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: **March 31, 2022**

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: **001-38951**

ARTELO BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Nevada	**33-1220924**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
505 Lomas Santa Fe, Suite 160, Solana Beach, CA USA	**92075**
(Address of principal executive offices)	(Zip Code)

(858) 925-7049
(Registrant's telephone number, including area code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ARTL**	**The Nasdaq Stock Market, LLC**
Warrants	**ARTLW**	**The Nasdaq Stock Market, LLC**

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated Filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

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

42,301,013 shares of common stock issued and outstanding as of May 10, 2022.

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ARTELO BIOSCIENCES, INC.
Consolidated Balance Sheets
(In thousands, except share data)

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current Assets		
Cash and cash equivalents	$ 10,350	$ 12,162
Trading marketable securities	11,162	11,951
Available-for-sale securities (amortized cost of $2,023 and $0, respectively)	1,999	-
Prepaid expenses and other current assets	1,078	496
Total Current Assets	24,589	24,609
Intangible asset	2,039	2,039
Available-for-sale securities (amortized cost of $0 and $1,524, respectively)	-	1,519
Operating lease right-of-use asset	73	81
Prepaid expenses and deposit	3	3
TOTAL ASSETS	$ 26,704	$ 28,251
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and accrued liabilities	$ 800	$ 975
Due to related parties	43	21
Operating lease liability - current portion	32	31
Total Current Liabilities	875	1,027
Operating lease liability	49	57
TOTAL LIABILITIES	924	1,084
STOCKHOLDERS' EQUITY		
Preferred Stock, par value $0.001, 6,250,000 shares authorized, 0 shares issued and outstanding	-	-
Common Stock, par value $0.001, 750,000,000 shares authorized, 42,301,013 shares issued and outstanding, respectively	42	42
Additional paid-in capital	48,705	48,081
Accumulated deficit	(22,903)	(20,938)
Accumulated other comprehensive loss	(64)	(18)
Total Stockholders' Equity	25,780	27,167
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 26,704	$ 28,251

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

ARTELO BIOSCIENCES, INC.
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share data)

	Three months ended March 31,	
	2022	**2021**
OPERATING EXPENSES		
General and administrative	$ 1,482	$ 1,389
Research and development	464	307
Total Operating Expenses	1,946	1,696
Loss from Operations	(1,946)	(1,696)
OTHER INCOME (EXPENSE)		
Interest income	1	-
Net change in fair value of marketable securities	(20)	1
Total other (expense) income	(19)	1
Provision for income taxes	-	-
NET LOSS	$ (1,965)	$ (1,695)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized loss of available-for-sale securities	(22)	-
Foreign currency translation adjustments	(24)	2
Total Other Comprehensive Income (Loss)	(46)	2
TOTAL COMPREHENSIVE LOSS	$ (2,011)	$ (1,693)
Basic and Diluted Loss per Common Share	$ (0.05)	$ (0.09)
Basic and Diluted Weighted Average Common Shares Outstanding	42,301	19,688

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

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

	Common stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Loss	Total
Balance, December 31, 2021	42,301	$ 42	$ 48,081	$ (20,938)	$ (18)	$ 27,167
Stock based compensation	-	-	624	-	-	624
Net loss for the period	-	-	-	(1,965)	-	(1,965)
Other comprehensive loss	-	-	-	-	(46)	(46)
Balance, March 31, 2022	42,301	$ 42	$ 48,705	$ (22,903)	$ (64)	$ 25,780

	Common stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Deficit	Income	Total
Balance, December 31, 2020	15,111	$ 15	$ 19,910	$ (11,531)	$ 41	$ 8,435
Common shares issued for cash, net of share issuance costs	8,022	8	6,008	-	-	6,016
Common shares issued for services - officers	-	-	11	-	-	11
Stock based compensation	-	-	519	-	-	519
Net loss for the period	-	-	-	(1,695)	-	(1,695)
Other comprehensive income	-	-	-	-	2	2
Balance, March 31, 2021	23,133	$ 23	$ 26,448	$ (13,226)	$ 43	$ 13,288

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

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

	Three months ended March 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (1,965)	$ (1,695)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	624	530
Net change in fair value of marketable securities	20	(1)
Non-cash lease expense	7	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(594)	58
Accounts payable and accrued liabilities	(160)	(634)
Accounts payable - related party	23	-
Fixed cash payments related to operating lease	(8)	-
Net cash used in operating activities	(2,053)	(1,742)
CASH FLOWS FROM INVESTING ACTIVITIES		
Investment in trading marketable securities	(1,947)	(2,044)
Investment in available-for-sale securities	(499)	-
Proceeds from disposition of marketable securities	2,703	-
Net cash provided by (used in) investing activities	257	(2,044)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of warrants	-	6,016
Repayments to related parties	-	(7)
Net cash provided by financing activities	-	6,009
Effect of exchange rate changes on cash	(16)	7
Net change in cash and cash equivalents	(1,812)	2,230
Cash and cash equivalents - beginning of period	12,162	5,783
Cash and cash equivalents - end of period	$ 10,350	$ 8,013
Supplemental Cash Flow Information		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
Non-cash financing and investing activities		
Unrealized loss from available-for-sale securities	$ (22)	$ -

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

ARTELO BIOSCIENCES, INC.
Notes to the Unaudited Consolidated Financial Statements
March 31, 2022
(In thousands, except share and per share data)

NOTE 1 - ORGANIZATION AND DESCRIPTION OF BUSINESS

ARTELO BIOSCIENCES, INC. ("we", "us", "our", the "Company") is a Nevada corporation incorporated on May 2, 2011, and 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 December 31.

The Company registered wholly-owned subsidiaries in Ireland, Trinity Reliant Ventures Limited, on November 11, 2016, and in the UK, Trinity Research & Development Limited, on June 2, 2017. On January 8, 2020, Trinity Research and Development Limited changed its name to Artelo Biosciences Limited. The Company incorporated a wholly-owned subsidiary in Canada, Artelo Biosciences Corporation, on March 18, 2020. Operations in the subsidiaries have been consolidated in the financial statements.

The Company is a clinical stage biopharmaceutical company focused on the development of therapeutics that target lipid-signaling pathways, including the endocannabinoid system (the "ECS"), a family of receptors and neurotransmitters that form a biochemical communication network throughout the body.

COVID-19

As the COVID-19 pandemic is still evolving at this time and much of its impact remains unknown, the Company is not able to predict the impact it may have on the development of its product candidates and business. The severity of the COVID-19 pandemic could also negatively impact the Company's access to its existing supply chain by delaying the delivery of key raw materials used in its product candidates and therefore delay the delivery of such products for use in its clinical trials. Any of these results could have a material adverse impact to our business.

