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, 2025**

or

☐ TRANSITION REPORT PERSUANT TO 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**

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 ☒

The Registrant had 3,281,032 shares of common stock issued and outstanding as of May 12, 2025.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash and cash equivalents	$ 746	$ 2,338
Prepaid expenses and other current assets	212	219
Deferred offering costs	424	-
Total Current Assets	1,382	2,557
Operating lease right-of-use assets	91	99
Intangible asset	2,039	2,039
Other assets	3	3
TOTAL ASSETS	$ 3,515	$ 4,698
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and accrued liabilities	$ 2,509	$ 1,676
Due to related parties	23	61
Operating lease liabilities - current portion	36	35
Advances from investors	236	-
Total Current Liabilities	2,804	1,772
Operating lease liabilities	59	69
TOTAL LIABILITIES	2,863	1,841
STOCKHOLDERS' EQUITY		
Preferred Stock, par value $0.001, 416,667 shares authorized, 0 shares issued and outstanding as of March 31, 2025 and December 31, 2024	-	-
Common Stock, par value $0.001, 50,000,000 shares authorized and 3,281,032 shares issued and outstanding as of March 31, 2025, and December 31, 2024	3	3
Additional paid-in capital	53,384	53,192
Accumulated deficit	(52,508)	(50,136)
Accumulated other comprehensive loss	(227)	(202)
TOTAL STOCKHOLDERS' EQUITY	652	2,857
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 3,515	$ 4,698

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

	Three months ended March 31,	
	2025	**2024**
OPERATING EXPENSES		
General and administrative	$ 995	$ 1,082
Research and development	1,384	1,507
Total Operating Expenses	2,379	2,589
Loss from Operations	(2,379)	(2,589)
OTHER INCOME		
Net change in fair value of trading marketable securities	-	106
Interest income	7	-
Total other income	7	106
Provision for income taxes	-	-
NET LOSS	$ (2,372)	$ (2,483)
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	(25)	-
Total Other Comprehensive Loss	(25)	-
TOTAL COMPREHENSIVE LOSS	$ (2,397)	$ (2,483)
Basic and Diluted Loss per Common Share	$ (0.72)	$ (0.78)
Basic and Diluted Weighted Average Common Shares Outstanding	3,281	3,197

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

	Common stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance, December 31, 2024	3,281	$ 3	$ 53,192	$ (50,136)	$ (202)	$ 2,857
Stock based compensation	-	-	192	-	-	192
Net loss for the period	-	-	-	(2,372)	-	(2,372)
Other comprehensive loss	-	-	-	-	(25)	(25)
Balance, March 31, 2025	3,281	$ 3	$ 53,384	$ (52,508)	$ (227)	$ 652

	Common stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance, December 31, 2023	3,189	$ 3	$ 52,262	$ (40,310)	$ (203)	$ 11,752
Common shares issued for cash	39	-	55	-	-	55
Stock based compensation	-	-	213	-	-	213
Net loss for the period	-	-	-	(2,483)	-	(2,483)
Balance, March 31, 2024	3,228	$ 3	$ 52,530	$ (42,793)	$ (203)	$ 9,537

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

	Three months ended March 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (2,372)	$ (2,483)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	192	213
Net change in fair value of trading marketable securities	-	(106)
Non-cash lease expense	8	8
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	9	5
Deferred offering costs	(424)	-
Accounts payable and accrued liabilities	800	(624)
Accounts payable - related parties	(38)	53
Advances from investors	236	-
Fixed cash payments related to operating leases	(8)	(8)
Net cash used in operating activities	(1,597)	(2,942)
CASH FLOWS FROM INVESTING ACTIVITIES		
Investment in trading marketable securities	-	(481)
Proceeds from disposition of marketable securities	-	1,750
Net cash provided by investing activities	-	1,269
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common shares for cash, net	-	55
Net cash provided by financing activities	-	55
Effect of exchange rate changes on cash	5	(2)
Net change in cash and cash equivalents	(1,592)	(1,620)
Cash and cash equivalents - beginning of period	2,338	2,815
Cash and cash equivalents - end of period	$ 746	$ 1,195
Supplemental Cash Flow Information		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Initial recognition of the right-of-use asset and lease liability	$ -	$ 111

ARTELO BIOSCIENCES, INC.
Notes to the Consolidated Financial Statements
(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 United Kingdom ("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 developing therapeutics that target lipid-signaling pathways, including treatments intended to modulate the endocannabinoid system (the "ECS"), a family of receptors and neurotransmitters that form a biochemical communication network throughout the body.

