for the conduct and scheduling of board and stockholder meetings;
- limiting the determination of the number of directors on our board and the filling of vacancies or newly created seats on the board to our Board then in office; and

· providing that directors may be removed by stockholders at any time.

These provisions, alone or together, could delay hostile takeovers and changes in control or changes in our management.

As a Nevada corporation, we are also subject to provisions of Nevada corporate law, including Section 78.411, et seq. of the Nevada Revised Statutes, which prohibits a publicly-held Nevada corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last two years has owned, 10% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that our stockholders could receive a premium for their common stock in an acquisition.

Our stock price may be volatile, which may result in losses to our stockholders.

The stock markets have experienced significant price and trading volume fluctuations, and the market prices of companies listed on the OTC Markets quotation system in which shares of our common stock have been listed, have been volatile in the past and have experienced sharp share price and trading volume changes. The trading price of our securities could be volatile and could fluctuate widely in response to many factors, including the

following, some of which are beyond our control:

- variations in our operating results;
- changes in expectations of our future financial performance, including financial estimates by securities analysts and investors;
- changes in operating and stock price performance of other companies in our industry;
- additions or departures of key personnel; and
- future sales of our securities.

Domestic and international stock markets often experience significant price and volume fluctuations. These fluctuations, as well as general economic and political conditions unrelated to our performance, may adversely affect the price of our securities.

Our business is subject to changing regulations related to corporate governance and public disclosure that have increased both our costs and the risk of noncompliance.

Because our common stock is publicly traded, we are subject to certain rules and regulations of federal, state and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the Public Company Accounting Oversight Board, the SEC and FINRA, have issued requirements and regulations and continue to develop additional regulations and requirements in response to corporate scandals and laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. Our efforts to comply with these regulations have resulted in, and are likely to continue resulting in, increased general and administrative expenses and diversion of management time and attention from revenue-generating activities to compliance activities. Because new and modified laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our securities less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until our fiscal year ending August 2020, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) August 2020, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities, and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We will incur significantly increased costs and devote substantial management time after we are no longer an “emerging growth company.”

After we no longer qualify as an “emerging growth company,” as defined under the JOBS ACT we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs to do so.

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

During the three months ended February 28, 2019, the Company recorded \$1,087,102 for 1,449,469 units at a price of \$0.75 per unit (a “Series D Unit”) pursuant to the Company’s Series D Offering. Each Series D Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series D Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$1.75 per share for a period of 5 years from the issue date.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit Number	Description
10.1+	First Amendment to Material and Data Transfer, Option and License Agreement by and between the Company and NEOMED Institute dated January 4, 2019.
(31)	Rule 13a-14 (d)/15d-14d) Certifications
31.1*	Section 302 Certification by the Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer
(32)	Section 1350 Certifications
32.1*	Section 906 Certification by the Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer
101	Interactive Data File
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith

** Furnished herewith. XBRL (eXtensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

+ Certain portions of this exhibit have been omitted.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ARTELO BIOSCIENCES, INC.

(Registrant)

Dated: April 15, 2019

/s/ Gregory D. Gorgas

Gregory D. Gorgas

President, Chief Executive Officer, Chief Financial
Officer, Treasurer and Director
(Principal Executive Officer, Principal Financial
Officer and Principal Accounting Officer)

CONFIDENTIAL TREATMENT REQUESTED

CERTAIN CONFIDENTIAL PORTIONS OF THIS DOCUMENT HAVE BEEN REDACTED BECAUSE THEY ARE BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. INFORMATION THAT WAS OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK “[***]”.

FIRST AMENDMENT TO MATERIAL AND DATA TRANSFER, OPTION AND LICENSE AGREEMENT

THIS FIRST AMENDMENT TO MATERIAL AND DATA TRANSFER, OPTION AND LICENSE AGREEMENT (this “**Amendment**”) is made and entered as of January 4, 2019 (“**Amendment Effective Date**”), by and between NEOMED Institute, a not-for-profit corporation established under the *Not-for-Profit Corporations Act* (Canada), having an address at 7171 Frederick-Banting, Saint-Laurent, Quebec H4S 1Z9, Canada (“**NEOMED**”), and Artelo Biosciences, Inc., a Nevada corporation, having an address at 888 Prospect Street, Suite 210, La Jolla, California 92037, U.S.A. (“**Artelo**”).

WHEREAS, NEOMED and Artelo are parties to that certain Material and Data Transfer, Option and License Agreement dated as of December 20, 2017 (the “**Agreement**”); and

WHEREAS, NEOMED and Artelo wish to amend the Agreement to take into account, among such other changes set forth below, the additional cash and equity consideration to be paid by Artelo in partial consideration for the waiver by NEOMED of the payment of the amount of One Hundred Thousand Dollars (US\$100,000) in cash that was due NEOMED on October 1, 2018 under the Agreement. All capitalized terms used in this Amendment which are not otherwise defined herein shall have the same meanings as set forth in the Agreement.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual covenants and promises contained in this Amendment and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, NEOMED and Artelo agree as follows:

1. Amendments to the Agreement.

a. Section 3.1 of the Agreement is hereby amended and restated to read in its entirety as follows:

“3.1 Option Grant. For a period commencing on the Effective Date and subject to early termination, ending on [***] (“**Option Period**”), Artelo shall have the sole and exclusive right, but not the obligation to receive an exclusive license under the Licensed IP Rights to research, develop, make, have made, use, offer for sale, sell, have sold and import Products and otherwise exploit the Licensed IP Rights in the Territory in the Field, subject to the terms and conditions of this Agreement (the “**Option**”). During the Option Period, NEOMED shall not, without Artelo’s prior written consent, directly or indirectly: (i) negotiate or enter into any agreement, arrangement or commitment according to which a Third Party is granted any right in the Territory under the Licensed IP Rights, (ii) take any action which may derogate from or conflict with, or refrain from taking any action which is necessary to preserve, the Option, or (iii) enter into any agreement, arrangement or commitment that would derogate from or conflict with the rights granted to Artelo under this Agreement.”

[***] Certain information in this document has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

b. Section 5.1.1 of the Agreement is hereby amended and restated to read in its entirety as follows:

“5.1.1 Equity Grant. As partial consideration for the grant of the Option by NEOMED to Artelo and the supply of the Technology Transfer Materials, Artelo shall grant NEOMED (a) on the Effective Date, 120,000 fully paid and non-assessable shares of Artelo’s common stock subject to Artelo and NEOMED then executing a Common Stock Purchase Agreement in substantially the form attached hereto as Exhibit D (the “**Purchase Agreement**”), and (b) (i) within ten (10) business days following the consummation of a public offering of Artelo’s common stock prior to April 25, 2019, that number of fully paid non-assessable shares of Artelo’s common stock equal to One Hundred Thousand Dollars (US\$100,000) divided by the price per share of common stock in such public offering, or (ii) if Artelo has not consummated a public offering of its common stock prior to April 25, 2019, then within ten (10) business days

following April 25, 2019, that number of fully paid non-assessable shares of Artelo's common stock equal to One Hundred Thousand Dollars (US\$ 100,000) divided by the closing bid price of Artelo's common stock as shown on the OTCQB Venture Market as of April 25, 2019, subject to in each case, as applicable, Artelo and NEOMED then executing a Common Stock Purchase Agreement in substantially the form attached hereto as Exhibit F (the "**Second Purchase Agreement**"). To the extent of any conflict between the terms of this Section 5.1.1 and the Purchase Agreement or the Second Purchase Agreement, the terms and conditions of the Purchase Agreement or the Second Purchase Agreement, as applicable, shall control and be determinative."

c. Section 5.1.2 of the Agreement is hereby amended and restated to read in its entirety as follows:

"5.1.2 Cash Consideration. As partial consideration for the grant of the Option by NEOMED to Artelo and the supply of the Technology Transfer Materials, Artelo shall make the following payments to NEOMED: (a) [***] due on the Effective Date, (b) [***], and (c) [***]; provided that if any of the foregoing payments have not accrued and become due prior to the earlier to occur of (i) the exercise of the Option by Artelo, and (ii) termination of this Agreement by Artelo pursuant to Section 12.2 hereof, then Artelo's payment obligations with respect to such payments that have not accrued and become due shall be extinguished and become null and void."

d. A new Section 5.1.3 is added to the Agreement as follows:

"5.1.3 Additional Cash Consideration. As partial consideration for the grant of the Option by NEOMED to Artelo and the supply of the Technology Transfer Materials, Artelo shall make an investment of no less than [***], which shall be used by Artelo exclusively for the synthesis of the Compound to be used for clinical studies.

e. The Second Purchase Agreement attached to this Amendment is hereby added to the Agreement as Exhibit F.

[***] Certain information in this document has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

2. No Other Modifications. Except as specifically provided in this Amendment, the terms and conditions of the Agreement remain in full force and effect. No provisions of this Amendment may be modified or amended except expressly in a writing signed by both parties, nor shall any terms be waived except expressly in a writing signed by the Party charged therewith.

3. Counterparts. This Amendment may be executed in any number of counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

[Signature Page Follows.]

***] Certain information in this document has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Amendment as of the Amendment Effective Date.

NEOMED INSTITUTE

By /s/ Donald Olds

Donald Olds, President & CEO

ARTELO BIOSCIENCES, INC.

By /s/ Gregory D. Gorgas
Gregory D. Gorgas, President & CEO

[Signature Page to First Amendment to Material and Data Transfer, Option and License Agreement]

***] Certain information in this document has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Greg Gorgas, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Artelo Biosciences, 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. I am 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;
5. I have disclosed, based on my 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: April 15, 2019

/s/ Gregory D. Gorgas

Gregory D. Gorgas
President, Chief Executive Officer, Chief Financial
Officer,
Treasurer and Director
(Principal Executive Officer, Principal Financial
Officer and Principal Accounting Officer)

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

The undersigned, Greg Gorgas, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the quarterly report on Form 10-Q of Artelo Biosciences, Inc. for the period ended February 28, 2019 (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 Artelo Biosciences, Inc.

Dated: April 15, 2019

/s/ Gregory D. Gorgas

Gregory D. Gorgas
President, Chief Executive Officer, Chief Financial
Officer,
Treasurer and Director
(Principal Executive Officer, Principal Financial
Officer
and Principal Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Artelo Biosciences, Inc. and will be retained by Artelo Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.