Liquidity

The Company has incurred losses since inception and a net loss of $1,965 during the three months ended March 31, 2022. However, in November 2021, we completed an equity offering which generated net proceeds of $18,262. Consequently, our existing cash resources and the cash received from the equity offering are expected to provide sufficient funds to carry out our planned operations into the second half of 2023.

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 ("SEC") and GAAP in the United States of America. The accompanying interim financial statements have been prepared in accordance with GAAP 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 three months ended March 31, 2022, 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 four-month transition period ended December 31, 2021, contained in the Company's Form 10-KT filed on March 21, 2022.

Basis of Consolidation

The financial statements have been prepared on a consolidated basis, with the Company's wholly-owned subsidiaries, Trinity Reliant Ventures Limited, Artelo Biosciences Limited and Artelo Biosciences Corporation. All intercompany transactions and balances have been eliminated.

Net Loss per Share of Common Stock

Basic (loss) earnings per share ("EPS") is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted EPS is computed based on the weighted average number of shares of common stock plus the effect of dilutive potential common shares outstanding during the period using the treasury stock method and as if converted method. Dilutive potential common shares include outstanding stock options and warrants.

For the three months ended March 31, 2022, and 2021, respectively, the following common stock equivalents were excluded from the computation of diluted net loss per share as the result was anti-dilutive.

	March 31, 2022	March 31, 2021
Stock options	4,751,332	2,966,934
Warrants	4,433,412	4,433,412
	9,184,744	7,400,346

Cash and Cash Equivalents

Cash and cash equivalents include cash in banks, money market funds, commercial paper, and certificates of term deposits with maturities of less than three months from inception, which are readily convertible to known amounts of cash and which, in the opinion of management, are subject to an insignificant risk of loss in value. The Company had $10,350 and $12,162 in cash and cash equivalents at March 31, 2022 and December 31, 2021, respectively.

Periodically, the Company may carry cash balances at financial institutions more than the federally insured limit of $250 per institution. The amount in excess of the FDIC insurance as of March 31, 2022, was approximately $9,850. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

Marketable Securities

Our investments in debt securities are carried at fair value. Investments in debt securities that are not classified as held-to-maturity are carried at fair value and classified as either trading or available-for-sale. Realized and unrealized gains and losses on trading debt securities are charged to income and unrealized gains and losses on available-for-sale debt securities are included in other comprehensive income. The marketable securities held by the Company, classified as trading securities, had an outstanding balance of $11,162 and $11,951 as of March 31, 2022, and December 31, 2021, respectively. The Company's holdings in US Treasury instruments, classified as available-for-sale investments had an outstanding balance of $1,999 and $1,519 as of March 31, 2022, and December 31, 2021, respectively.

Financial Instruments

The Company follows ASC 820, "Fair Value Measurements and Disclosures", which defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

Level 1

Level 1 applies to assets or liabilities for which there are quoted prices in active markets for identical assets or liabilities.

Level 2

Level 2 applies to assets or liabilities for which there are inputs other than quoted prices that are observable for the asset or liability such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical assets or liabilities in markets with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which significant inputs are observable or can be derived principally from, or corroborated by, observable market data.

Level 3

Level 3 applies to assets or liabilities for which there are unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of the assets or liabilities.

The carrying amounts of the Company's financial instruments including cash and cash equivalents and accounts payable approximate fair value due to the short-term maturities of these instruments.

Set out below are the Company's financial instruments that are required to be remeasured at fair value on a recurring basis and their fair value hierarchy as of March 31, 2022, and December 31, 2021:

	March 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Marketable securities – trading securities				
Commercial paper	$ -	$ 10,409	$ -	$ 10,409
Asset-backed securities	-	753	-	753
	-	11,162	-	11,162
Available-for sale securities				
US Treasury	-	1,999	-	1,999
	-	1,999	-	1,999
	$ -	$ 13,161	$ -	$ 13,161

	December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Marketable securities – trading securities				
Commercial paper	$ -	$ 10,486	$ -	$ 10,486
Asset-backed securities	-	1,165	-	1,165
Corporate debt securities	-	300	-	300
	-	11,951	-	11,951
Available-for sale securities				
US Treasury	-	1,519	-	1,519
	-	1,519	-	1,519
	-	13,470	-	13,470

NOTE 3 - RELATED PARTY TRANSACTIONS

During the three months ended March 31, 2022, a company owned by the Senior Vice President, European Operations, provided consulting services totaling $9, of which $3 and $5 was outstanding, as of March 31, 2022, and December 31, 2021, respectively.

During the three months ended March 31, 2022, a company significantly influenced by a director of a subsidiary of the Company provided professional services totaling $22, of which $12 and $11 was outstanding as of March 31, 2022, and December 31, 2021, respectively.

During the three months ended March 31, 2022, a company controlled by a director of a subsidiary of the Company provided professional services totaling $23, of which $20 and $5 was outstanding as of March 31, 2022, and December 31, 2021, respectively.

NOTE 4 – INTANGIBLE ASSET

The Company has capitalized the costs associated with acquiring the exclusive worldwide license to develop and commercialize products comprising or containing the proprietary therapeutic compound ART27.13, formerly known as NEO1940 as an intangible asset at a value of $2,039 as of March 31, 2022, and December 31, 2021.

The amount capitalized consisted of a $1,500 payment and the fair value of 61,297 shares of common stock of $539. During the three months ended March 31, 2022, no additional costs met the criteria for capitalization as an intangible asset.

NOTE 5 - EQUITY

Preferred shares

The Company has authorized 6,250,000 shares of preferred stock with a par value of $0.001 per share.

During the three months ended March 31, 2022, there were no issuances of preferred stock.

Common Shares

The Company has authorized 750,000,000 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.

Warrants

A summary of activity during the three months ended March 31, 2022, follows:

	Number of shares	Weighted Average Exercise Price	Weighted Average Life (years)
Outstanding, December 31, 2021	4,433,412	$ 4.63	2.83
Forfeited	-	-	-
Exercised	-	-	-
Outstanding, March 31, 2022	4,433,412	$ 4.63	2.58

The intrinsic value of the warrants as of March 31, 2022, is $0. All of the outstanding warrants are exercisable as of March 31, 2022.

Stock Options

Amended and Restated 2018 Equity Incentive Plan

On February 15, 2022, 257,652 shares of common stock were returned to the option pool and on February 18, 2022, the number of shares of Common Stock reserved for issuance under the 2018 Plan increased by 2,115,051 shares to a total of 4,586,554 shares available to be issued.