Going concern

The Company has incurred losses since inception and incurred a net loss of $2,372 during the three months ended March 31, 2025. As of March 31, 2025, we had cash and cash equivalents of $0.7 million. In May 2022, the Company entered into a purchase agreement and a registration rights agreement (the "Equity Line") with an institutional investor, providing for the sale of up to $20,000 worth of the Company's Common Stock, over the thirty-six (36) month term of the purchase agreement. Under the terms and subject to the conditions of the purchase agreement, the Company has the right, but not the obligation, to sell to the institutional investor, and the institutional investor is obligated to purchase, up to $20,000 worth of shares of the Company's Common Stock, subject to certain limitations.

In July 2023, the Company filed a $75,000 in aggregate value shelf registration statement on Form S-3 which became effective on July 14, 2023. The shelf registration statement is effective for three years and permits the Company to sell, from time to time, up to $75,000 of the Company's Common Stock, preferred stock, debt securities, warrants, and/or units subject to a limit of one-third (1/3) of the Company's public float within a twelve (12) month period if the public float of the Company is less than $75,000.

To continue operations, the Company will be required to raise additional funds by completing additional equity or debt offerings or licensing our product candidates. There can be no assurance that the Company will be successful in acquiring additional funding, that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The accompanying consolidated financial statements do not include any adjustments to reflect the future effects on the recoverability and classification of assets or the amounts and classification of liabilities if the Company is unable to continue as a going concern.

Negative Global or National Events

Businesses have been and will continue to be impacted by a number of challenging global and national events and circumstances that continue to evolve, including tariffs, trade disputes, pandemics, extreme weather conditions, increased economic uncertainty, inflation, interest rate fluctuation, recent and any potential future financial institution failures, and conflicts in Eastern Europe, the Middle East and in other countries. The extent of the impact of these events and circumstances on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and scope of the events and their impact on our development activities, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. We have been and continue to actively monitor the potential impacts that these various events and circumstances may have on our business, and we take steps, where warranted, to minimize any potential negative impacts on our business resulting from these events and circumstances. The ultimate impact of these global and national events and circumstances, either individually or in aggregate, is highly uncertain and subject to change.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company prepares its financial statements in accordance with rules and regulations of the U.S. 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, 2025, are not necessarily indicative of the results for the full year. While management of the Company believes that the disclosures presented herein are adequate and not misleading, these interim financial statements should be read in conjunction with the audited financial statements and the footnotes thereto for the year ended December 31, 2024, contained in the Company's Form 10-K filed with the SEC on March 3, 2025.

All amounts in these financial statements, notes and tables have been rounded to the nearest thousand dollars, except share and per share amounts, unless otherwise indicated.

Basis of Consolidation

The financial statements have been prepared on a consolidated basis including 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.

Research and Development ("R&D")

R&D expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, and other R&D expenses. Clinical studies and outside services costs relate primarily to services performed by clinical research organizations and related clinical or development manufacturing costs, materials, and supplies, filing fees, regulatory support, and other third-party fees. Personnel expenses relate primarily to salaries and benefits. R&D expenditures are charged to operations as incurred.

The Company recognizes R&D tax credits received from the United Kingdom government for spending on R&D as an offset of R&D expenses. The Company did not receive R&D tax credits during the three months ended March 31, 2025, and 2024, respectively.

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 $746 and $2,338 in cash and cash equivalents at March 31, 2025 and December 31, 2024, 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 Federal Deposit Insurance Corporation insurance as of March 31, 2025, was approximately $450. 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 or loss. The marketable securities held by the Company, classified as trading marketable securities, had an outstanding balance of $0 as of March 31, 2025, and December 31, 2024.

Deferred Stock Issuance Costs

Deferred stock issuance costs represent amounts paid for legal, consulting, and other offering expenses in conjunction with the future raising of additional capital to be performed within one year. These costs are netted against additional paid-in capital as a cost of the stock issuance upon closing of the respective stock placement.

Intangible Assets

The Company capitalizes certain costs related to the acquisition of intangible assets. If such assets are determined to have a finite useful life they are amortized on a straight-line basis over the estimated useful life.

The Company tests its intangible assets for impairment at least annually and whenever events or circumstances change that indicate impairment may have occurred. A significant amount of judgment is involved in determining if an indicator of impairment has occurred. Such indicators may include, among others and without limitation: a significant decline in the Company's expected future cash flows; a sustained, significant decline in the Company's stock price and market capitalization; a significant adverse change in legal factors or in the business climate of the Company's segments; unanticipated competition; and slower growth rates. The Company determined that there was no impairment of its intangible assets at March 31, 2025, and December 31, 2024.