During the three months ended March 31, 2022, the Company recognized stock-based compensation expense of $624, of which $563 was for related parties, and as of March 31, 2022, $3,564 remains unamortized, of which $2,853 is for related parties. The intrinsic value of the 4,751,332 options outstanding as of March 31, 2022, is $0.

The following is a summary of stock option activity during the three months ended March 31, 2022:

	Options Outstanding		Weighted Average Remaining life (years)
	Number of Options	Weighted Average Exercise Price	
Outstanding, December 31, 2021	5,008,984	$ 1.63	9.36
Granted	-	-	-
Exercised	-	-	-
Forfeited/canceled	(257,652)	1.29	9.54
Outstanding, March 31, 2022	4,751,332	$ 1.65	9.10
Exercisable options, March 31, 2022	1,279,584	$ 2.68	8.46

NOTE 6 – COMMITMENTS AND CONTINGENCIES

The Company has certain financial commitments relating to research and development contracts as of March 31, 2022, as follows:

- The Company is invoiced monthly and quarterly in connection with 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.
- The Company's principal executive office is currently located at 505 Lomas Santa Fe Drive, Suite 160, Solana Beach, CA, US. Additionally, we have offices in Dublin, Ireland and outside Manchester, UK, which serve as administrative spaces for managing our subsidiaries Trinity Reliant Ventures, Ltd (Ireland) and Artelo Biosciences Limited (UK). We do not currently own any properties, laboratories, or manufacturing facilities. All leases for our office space, other than for the principal executive office, are month-to-month.

NOTE 7 - LEASE

On May 12, 2021, the Company entered into a lease arrangement for office space with Beckman/Lomas LLC, an entity controlled by a close family member of a director.

The following summarizes the right-of use asset and lease information about the Company's operating lease as of March 31, 2022:

	Three months ended March 31, 2022
Lease cost:	
Operating lease cost	$ 7
Other information:	
Cash paid for operating cash flows from operating leases	$ 8
Right-of-use assets obtained in exchange for new operating lease liability	$ -
Weighted-average remaining lease term — operating leases (year)	2.42
Weighted-average discount rate — operating leases	3.00%

Future minimum lease payments under the operating lease liability has non-cancelable lease payments at March 31, 2022 as follows:

	Total
Year Ended December 31,	
Remaining 9 months of 2022	25
2023	34
2024	24
Thereafter	-
	83
Less: Imputed interest	(2)
Operating lease liabilities	81
Operating lease liability - current	32
Operating lease liability - non-current	$ 49

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements in the sections captioned "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business," and elsewhere contain forward-looking statements. In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these terms.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our plans to obtain funding for our operations, including funding necessary to develop, manufacture and commercialize our product candidates;
- the ability of any current and future funding to meet our capital requirements;
- the expected timing of the initiation and completion of our clinical studies;
- the size and growth of the markets for our product candidates;
- our commercialization, marketing, and manufacturing capabilities and strategies;
- any impact of the global COVID-19 pandemic, or responses to the pandemic, on our business, clinical trials or personnel;
- our ability to compete with companies currently producing alternative treatment methods;
- the cost, timing and outcomes of any potential litigation involving our product candidates;
- regulatory developments in the US and in non-US countries;
- the development, regulatory approval, efficacy and commercialization of competing product candidates;
- our ability to retain key scientific or management personnel;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and technology;
- the terms and conditions of licenses granted to us and our ability to license additional intellectual property related to our product candidates, as appropriate;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- potential claims related to our intellectual property;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to regain compliance with applicable stock exchange listing requirements;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our ability to develop innovative new product candidates; and
- our financial performance.

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in Part II, Item 1A. "Risk Factors" of this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Quarterly Report on Form 10-Q. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, statements such as "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this filing, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

Our unaudited financial statements are stated in United States Dollars ("USD") and are prepared in accordance with 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 USD 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, Artelo Biosciences Limited, in England and Wales, and Artelo Biosciences Corporation, in Canada, unless otherwise indicated.

General Overview

We incorporated in the State of Nevada on May 2, 2011, and are presently based in San Diego County, California. We are a clinical stage biopharmaceutical company focused on the development of therapeutics that target lipid-signaling pathways, including the endocannabinoid system (the "ECS"), a family of receptors and neurotransmitters that form a biochemical communication network throughout the body. Our board of directors and management team are highly experienced and have a successful history of development, obtaining required regulatory approval and commercialization of pharmaceuticals.

Our product candidate pipeline broadly leverages leading scientific methodologies, balances risk across mechanism of action and stages of development. Our programs represent a comprehensive approach in utilizing the power and promise of lipid signaling to develop pharmaceuticals for patients with unmet healthcare needs. We are currently developing a cannabinoid agonist G protein-coupled receptor ("GPCR") targeting synthetic small molecule program, ART27.13, as a potential treatment for anorexia associated with cancer in a Phase 1b/2a trial, designated CAReS (Cancer Appetite Recovery Study). Our second program, ART26.12 is a small molecule platform of inhibitors of fatty acid binding proteins, notably Fatty Acid Binding Protein 5 ("FABP5"), being studied both a cancer therapeutic, for pain and inflammation, and in anxiety-related disorders, including post-traumatic stress disorder. In addition, we are also developing ART12.11 ("CBD cocrystal"), our patented solid-state composition of cannabidiol ("CBD"). The COVID-19 pandemic has created uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as us, and because of such uncertainties, we are unable to predict our expected timelines with any degree of certainty at this time.

We are currently developing two patent protected product candidates that we obtained through our in-licensing activities. Our first program, ART27.13, is being developed for cancer-related anorexia. ART27.13 and is a peripherally-restricted high-potency dual CB_1 and CB_2 receptor full-receptor agonist, which was originally invented at AstraZeneca plc ("AstraZeneca"). We exercised our option to exclusively license this product candidate through the NEOMED Institute ("NEOMED"), a Canadian not-for-profit corporation, renamed adMare in June 2019. In Phase 1, single dose studies in healthy volunteers and a multiple ascending dose study in individuals with chronic low back pain conducted by AstraZeneca, ART27.13 exhibited an attractive pharmacokinetic and absorption, distribution, metabolism, and excretion 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 central nervous system ("CNS") side effects. Discussions with UK, US and Canadian regulators indicate 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 commenced enrollment and dosed the first patient in CAReS, our Phase 1b/2a clinical study of cancer-related anorexia with ART27.13 in April 2021. We have been enrolling patients steadily since that time. The results of the Phase 1 stage are intended to determine the most effective and safe dose recommended for the Phase 2 portion of CAReS. We expect patient enrollment will be completed for the planned three dosing cohorts of Phase 1 in the first half of 2022 and we plan to announce results immediately after the data is verified. Depending on the results, we may elect to enroll an optional fourth cohort of six patients at a higher dose before making a determination as to which dose is selected for the Phase 2 stage of CAReS. We experienced minor delays due to COVID-19; however, we do not foresee significant impacts, but we are aware the situation could change and we are working to mitigate any adverse effects that may materialize due to the pandemic or its aftermath.