Foreign Currency Transactions

The Company has operations outside of the United States, which results in exposure to market risks from changes in foreign currency rates. The financial risk arises from the fluctuations in foreign exchange rates and the degrees of volatility in these rates. Currently the Company does not use derivative instruments to reduce its exposure to foreign currency risk. Nonmonetary assets and liabilities are translated at historical rates and monetary assets and liabilities are translated at exchange rates in effect at the end of the year. Revenues and expenses are translated at average rates for the year. Gains and losses from translation of foreign currency financial statements into U.S. dollars are included as other comprehensive income.

Financial Instruments

The Company follows ASU 2022-03, ASC Subtopic "Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions" ("ASC 820"), 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 shown 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.

Stock-Based Compensation

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of stock option awards at the date of grant, which requires the input of highly subjective assumptions, including expected volatility and expected life. Changes in these inputs and assumptions can materially affect the measure of estimated fair value of our share-based compensation. These assumptions are subjective and generally require significant analysis and judgment to develop. When estimating fair value, some of the assumptions will be based on, or determined from, external data and other assumptions may be derived from our historical experience with stock-based payment arrangements. The appropriate weight to place on historical experience is a matter of judgment, based on relevant facts and circumstances. The Company accounts for forfeitures of stock options as they occur.

Net Loss per Share of Common Stock

Basic 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, 2025, and 2024, the following Common Stock equivalents were excluded from the computation of diluted net loss per share as the result was anti-dilutive.

	March 31, 2025	March 31, 2024
Stock options	773,605	763,105
Warrants	139,897	239,357
	913,502	1,002,462

Segment Reporting

Operating segments are defined as components of an enterprise about which separate and discrete information is available for evaluation by the chief operating decision-maker ("CODM") in deciding how to allocate resources and assess performance. The Company's CODM is its chief executive officer. The Company's CODM evaluates the Company's operations and manages its business as a single operating segment. All of the Company's long-lived assets are held in the United States. Refer to Note 3 for the Company's disclosure on its single operating segment.

New Accounting Standards Adopted

There were no new accounting standards adopted during the three months ended March 31, 2025.

NOTE 3 – SEGMENT REPORTING

Operating segments comprised of the components of an entity in which separate information is available for evaluation by the Company's chief operating decision maker, or group of decision makers, in determining how to allocate resources in evaluating performance. The Company consists of a single reporting segment: life science. The life science segment is comprised of the Company's development of therapeutics that target lipid-signaling modulation pathways, including the endocannabinoid system (the "ECS"), a network of receptors and neurotransmitters that form a biochemical communication system throughout the body. The Company's CODM is its Chief Executive Officer.

The accounting policies of the life science segment are as described in the summary of significant accounting policies. The CODM evaluates the performance of the life science segment based on the Company's net loss as reported on the income statement as consolidated net loss. The Company's segment assets are reported on the balance sheet as its total consolidated assets.

The Company has not generated any revenue since its inception and expects to continue to incur losses into the foreseeable future as it continues to conduct research and development related activities through all stages of product development and clinical trials and subsequently seek approval from the respective regulatory authorities.

The Company's CODM utilizes cash forecast models to determine the Company's investment in the life sciences segment. These models are reviewed regularly to monitor the Company's operating results and performance and compared to the Company's cash-based forecasts.

	Three months ended March 31,	
	2025	**2024**
General and administrative		
Employee and director compensation	$ 239	$ 244
Stock-based compensation	114	139
Professional fees	325	390
Other general and administrative [(a)]	317	309
Total general and administrative	995	1,082

	Three months ended March 31,	
	2025	**2024**
Research and development		
Employee compensation	$ 233	$ 229
Stock-based compensation	78	74
Professional fees	1,010	973
Other research and development [(b)]	63	231
Total research and development	1,384	1,507

(a) Consists of sales and marketing, investor relations, travel and other office expenses.

(b) Consists of supplies and other items used in research and development activities.

NOTE 4 – RELATED PARTY TRANSACTIONS

During the three months ended March 31, 2025, and 2024, a company owned by the Senior Vice President, European Operations, provided consulting services totaling $5 and $2, respectively. As of March 31, 2025, and December 31, 2024, there was $5 and $1, outstanding, respectively.

During the three months ended March 31, 2025, and 2024, a company significantly influenced by a director of a subsidiary of the Company provided professional services totaling $12 and $54, respectively. As of March 31, 2025, and December 31, 2024, there was $12 and $36 outstanding, respectively.

During the three months ended March 31, 2025, and 2024, a company controlled by a director of a subsidiary of the Company provided professional services totaling $20 and $23, respectively. As of March 31, 2025, and December 31, 2024, there was $6 and $24 outstanding, respectively.

NOTE 5 - EQUITY

Preferred shares

The Company has authorized 416,667 shares of preferred stock with a par value of $0.001 per share.

As of March 31, 2025, and December 31, 2024, there were no shares of preferred stock issued or outstanding.

Common Shares

The Company has authorized 50,000,000 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.

As of March 31, 2025, and December 31, 2024, there were 3,281,032 and 3,281,032 shares of Common Stock issued and outstanding, respectively.

Warrants

A summary of activity of the warrants during the three months ended March 31, 2025, is as follows:

	Number of shares	Weighted Average Exercise Price	Weighted Average Life (years)
Outstanding, December 31, 2024	139,897	$ 11.25	0.79
Granted	-	-	-
Expired	-	-	-
Exercised	-	-	-
Outstanding, March 31, 2025	139,897	$ 11.25	0.54

The intrinsic value of the warrants as of March 31, 2025, is $0. All of the outstanding warrants are exercisable as of March 31, 2025.

2018 Equity Incentive Plan, as amended

On February 28, 2025, the number of shares available under the Company's 2018 Equity Incentive Plan, as amended (the "2018 Plan") was increased by 484,155 shares of Common Stock.

As of March 31, 2025, the 2018 Plan permits the Company to issue up to an aggregate of 2,013,378 shares of Common Stock of which 1,239,773 shares are available to be issued.

The following is a summary of stock option activity during the three months ended March 31, 2025:

	Options Outstanding		Weighted Average
	Number of Options	Weighted Average Exercise Price	Remaining life (years)
Outstanding, December 31, 2024	773,605	$ 1.84	7.76
Granted	-	-	-
Exercised	-	-	-
Forfeited/canceled	-	-	-
Outstanding, March 31, 2025	773,605	$ 1.84	7.51
Exercisable options, March 31, 2025	271,943	$ 2.43	7.35

Valuation

The Company utilizes the Black-Scholes model to value its stock options.

During the three months ended March 31, 2024, the Company granted244,000 options, valued at $299 of which 102,000 options, valued at $128, were for related parties. As of March 31, 2025, $820 remains unamortized, of which $543 is for related parties. The intrinsic value of options outstanding as of March 31, 2025, and December 31, 2024, is $0.

NOTE 7– INTANGIBLE ASSET

The Company has capitalized the costs associated with acquiring the exclusive worldwide license to develop and commercialize products comprising or containing the compound ART27.13 as an intangible asset at a value of $2,039 as of March 31, 2025, and December 31, 2024.

The amount capitalized consisted of a $1,500 payment and the fair value of4,087 shares of Common Stock of $539. During the three months ended March 31, 2025, no additional costs met the criteria for capitalization as an intangible asset.

NOTE 8 - LEASE

On May 12, 2021, the Company entered into a lease arrangement for office space in the U.S. with Beckman/Lomas LLC, an entity controlled by a close family member of a director. Effective June 1, 2022, the related party divested its interests in the property, and as such, the lease agreement no longer constitutes a related party transaction. On March 6, 2024, the Company entered into an amended agreement with the landlord to extend the lease commencing in September 2024, and effective until August 2027.

The following summarizes right-of use asset and lease information about the Company's operating leases as of March 31, 2025:

	Three months ended March 31,	
	2025	**2024**
Lease cost		
Operating lease cost	$ 8	$ 8
Other information		
Cash paid for operating cash flows from operating leases	$ 8	$ 8
Right-of-use assets obtained in exchange for new operating lease liability	$ -	$ 111
Weighted-average remaining lease term — operating leases (years)	2.33	3.33
Weighted-average discount rate — operating leases	7.50%	7.50%

Future minimum lease payments under the operating lease liability have non-cancellable lease payments at March 31, 2025, as follows:

	Total
Year Ended December 31,	
2025	$ 31
2026	43
2027	30
2028	-
Thereafter	-
	104
Less: Imputed interest	(9)
Operating lease liabilities	95
Operating lease liability - current	36
Operating lease liability - non-current	$ 59

NOTE 9 – COMMITMENTS AND CONTINGENCIES

The Company has certain financial commitments relating to research and development contracts as of March 31, 2025, 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 an office outside Manchester, UK, which serves 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. The Solana Beach lease runs through August 2027 and the Manchester UK lease is month-to-month.

NOTE 10 – SUBSEQUENT EVENTS

On May 1, 2025, the Company issued at-market, unsecured convertible notes with gross proceeds of $650. Funds totaling $236 received from investors as of March 31, 2025, prior to the issuance of the convertible notes, are reflected in the consolidated balance sheet as advances from investors. The convertible notes bear interest at 12.0% and have a maturity of 180 days. The convertible notes are subject to voluntary and automatic provisions for conversion into the Company's common stock, as well as conversion into warrants to purchase the Company's common stock for a five-year period at a price of $1.04. Certain members of the Company's board of directors, an officer and consultants to the Company acquired $350 of the convertible notes.