Our second in-licensed program is a platform of small-molecule inhibitors of fatty acid binding proteins, notably FABP5 acquired from Stony Brook University ("SBU"), which we have designated ART26.12. To date, SBU has received approximately $8.0 million in funding from the National Institutes of Health to develop these candidates including a $4.2 million grant in 2020 to advance research of FABP5 inhibition in prostate cancer. Fatty acid binding proteins ("FABPs") are attractive therapeutic targets, however, the high degree of sequence and structural similarities among family members have made the creation of drugs targeting specific FABPs challenging. 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, researchers at SBU discovered the chemistry for creating what we believe to be highly specific and potent small molecule inhibitors of FABP5. In addition to its potential as a synthetic endocannabinoid modulator, FABP5 plays an important role in lipid signaling and is believed to be an attractive target for cancer drug development. Large amounts of human biomarker and animal model data support FABP5 as an oncology target, including triple negative breast cancer and castration-resistant prostate cancer. We licensed exclusive world-wide rights to these inhibitors from SBU in all fields. Through our sponsored research we have subsequently identified a potential role for FABP5 inhibition to treat anxiety disorders, such as Post Traumatic Stress Disorder ("PTSD"), and have filed a patent with method claims covering the use in psychological disorders. We have also been awarded a research grant in Canada to expand on our earlier research at the University of Western Ontario in this new development area. While anxiety, pain, and inflammation are in early research stage, the potential use in treating cancer is our current focus. The program is in the beginning stages of regulatory-enabling studies. We anticipate clinical studies in cancer could begin in early 2023 depending, in part, on the ongoing impact of the COVID-19 pandemic and the ability of selected contract research organizations to perform required studies. The COVID-19 global pandemic has created uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as us, and because of such uncertainties, we are unable to accurately predict our expected timelines at this time.

In addition to our in-licensed programs, we have internal discovery research initiatives which resulted in ART12.11, a proprietary cocrystal composition of CBD. The crystal structure of CBD is known to exhibit solid polymorphism, or the ability to manifest in different forms. Polymorphism can adversely affect stability, dissolution, and bioavailability of a drug product and thus may affect its quality, safety, and efficacy. Based upon our research, we believe our cocrystal exists as a single crystal form and as such is anticipated to have advantages over other solid 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 and improved bioavailability and may lead to improved safety and efficacy.

Presently, we have one U.S. patent, one US patent application, and two foreign patent applications directed to our cocrystal composition of CBD. Composition claims are generally known in the pharmaceutical industry as the most desired type of intellectual property and should provide for long lasting market exclusivity for our synthetic CBD cocrystal drug product candidate. In addition, due to the reasons outlined above, we believe that our synthetic CBD cocrystal will have superior pharmaceutical properties compared to non-cocrystal CBD products under development at other competing companies to treat cancer, Inflammatory Bowel Disease ("IBD"), PTSD, and other potential indications.

We are developing our product candidates in accordance with traditional drug development standards and expect to make them available to patients via prescription or physician orders only after obtaining marketing authorization from a regulatory authority, such as the US 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.

Product Candidate Pipeline:

Product Candidate	**Target Indications**	**Development Phase**	**Market Size**
ART27.13 – Synthetic Cannabinoid Agonist	Anorexia associated with cancer	Clinical	Cancer anorexia cachexia syndrome: >$2 billion
ART26.12 – FABP5 inhibitors	Prostate cancer and Breast cancer, pain, and Post-Traumatic Stress Disorder (PTSD)	Pre-clinical	Prostate cancer: $9 billion Breast cancer: $18 billion PTSD: $7 billion
ART12.11 – Synthetic CBD Cocrystal	Inflammatory Bowel Disease (IBD), Post-Traumatic Stress Disorder (PTSD), and other potential indications including cancer	Pre-clinical	IBD: $7 billion PTSD: $7 billion

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 and lipid-signaling system, the ECS plays important roles in the CNS, development, synaptic plasticity, and the response to endogenous and environmental factors.

The modulation of the ECS can be affected by using selective or non-selective agonists, partial agonists, inverse agonists, and antagonists of the cannabinoid receptors, CB_1 and CB_2. The CB_1 receptor is distributed in brain areas associated with motor control, emotional responses, motivated behavior and energy homeostasis. In the periphery, CB_1 is ubiquitously expressed in the adipose tissue, pancreas, liver, gastrointestinal tract, skeletal muscles, heart and the reproductive system. The CB_2 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 be derived from plants (phytocannabinoids), can be semi-synthetic derivatives of phytocannabinoids or endocannabinoids, or can be completely synthetic new chemical entities. We plan to develop approaches within our portfolio that address receptor binding and endocannabinoid transport modulation using only synthetic new chemical entities. 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: anxiety, pain, inflammation, anorexia, and cancer.

Business Strategy

Our objective is to develop and commercialize ethical pharmaceutical products that provide physicians access to the therapeutic potential lipid signaling of modulators, including modulating the ECS. We intend to pursue technologies and compounds that offer promising therapeutic approaches to known and validated signaling pathways, specifically lipid signaling and including compounds that promote the effectiveness of the ECS.

Results of Operations

The following summary of our results of operations, for the three months ended March 31, 2022, and 2021, should be read in conjunction with our interim unaudited financial statements, as included in this Form 10-Q and our audited financial statements for the four month transition period ended December 31, 2021, as included in Form 10-KT filed with the SEC on March 21, 2022.

We do not have any revenue. We classify our operating expenses into research and development, and general and administrative expenses. Research and development expense consists of expenses incurred while performing research and development activities to discover and develop our product candidates. This includes conducting preclinical studies and clinical trials, development efforts and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expense primarily consists of costs incurred in research and development partnerships, preliminary studies, development of potential intellectual property, and research initiatives.

The following table provides selected financial data as of March 31, 2022, and December 31, 2021.