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. Unless otherwise noted, all amounts are expressed in United States dollars ("USD") and "we", "us", "our" and the "Company" refer to Artelo Biosciences, Inc., including its subsidiaries unless otherwise indicated.

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 complete our clinical trials, develop, manufacture and commercialize our product candidates;
- our ability to raise any current or future funding to meet our capital requirements;
- the expected timing of the initiation and completion of our clinical studies for our product candidates;
- the size and growth of the markets for our product candidates;
- our commercialization, marketing, and manufacturing capabilities and strategies;
- geopolitical tensions, including tariffs and any war, regional conflict, or acts of terror, that can disrupt investment, supply chains and the economy generally;
- 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 U.S. and internationally;
- the development, regulatory approval, efficacy and commercialization of competing product candidates;
- our ability to attract and 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;
- 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 maintain compliance with Nasdaq 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, or at all. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Quarterly Report on Form 10-Q. 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 that include terms such as "we believe" and similar terms 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 interim financial statements are stated in USD and are prepared in accordance with generally accepted accounting principles 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 annual 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 annual report.

In this quarterly report, unless otherwise specified, all dollar amounts are expressed in USD and all references to "Common Shares" refer to shares of our common stock.

As used in this annual 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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis provides information that our management believes is relevant to an assessment and understanding of Artelo Biosciences, Inc.'s ("Artelo" or the "Company") condensed consolidated results of operations and financial condition. The discussion should be read together with the condensed consolidated financial statements and the accompanying notes to those statements that are included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements for the year ended December 31, 2024, and the related notes included in our Annual Report on Form 10-K filed with the SEC on March 3, 2025. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Artelo's actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" in Part II, Item 1A as set forth in this Quarterly Report on Form 10-Q.

General Overview

We incorporated in the State of Nevada on May 2, 2011, and are presently based in the County of San Diego, California. We are a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics that target lipid-signaling modulation pathways, including the endocannabinoid system (the "ECS"), a network of receptors and neurotransmitters that form a biochemical communication system throughout the body.

Our product candidate pipeline broadly leverages leading scientific methodologies and balances risk across mechanisms 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 dual cannabinoid (CB) agonist that targets both the CB_1 and CB_2 receptors. This synthetic small molecule program is a G protein-coupled receptor ("GPCR") designated ART27.13. We are developing ART27.13 as a potential treatment for cancer-related anorexia in a Phase 1b/2a trial, titled the Cancer Appetite Recovery Study ("CAReS").

Our second program, ART26.12 is a small molecule and the lead product candidate from our chemical library of inhibitors of fatty acid binding proteins, notably Fatty Acid Binding Protein 5 ("FABP5"). We received U.S. Food & Drug Administration (the "FDA") clearance for our Investigational New Drug ("IND") application for ART26.12 in July 2024 and have completed enrolment to a Phase 1 clinical trial in healthy subjects to support the development towards an agent intended to treat chemotherapy-induced peripheral neuropathy. In addition, ART26.12 may have broad applications as a cancer therapeutic, as a treatment for dermatologic conditions, such as psoriasis, as a treatment for pain and inflammation, and potential use in anxiety-related disorders, including post-traumatic stress disorder.

We are also developing our own invention ART12.11 (the "CBD cocrystal"). ART12.11 is our patented solid-state composition of cannabidiol ("CBD") and tetramethylpyrazine ("TMP"). TMP serves as the coformer in the CBD cocrystal. ART12.11 may be considered by the regulatory authorities as a fixed drug combination instead of a new chemical entity ("NCE").

We obtained two of our patent protected product candidates through our in-licensing activities. Our first in-licensed program, ART27.13, is being developed for cancer-related anorexia. ART27.13 is a peripherally-selective high-potency dual CB_1 and CB_2 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 Bioinnovations ("adMare") in June 2019, which had obtained rights to ART27.13 from AstraZeneca. 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 United Kingdom ("UK"), U.S. 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, and completed enrolling patients in the Phase 1b during the first quarter 2023. Data from the Phase 1b stage was used to determine the most effective and safe dose selected as the starting dose for the Phase 2a portion of CAReS. We received approval from the regulatory authorities in the UK, Ireland and Norway to increase the daily dose from the starting dose of 650 micrograms to 1,000 micrograms after 4 weeks and up to 1,300 micrograms initiated at 8 weeks in patients for whom intra-patient dose escalation is expected to be well tolerated. We also received approval from the regulatory authorities to enroll 40 evaluable patients into the Phase 2a stage with a 3:1 randomization of ART27.13 to placebo. We initiated the Phase 2a portion of CAReS during April 2023. As of May 6, 2025, 18 clinical sites across five countries are open and enrollment of approximately 40 participants is projected during the first half of 2025.

Our second in-licensed patented program is being advanced from our platform of small-molecule inhibitors of fatty acid binding proteins, notably FABP5. Fatty acid binding proteins ("FABPs") are attractive therapeutic targets, however, the high degree of sequence and structural similarities among family members 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 Stony Brook University ("SBU") discovered the chemistry for creating a large library of compounds which we believe to be highly specific and potent small molecule inhibitors of FABP5 and other isoforms. SBU had received approximately $8.0 million in funding from the National Institutes of Health to develop FABP5 inhibitor candidates including a $4.2 million grant in 2020 to advance research of FABP5 inhibition in prostate cancer. We licensed the rights to world-wide intellectual property in all fields and certain know-how to these inhibitors from SBU.

Our lead FABP5 inhibitor program is designated ART26.12. Preclinical research with ART26.12 showed evidence of activity in multiple pain models including osteoarthritis, cancer bone pain, and neuropathic pain. Based upon positive preclinical evidence from five separate studies showing promising activity and a differentiated mechanism-of-action for the prevention and treatment of painful neuropathies, including diabetic neuropathy and Chemotherapy Induced Peripheral Neuropathy ("CIPN"), we prioritized CIPN as the initial indication for development of ART26.12. Treatment and/or prevention of CIPN is a significant unmet need, often resulting in anti-cancer treatment delays or discontinuations, and there are currently no approved treatments for CIPN by the regulatory authorities in the U.S., UK or EU. We submitted an IND application for ART26.12 to the FDA on 10th of June 2024 and received a study may proceed notice from the FDA on the 8th of July 2024. First-in-human studies for ART26.12 began in Q4 of 2024 and we successfully completed dosing all 48 healthy volunteers planned for the Phase 1 Single Ascending Dose study at the end of April 2025. In addition to its potential as a synthetic endocannabinoid modulator with development targeting pain, inflammation, dermatologic conditions such as psoriasis, FABP5 is understood to play an important role in lipid signaling and is believed to be an attractive strategy for drug development in oncology. Large amounts of human biomarker and animal model data support FABP5 as an oncology target, including triple negative breast cancer, ovarian cancer, cervical cancer, and castration-resistant prostate cancer. Through our sponsored research we have also subsequently identified a potential role for FABP5 inhibition to treat anxiety disorders, such as Post Traumatic Stress Disorder ("PTSD"). We have been awarded a research grant in Canada to expand on our earlier research at the University of Western Ontario in this new development area.

In addition to our in-licensed programs, we have internal discovery research initiatives which resulted in ART12.11, a proprietary cocrystal composition of CBD and TMP. 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 CBD cocrystal exists as a single crystal form and as such is anticipated to have advantages over other solid forms of CBD that exhibit polymorphism. Emerging data demonstrates potential advantages of this single crystal structure, including improved stability, solubility, and a more consistent absorption profile. We believe these features have contributed to a more consistent and improved bioavailability and pharmacokinetic profile which may ultimately lead to improved safety and efficacy in human therapeutics, as already demonstrated in animal studies.

Presently, we have two U.S. patents, one pending U.S. patent application, six foreign patents (Australia, Brazil, China, Mexico, Japan and Taiwan) and three pending foreign patent applications (Canada, Europe, and South Korea) 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 continue to demonstrate a superior set of pharmaceutical properties compared to non-cocrystal CBD compositions. We plan to develop ART12.11 for multiple potential indications where CBD has shown activity of such anxiety disorders, including PTSD, depression, and other possible uses such as epilepsy and insomnia.

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

Product Candidate Pipeline:

Product Candidate	Target Indication(s)	Development Phase	Estimated Global Market Size
ART27.13 – Synthetic Dual Cannabinoid GPCR Agonist	Cancer-related anorexia	Clinical	Cancer anorexia cachexia syndrome: >$3 billion
ART26.12 – FABP5 inhibitor	CIPN, prostate cancer and breast cancer, pain, dermatologic conditions, and anxiety disorders	Clinical	CIPN: >$2 billion Prostate cancer: approximately $13 billion Breast cancer: approximately $33 billion Psoriasis: $31 billion PTSD: approximately $13 billion
ART12.11 – Synthetic CBD Cocrystal	Anxiety, depression, PTSD, and other potential indications	Pre-clinical	Anxiety disorders: >$13 billion PTSD: approximately $13 billion

Background

Emerging science suggests that modulating lipid-signaling pathways can unlock novel therapeutic strategies for diseases and medical conditions for which there are no or limited options. Lipids are critical to certain cell signaling pathways. Lipid-signaling modulation is the alteration of the signaling of lipid molecules to change biological activity or function within cellular communication pathways. Lipids contain various fatty acids as their building blocks and are the key components of lipid activity. Fatty Acid Binding Proteins (FABPs) facilitate lipid-signaling by binding to fatty acids which control various cellular functions. FABPs are essential mediators of normal cell signaling processes and under certain conditions can be associated with dysfunctional signaling. Inhibition of specific FABPs may correct abnormal lipid-signaling or improve the function of the ECS, which holds promise as new treatment modalities. We are at the forefront of advancing the application of lipid-modulating therapeutics.