(In thousands)	March 31, 2022	December 31, 2021	Change
Cash	$ 10,350	$ 12,162	$ (1,812)
Total Assets	$ 26,704	$ 28,251	$ (1,547)
Total Liabilities	$ 924	$ 1,084	$ (160)
Stockholders' Equity	$ 25,780	$ 27,167	$ (1,387)

Balance Sheet Data

The decrease in cash was primarily due to a net loss of $2.0 million during the three months ended March 31, 2022.

For the Three Months Ended March 31, 2022, compared to the Three Months Ended March 31, 2021

	Three months ended March 31,		
(In thousands)	2022	2021	Change
Operating Expenses			
General and administrative	$ 1,482	$ 1,389	$ 93
Research and development	464	307	157
Total Operating Expenses	1,946	1,696	250
Loss from Operations	(1,946)	(1,696)	(250)
Other income	(19)	1	(20)
Net Loss	$ (1,965)	$ (1,695)	$ (270)

Through March 31, 2021, we have not generated any revenues since inception.

Our operating expenses, for the three months ended March 31, 2022, was $1.9 million compared to $1.7 million for the same period in 2021. Our operating expenses were the result of research and development and general and administrative expenses, including professional fees for ongoing regulatory requirements. General and administrative expenses were consistent with the same period in the prior year and the increase in research and development expenses were primarily due to increases in payroll and subcontractor expenditures relating to the Company's ART27.13 clinical trials.

Liquidity and Capital Resources

Liquidity is the ability of a company to generate funds to support its current and future operations, satisfy its obligations and otherwise operate on an ongoing basis.

We incurred a net loss of $2.0 million and $1.7 million for the three months ended March 31, 2022, and 2021, respectively. As of March 31, 2022, we had cash and cash equivalents of $10.4 million and short-term investments comprised of trading marketable securities and available-for-sale investments of $13.2 million. We anticipate that operating losses and net cash used in operating activities will increase over the next few years as we advance our programs under development.

As of March 31, 2022, we had an accumulated deficit of $22.9 million and working capital of $23.7 million. We believe our cash and cash equivalents and marketable securities will be sufficient to fund our operations into the second half of 2023.

Working Capital

(In thousands)	March 31, 2022	December 31, 2021	Change
Current Assets	$ 24,589	$ 24,609	$ (20)
Current Liabilities	875	1,027	(152)
Working Capital	$ 23,714	$ 23,582	$ 132

Cash Flows

	Three months ended March 31,		
(In thousands)	2022	2021	Change
Cash Flows used in operating activities	$ (2,053)	$ (1,742)	$ (311)
Cash Flows provided by (used in) investing activities	257	(2,044)	2,301
Cash Flows provided by financing activities	-	6,009	(6,009)
Effect of exchange rate changes on cash	(16)	7	(23)
Net change in cash and cash equivalents during period	$ (1,812)	$ 2,230	$ (4,042)

Our total current assets as of March 31, 2022, were $24.6 million compared to $24.6 million as of December 31, 2021. The current assets primarily consist of cash and cash equivalents of $10.4 million and $12.2 million and a total of investments classified as trading marketable securities and available-for-sale securities of $13.2 million and $12.0 million as of March 31, 2022, and December 31, 2021, respectively.

Our total current liabilities as of March 31, 2022, were $0.9 million as compared to total current liabilities of $1.0 million as of December 31, 2021. The current liabilities primarily consist of accounts payable and accrued liabilities of $0.8 million and $1.0 million, as of March 31, 2022, and December 31, 2021, respectively.

We have generated no operating revenues since our inception. We have been dependent on sales of equity securities to conduct operations. Unless and until we commence material operations and achieve material revenues, we will remain dependent on financings to continue our operations.

Cash Flows from Operating Activities

During the three months ended March 31, 2022, cash used in operating activities was $2.1 million compared to $1.7 million during the period ended March 31, 2021. The cash used in operating activities during the three months ended March 31, 2022, was primarily attributed to net loss of $2.0 million and an increase in net operating assets and liabilities of $0.7 million offset by stock-based compensation of $0.6 million. The cash used in operating activities during the three months ended March 31, 2021, was primarily attributed to net loss of $1.7 million and an increase in net operating asset and liabilities of $0.6 million offset by stock-based compensation of $0.5 million.

Cash Flows from Investing Activities

During the three months ended March 31, 2022, cash flows provided by investing activities of $0.3 million consisted of $2.7 million received upon the disposition of marketable securities offset by $2.4 million invested in trading marketable securities and available-for-securities investments. During the three months ended March 31, 2021, we used $2.0 million in investment in trading marketable securities.

Cash Flows from Financing Activities

During the three months ended March 31, 2022, we had no financing activities.

During the three months ended March 31, 2021, we received $6.0 million from exercise of warrants.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with the accounting principles generally accepted in the United States of America. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management's application of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved with the following aspects of our financial statements is critical to an understanding of our financial statements.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. The estimates and judgments will also affect the reported amounts for certain revenues and expenses during the reporting period. Actual results could differ from these good faith estimates and judgments.

Recent Accounting Pronouncements

In November 2021, the FASB issued ASU 2021-10, "*Government Assistance (Topic 832)*" which enhances disclosure of transactions with governments that are accounted for by applying a grant or contribution model. The new pronouncement requires entities to provide information about the nature of the transaction, terms and conditions associated with the transaction and financial statement line items affected by the transaction. The standard must be adopted for year ends beginning after December 15, 2021, with early adoption permitted. We adopted the standard on January 1, 2022, and the adoption of this standard did not have a material impact on 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, principal financial 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 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 and financial officer, as appropriate to allow timely decisions regarding required disclosure.

C*hanges 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.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business, financial condition, and results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as other information included in our 2021 Transition Report on Form 10-KT, 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 securities. 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.

Risk Factor Summary

Risks Related to our Business and Product Candidates:

- 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.
- We are currently receiving Research and Development, or R&D, tax credits from the United Kingdom ("UK") in connection with our clinical trials being conducted in the UK. If the UK government discontinues these tax credits, or we decide to conduct our clinical trials in another jurisdiction, our costs to develop our product candidates could increase significantly.
- If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are vital to our business.
- Changes in regulatory requirements or other unforeseen circumstances may impact the timing of the initiation or completion of our clinical trials.
- We face many of the risks and difficulties frequently encountered by relatively new companies with respect to our operations.
- We have no mature product candidates and may not be successful in licensing any.
- Even if we are successful in licensing lead product candidates, resource limitations may limit our ability to successfully develop them.