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 of lipid signaling modulation, including within the ECS. We intend to pursue technologies and compounds that offer promising therapeutic approaches to known and validated signaling pathways, specifically lipid-signaling which includes compounds that promote the effectiveness of the ECS. While several of our programs are directed towards improving the lives of people suffering with cancer and cancer treatments, our portfolio may ultimately be used to treat a wide range of diseases and conditions where lipid-signaling modulation is particularly promising, including pain, inflammation, various neurological diseases, epilepsy, anxiety disorders, and dermatologic conditions.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue and we may not generate any revenue from the sale of products or from other sources in the near future.

Operating Expenses

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. General and administrative expense consists of professional fees, stock-based compensation, executive and director compensation and other administrative costs.

Other Income

Our other income consists of interest income and changes in fair value of our trading marketable securities.

Three months ended March 31, 2025, compared to the three months ended March 31, 2024

	Three months ended March 31,		
(In thousands)	2025	2024	Change
Operating Expenses			
General and administrative	$ 995	$ 1,082	$ (87)
Research and development	1,384	1,507	(123)
Total Operating Expenses	2,379	2,589	(210)
Loss from Operations	(2,379)	(2,589)	210
Other income (expense)	7	106	(99)
Net Loss	$ (2,372)	$ (2,483)	$ 111

Our operating expenses for the three months ended March 31, 2025, were $2.4 million compared to $2.6 million for the same period in 2024. The decrease in operating expenses for the three months ended March 31, 2025, was primarily the result of decreased corporate and research and development activity as a result of our cash preservation actions.

Liquidity and Capital Resources

Sources of Liquidity

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.

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Our net loss was $2.4 million for the three months ended March 31, 2025. As of March 31, 2025, we had cash and cash equivalents of $0.7 million. In May 2022, we entered into a purchase agreement and a registration rights agreement (the “Equity Line”) with an institutional investor, providing for the sale of up to $20.0 million worth of our Common Stock over the thirty-six (36) month term of the purchase agreement. Under the terms and subject to the conditions of the purchase agreement we have the right, but not the obligation, to sell to the institutional investor and the institutional investor is obligated to purchase, up to $20.0 million worth of shares of our Common Stock, subject to certain limitations. As of March 31, 2025, in accordance with the Equity Line we have issued a total of 425,344 shares of our Common Stock under the purchase agreement with aggregate proceeds of $679.

In July 2023 we filed a $75.0 million shelf registration statement on Form S-3 which became effective on July 14, 2023. The shelf registration statement is effective for three years and permits us to sell, from time to time, up to $75.0 million in aggregate value of our Common Stock, preferred stock, debt securities, warrants and/or units subject to a limit of one-third (1/3) of our public float within a twelve (12) month period if our public float is less than $75,000. The shelf registration statement was intended to provide us with flexibility to access additional capital when market conditions are appropriate.

In order to continue operations, we will be required to raise additional funds by completing additional equity or debt offerings or licensing our product candidates. We are currently pursuing various financing strategies. There can be no assurance that we will be successful in acquiring additional funding, that our projections of our future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The accompanying consolidated financial statements do not include any adjustments to reflect the future effects on the recoverability and classification of assets or the amounts and classification of liabilities if we are unable to continue as a going concern.

Funding Requirements

To date, we have not generated any revenue and we may not generate any revenue from the sale of products or from other sources in the near future. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- continue our research and development activities;
- maintain, protect and expand our intellectual property portfolio, including patents, trade secrets and know how;
- implement operational, financial and management information systems;
- attract, hire and retain additional management, scientific and administrative personnel; and
- operate as a public company.

We continue to face challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to: delays in execution of our product development plans; the scope and timing of our investment in our research and development activities and capabilities; changes we may make to the business that affect ongoing operating expenses; the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; changes we may make in our business strategy; the scope and timing of our investment in sales, marketing and distribution capabilities; our need to implement additional infrastructure and internal systems; the impact of the conflicts in Eastern Europe, the Middle East and in other countries; and other items affecting our forecasted level of expenditures and use of cash resources including potential acquisitions.