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.
- 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.
- We may be subject to claims challenging the inventorship of our patents and other intellectual property.
- Intellectual property rights do not necessarily address all potential threats.
- Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Risks Related to our Securities:

- Our common stock may be delisted from The Nasdaq Capital Market if we cannot regain compliance with Nasdaq's continued listing requirements.
- If we sell securities in future financings stockholders may experience immediate dilution and, as a result, our stock price may decline.
- The price of our securities may be volatile, and you could lose all or part of your investment. Further, we do not know whether an active, liquid and orderly trading market will sustain 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.
- 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."
- 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.

RISKS RELATED TO OUR BUSINESS AND PRODUCT CANDIDATES

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 research and operations and expect our expenses to increase substantially in the foreseeable future as developing our product candidates and conducting clinical trials 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.

Our current financial resources are limited. We may 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 may 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 US Drug Enforcement Agency (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 costs associated with attracting and retaining 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.

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 are currently receiving Research and Development ("R&D"), tax credits from the UK in connection with our clinical trials being conducted in the UK. If the UK government discontinues these tax credits, or we decide to conduct our clinical trials somewhere else, our costs to develop our product candidates would increase significantly.

The UK government grants R&D tax credits to companies conducting clinical trials in the UK, as we are currently doing. This effectively reduces the costs, and the cash we use, for our current trials. Should the UK government discontinue, or not renew, these R&D tax credits, or if we decide to conduct our R&D or clinical trials elsewhere, our cash use would increase significantly which may require us to raise even more additional capital to complete the development of our product candidates.

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are vital to our business.

We are a party to license agreements with NEOMED Institute and the Research Foundation at Stony Brook University, pursuant to which we in-license key patents and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the licenses, in which event we would not be able to develop or market the products covered by such licensed intellectual property. In particular, on April 24, 2019, we exercised our option (the "Option Exercise") pursuant to the Material and Data Transfer, Option and License Agreement with NEOMED dated as of December 20, 2017, as amended on January 4, 2019 (the "NEOMED Agreement"). In the future, if we are found not to be in compliance with the NEOMED Agreement, our license agreement with the Research Foundation at Stony Brook University (the "Stony Brook Agreement"), or any other license agreements it could materially adversely affect our business, results of operations, financial condition and prospects. If we fail to comply with any of our license 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. We may enter into additional licensing agreements in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

Changes in regulatory requirements or other unforeseen circumstances may impact the timing of the initiation or completion of our clinical trials.

Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols or our development plan to reflect these changes. Amendments may require resubmitting clinical trial protocols to the FDA or other similar authorities in other jurisdictions and institutional review boards ("IRBs") for re-examination, which may impact the costs, timing or successful completion of our clinical trials. If we experience delays in completion of, or if we terminate any planned clinical trials, the commercial prospects for product candidates may be harmed, and the ability to generate product revenues will be delayed. 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 product candidates.

The full impact of the COVID-19 pandemic on our clinical trial plans, product development, and how a regulatory body reviews study data is difficult to predict, but the pandemic may have a material adverse impact on our business operations, clinical trial plans, and product development, including delays in clinical trial and study participant recruitment, delays in regulatory approval of our product candidates, and the need to expend additional costs and resources. The pandemic's impact on the US and global economy and drug product manufacturing and supply chain may also adversely affect our clinical trial plans and drug development. Additionally, depending on the duration of shelter-in-place, social distancing, mask-wearing, and similar measures, such as proof of vaccination cards (or vaccination passports), mandated booster shots, as well as business closures, travel restrictions, and stresses on healthcare systems and our clinical trial sites, our ability to recruit participants for its clinical trials may be significantly impacted, and we may not be able to commence or complete its clinical trials as currently planned. We may also be required to significantly modify its study protocol, policies and procedures in order to address or accommodate patients and study site needs during the pandemic or some time after the immediate concerns have been reduced. Such changes can include modification to protocol inclusion and exclusion criteria, extending the time for patient follow up visits, using telemedicine, phone interviews and other technology to monitor patient safety, all of which will need to be approved by applicable IRBs, ethics committees, and regulatory authorities.

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 modulate lipid-signaling pathways, including 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 may lose all your investment.

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 for licenses to available technologies and compounds with companies that are more established than us and have greater financial resources than us. 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 full development of any lead product candidate to commercialization and there is no assurance that we can raise enough capital to fund full 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.

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 in the future. 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 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.

We have very limited operating history and capabilities.

Although our company was formed in 2011, our current business focus and operations in pharmaceutical development began in 2017. We do not currently have the ability to perform all the functions necessary to develop and commercialize 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; and
- 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.

Our operations and financial results could be adversely impacted by the COVID-19 pandemic.

In December 2019, a novel strain of coronavirus, subsequently named SARS-CoV-2 (and which causes a disease called "COVID-19"), was reported to have surfaced in Wuhan, China, which then spread rapidly throughout the globe resulting in significant disruptions to manufacturing, supply chain, markets, and travel world-wide, especially businesses involving activities or operations in China. On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (the "WHO") declared the COVID-19 outbreak a public health emergency of international concern and on March 12, 2020 the WHO announced the outbreak was a global pandemic. While the extent of the impact of the current COVID-19 pandemic and its aftermath on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 outbreak and subsequent variants could have a negative impact on our business, financial condition and operating results. Due to the global pandemic, our recruiting of clinical trial participants could also be slowed or delayed, or in a more severe scenario, our business, financial condition and operating results could be more severely affected. Given the dynamic nature of these circumstances, including the emergence of new variants of the virus and resulting restrictions imposed by various governments, the duration of any business disruption or potential impact to our business resulting from the COVID-19 pandemic is difficult to predict and it may increase our costs or expenses.

We may experience delays in providing sufficient product for future testing of our candidates due to the ongoing supply chain limitations caused by COVID-19.

Due to current supply chain disruptions caused by COVID-19, our contract manufacturing organizations may experience an inability to manufacture and produce sufficient quantities of our drug candidates as we progress through our regulatory testing and/or approval. Should this happen, we may not be able to provide sufficient quantities of our drug candidates to complete our testing as currently planned which could delay our ability to bring an approved drug to market. Such a delay may cause us to use more capital than currently planned which may have a material adverse effect on our projected timing of product approval and financials.

We may not be able to file Investigational New Drug applications to commence 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 territories with a regulatory authority we must obtain the necessary approvals to commence the clinical studies. For example, before initiating a clinical trial in the United States for any of our product candidates, we may be required to have an IND in effect 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. Once an IND is submitted, the sponsor must wait 30 calendar days before initiating the clinical trial, during which FDA will review the IND and either provide comments or allow the trial to proceed. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a clinical trial application (the equivalent of an IND in foreign jurisdictions), 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.

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

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 if we are found liable.

The emergence of unforeseen safety issues or adverse events may lead to regulatory agencies requiring us 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 CROs and clinical trial sites;
- obtain and maintain 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;
- 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 GCPs or the approved clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in a finding of non-compliance, 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 the future marketing 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.

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 these third parties' 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 will delay our product development activities.

Our reliance on third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory 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 are 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, as well as CROs. If we or our CROs 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. These third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. 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, if approved in the future, we may not be able to generate product revenue.

We currently do not have sales, marketing or distribution capabilities and do not have experience as a company in commercializing 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 future 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 future 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, if approved. 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.

If our contract manufacturing organization for materials to be used in our clinical trials fails to supply us with the necessary materials, we may be unable to complete our clinical trials on a timely basis, if at all.

We have entered into an agreement with a third party to handle the manufacturing supply chain for our product candidate ART27.13. If this manufacturer is unable or unwilling to provide us with sufficient quantities of our product candidate to meet its demands or fails to meet its standards of quality or other specification or to achieve drug cGMP compliance, we may not be able to locate any alternative suppliers or enter into commercially reasonable agreements with substitute suppliers in a timely manner or at all.

We may depend on third parties for clinical and commercial supplies, including, in some instances, a single supplier.

We may depend on third-party suppliers for clinical and commercial supplies, including the active ingredients which are used in our product candidate. These supplies may not always be available to us at the standards we require or on terms acceptable to us, or at all, and we may not be able to locate alternative suppliers in a timely manner, or at all. If we are unable to obtain necessary clinical or commercial supplies, its manufacturing operations and clinical trials and the clinical trials of our collaborators may be delayed or disrupted, and its business and prospects may be materially and adversely affected as a result.

We may rely on a single supplier for certain of its supplies. If this supplier is unable to supply to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all.

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 leased office space in Solana Beach, California and a location near Manchester, United Kingdom. Our facilities could be harmed or rendered inoperable by natural or human-made disasters, including earthquakes, fires, power shortages, nuclear, and radiation accidents, telecommunications failures, water shortages, famines, pestilence, floods, hurricanes, typhoons, tornadoes, extreme weather conditions, medical epidemics, pandemics, such as the COVID-19 global pandemic, cyber warfare, national and international conflict, terrorism, climate change, and other natural or human-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.

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, we have one US patent, one US patent application, and two foreign patent applications directed 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, including global waivers and patent removals which are being considered for COVID vaccines, 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 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 generally 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.

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 controlled substances and the dispensing of prescription products.

In the United States, the DEA regulates the use of chemicals for medical research and/or commercial development, including the requirement of annual registrations to manufacture or distribute cannabinoid-based pharmaceuticals. We do not currently conduct manufacturing or repackaging/relabeling of any product candidates in the United States, however we intend to conduct research on cannabinoids, including naturally-occurring cannabinoids, which are currently considered Schedule 1 controlled substances. We plan to obtain the required licenses in the territories 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 are conducting a significant portion of our research in the United Kingdom, where licenses to cultivate, possess and supply certain cannabinoids for medical research are granted by the Home Office on an annual basis. We currently possess the required licenses to do our research in the United Kingdom. Our research must be conducted within research institutions that also possess required licenses. If we are unable to conduct research at institutions that possess required licenses, or if those licenses are not obtained or renewed in the future, we may not be in a position to engage in or carry out 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 may be required to be issued by the relevant authority in each country. In addition, we will be required to obtain licenses to export from the US or the UK, and to import into the recipient country. We may also conduct a portion of our research in Canada, where we are currently collaborating on certain research at the University of Western Ontario, and in Ireland, where we currently have a research collaboration with Trinity College Dublin.

To date, we have not obtained controlled substance import, export, or supply licenses in any countries, except the United Kingdom. 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 our lead products.

Any product candidates we develop may be subject to US controlled substance laws and regulations and similar controls in territories outside the US where we are conducting research. 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 (the "CSA") in the US Controlled substances 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 that are administered and enforced 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, have 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 US Pharmaceutical products approved for use in the United States that comprise or contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances presenting 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 by licensed and DEA-registered health care providers is further restricted. For example, they may not be refilled without a new prescription.

Schedule I controlled substances once approved for medical use in the United States may be placed in Schedules II-V, since marketing 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 within ninety days, taking into account recommendations from the FDA controlled substances staff, in order to place the product in a schedule other than Schedule I so that it may be prescribed to patients in the US Furthermore, if the FDA, DEA, or any foreign regulatory authority subsequently determines that any approved and commercialized cannabinoid-based products may have potential for abuse, it may require us to generate more clinical or other data to establish whether or to what extent the substance has an abuse potential, which could result in a re-scheduling of the product and increase the costs associated with marketing that product. Prior to June 2018, GW Pharmaceuticals was developing a phytocannabinoid CBD product designated as Schedule I. Since the FDA approval in June 2018 of Epidiolex® in the US, the DEA has removed it from the list of Schedule I chemicals and from the list of controlled substances.

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.

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 cannabinoids, which may be designated as 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, clinical material manufacturing or repackaging/relabeling in the US; however, we are subject to similar laws and regulations in the UK and other countries where we are conducting a clinical trial and have contracted for clinical material manufacturing.

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, 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.

Manufacturing 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 for clinical material, 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, if the active ingredient in the final dosage form is a cannabinoid and is currently a Schedule I controlled substance it 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.

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 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 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 and lipid-signalling modulators 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 related to cannabinoids and lipid-signalling modulators 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.

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 cannabinoids 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, and specifically ART12.11, our CBD cocrystal. We believe that as cannabinoid-derived products become more widely accepted by the medical and scientific communities and the public at large, stigma associated with cannabinoid-derived products and treatments will moderate and, as a result, consumer demand is likely to 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 in the US 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 misuse or adverse side effects from 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.

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 or scrutiny. 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 misuse or adverse side effects 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.

To date, the FDA has only approved one plant-derived cannabinoid product as safe and effective for initial 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 US 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 US 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 violations 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 and harmful to our business.

Cannabinoid-based research activities in the pharmaceutical 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 US, 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 expensive for us to find because of our research directions utilizing 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.

The emerging markets for cannabinoid-derived products and medical research and development are and will likely remain competitive. The development and commercialization of pharmaceutical products in general 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 US 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 reduce health care costs may adversely affect our ability to achieve profitability.

In certain foreign markets, including countries in the European Union ("E.U.") and the UK, 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 reimbursements of our products are 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 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. Additionally, although we have entered into an employment agreement with Mr. Gorgas, 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 maintain a "key person" insurance policy on the life of Mr. Gorgas.

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. Our success depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers and 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.

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

To execute our business plan, we will need to rapidly add other management, accounting, regulatory, and scientific staff. We currently have four employees and approximately twenty consultants and contractors. 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. 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 employees 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 employees 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.

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 US 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.

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 United States Patent and Trademark Office (the "USPTO") and various government patent agencies outside of the US over the lifetime of our and our licensors' patents and applications. The USPTO and various non-US 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;
- 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 common stock may be delisted from The Nasdaq Capital Market if we cannot regain compliance with Nasdaq's continued listing requirements.

In order to maintain our listing on Nasdaq, we are required to comply with the Nasdaq requirements, which includes maintaining a minimum bid price and a minimum public float. In particular, we are required to maintain a minimum bid price of $1.00 per share, and we traded below that threshold regularly during and prior to our fiscal year ended August 31, 2021. On September 13, 2021, we received a notice from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Rule") because our common stock failed to maintain a minimum closing bid price of $1.00 for 30 consecutive business days. This notice had no immediate effect on the Nasdaq listing or trading of the company's common stock.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were afforded an initial period of 180 calendar days, or until March 14, 2022, to regain compliance with the Minimum Bid Price Rule. We were then afforded a second grace period of an additional 180 calendar days, or until September 12, 2022, to regain compliance with the Minimum Bid Price Rule. If we have not regained compliance with the Minimum Bid Price Rule within such time period, we will receive a written delisting notice from Nasdaq that our common stock will be delisted from the Nasdaq Capital Market

If we fail to effect a reverse stock split which allows us to regain compliance with the Minimum Bid Price Rule, our stock may be delisted. Delisting from the Nasdaq Capital Market or any Nasdaq market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system. If our common stock is delisted, it may come within the definition of "penny stock" as defined in the Securities Exchange Act of 1934 as amended (the "Exchange Act") and would be covered by Rule 15g-9 of the Exchange Act. That Rule imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For transactions covered by Rule 15g-9, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written agreement to the transaction prior to the sale. Consequently, Rule 15g-9, if it were to become applicable, would affect the ability or willingness of broker-dealers to sell our securities, and accordingly would affect the ability of stockholders to sell their securities in the public market. These additional procedures could also limit our ability to raise additional capital in the future.

If we sell securities in future financings our stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current market price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any of our securities sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders could experience additional dilution and, as a result, our stock price may decline.

The price of our securities may be volatile, and you could lose all or part of your investment. Further, we do not know whether an active, liquid and orderly trading market will sustain 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.

Although our securities are listed on the Nasdaq Capital Market, an active, liquid, and orderly trading market for our securities may not be sustained, and 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. In addition, the trading price of our securities is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume.

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 was previously listed for trading on the OTC Market's OTCQB service under the symbol "ARTL." Our stock may experience limited trading volume. Many of 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. An investor may be unable to sell such securities at the time or at the price or upon such other terms and conditions as the investor desires, and the terms of such sale may be less favorable 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 expect to remain subject to the reporting requirements under the Exchange Act. However, even then, many of our stockholders may 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.

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 professional 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.

Many of the outstanding shares of common stock are "restricted securities" within the meaning of Rule 144. As restricted securities, 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 part, 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. 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.

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 will be required to devote substantial time to new compliance initiatives.

As a public company, we will continue to incur significant legal, accounting, and other expenses. We are subject to the reporting requirements of 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 (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. 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.

If the listing requirements of the Nasdaq Capital Market divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our board committees, or as executive officers.

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.

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, and 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.

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 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 and our public warrants are 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 Nasdaq, 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 a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our securities less attractive to investors.

For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, 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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our securities will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable or fair-balanced coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description	Form	File No.	Filing Date	Filed Herewith
3.1	Articles of Incorporation	S-1	333-199213	10/8/2014	
3.2	Certificate of Amendment filed with the Nevada Secretary of State on February 2, 2017 with an effective date of February 10, 2017.	8-K	333-199213	2/9/2017	
3.3	Certificate of Change.	8-K	333-199213	4/17/2017	
3.4	Certificate of Change.	10-K	001-38951	11/29/2021	
3.5	Bylaws	S-1	333-199213	10/8/2014	
3.6	Amendment to the Bylaws	8-K	333-199213	3/10/2022	
4.1	Description of Securities	10-KT	001-38951	03/21/2022	
10.1#	Amended and Restated Employment Agreement by and between the Company and Gregory D. Gorgas dated August 30, 2019.	10-K	001-38951	11/25/2019	
10.2	Securities Purchase Agreement by and between the Company and Gregory D. Gorgas dated April 3, 2017.	8-K	333-199213	4/7/2017	
10.3#	Form of Indemnification Agreement	8-K	333-199213	5/8/2017	
10.4	Stock Purchase Agreement dated May 4, 2017	8-K	333-199213	5/8/2017	
10.5	Form of Private Placement Subscription Agreement	8-K	333-199213	8/4/2017	
10.6	Form of Registration Rights Agreement	8-K	333-199213	8/4/2017	
10.7	Stock Purchase Agreement dated as of August 1, 2017	8-K	333-199213	8/4/2017	
10.8	Material and Data Transfer, Option and License Agreement dated as of December 20, 2017 by and between the Company and NEOMED Institute+	10-Q	333-199213	1/16/2018	
10.9+	First Amendment to Material and Data Transfer, Option and License Agreement by and between the Company and NEOMED Institute, dated as of January 4, 2019	10-Q	333-199213	4/15/2019	
10.10#	2018 Equity Incentive Plan	S-1	333-227571	9/27/2018	
10.11#	Form of Stock Option Agreement—2018 Equity Incentive Plan	S-1	333-227571	9/27/2018	
10.12+	License Agreement with Stony Brook University, by and between the Company and Stony Brook University, dated January 18, 2018	S-1/A	333-222756	4/17/2018	
31.1	Section 302 Certification				*
31.2 **	Section 906 Certification				*
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				

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Management contracts or compensatory plans, contracts or arrangements.

\+ Certain portions of this exhibit have been omitted.

** The certification attached as Exhibits 32.1 that accompany this Transition Report, is deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Artelo Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Transition Report, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Artelo Biosciences, Inc.
(Registrant)

Dated: May 12, 2022

/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)

EXHIBIT 31.1

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

I, Gregory D. 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 my 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 my 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 my 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: May 12, 2022

/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)

EXHIBIT 32.1

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

The undersigned, Gregory D. 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 March 31, 2022 (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: May 12, 2022

/*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)