Until such time as we can generate significant revenue, if ever, we will continue to require substantial additional capital to fund operations for the foreseeable future. We intend to obtain such capital through public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. We may also seek additional financing opportunistically. We may be unable to raise additional funds on favorable terms or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and, recent and any potential future financial institution failures, the conflicts in Eastern Europe, the Middle East and in other countries, and otherwise. Our failure to raise additional capital, if needed, would have a negative impact on our financial condition and our ability to execute our business plan.

Our expected future capital requirements depend on many factors including expansion of our product portfolio and the timing and extent of spending on research and development activities and sales and marketing. If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt or additional equity financings that we complete may contain terms that are not favorable to us or our stockholders.

Working Capital

(In thousands)	March 31, 2025	December 31, 2024	Change
Current Assets	$ 1,382	$ 2,557	$ (1,175)
Current Liabilities	2,804	1,772	1,032
Working Capital	$ (1,422)	$ 785	$ (2,207)

Our total current assets as of March 31, 2025, were $1.4 million as compared to total current assets of $2.6 million as of December 31, 2024. The decrease in current assets was primarily due to the funding of our operating activities.

Our total current liabilities as of March 31, 2025, were $2.8 million as compared to total current liabilities of $1.8 million as of December 31, 2024, the result of our deferring payment on certain payables as a result of our cash preservation strategy.

Historical Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Three months ended March 31,		
(In thousands)	2025	2024	Change
Cash Flows used in operating activities	$ (1,597)	$ (2,942)	$ 1,345
Cash Flows provided by investing activities	-	1,269	(1,269)
Cash Flows provided by financing activities	-	55	(55)
Effect of exchange rate changes on cash	5	(2)	7
Net change in cash and cash equivalent during period	$ (1,592)	$ (1,620)	$ 28

Cash Flows from Operating Activities

During the three months ended March 31, 2025, cash used in operating activities was $1.6 million compared to $2.9 million during the three months ended March 31, 2024. Cash used in operating activities during the three months ended March 31, 2025, was attributed to a net loss of $2.4 million offset by decreases in operating assets and liabilities of $0.6 million and non-cash stock-based compensation of $0.2 million. Cash used in operating activities during the three months ended March 31, 2024, was attributed to a net loss of $2.5 million and a non-cash gain of $0.1 million associated with our trading of marketable securities and decreases in operating assets and liabilities of $0.6 million offset by stock-based compensation of $0.2 million.

Cash Flows from Investing Activities

During the three months ended March 31, 2025, cash provided by investing activities was $0.0 million compared to $1.3 million during the three months ended March 31, 2024. During the three months ended March 31, 2024, cash flows provided by investing activities of $1.3 million was the result of $1.8 million received from dispositions of trading marketable securities offset by $0.5 million from purchases of trading marketable securities

Cash Flows from Financing Activities

During the three months ended March 31, 2025, cash flows provided by financing activities was $0.0 million compared to $0.1 million during the three months ended March 31, 2024. During the three months ended March 31, 2024, cash flows provided by financing activities was comprised of proceeds from the issuance of common stock of $0.1 million.

Contractual Obligations and Commitments

For a discussion of our contractual obligations and commitments, refer to Part II, Item 8, Note 8, “Commitments and Contingencies” to the financial statements in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

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. We evaluate our estimates and assumptions on an ongoing basis and base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for the judgments we make about the carrying value of assets and liabilities that are not readily apparent from other sources. Because these estimates can vary depending on the situation, actual results may differ from these estimates. Making estimates and judgments about future events is inherently unpredictable and is subject to significant uncertainties, some of which are beyond our control. Should any of these estimates and assumptions change or prove to have been incorrect, it could have a material impact on our results of operations, financial position and statement of cash flows.

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.

New Accounting Standard Adopted

There were no new accounting standards adopted during the three months ended March 31, 2025.

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. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2025.

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.

Inherent Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

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

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our Common Stock would likely decline. 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 UK in connection with our clinical trials being conducted in the UK. With effect for accounting periods starting on or after April 1, 2024, expenditure on certain staffing costs in connection with activities which take place outside the UK as part of our clinical trials, will not qualify for R&D tax credits unless restrictive conditions are met.
- 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 maintain 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 continue 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 its Common Stock.

RISKS RELATED TO OUR BUSINESS AND PRODUCT CANDIDATES

Our financial condition raises substantial doubt as to our ability to continue as a going concern.

As of March 31, 2025, we had approximately $0.7 million in cash and cash equivalents, and working capital of negative $1.4 million, and we have incurred and expect to continue to incur significant costs in pursuit of our drug candidates. For the three months ended March 31, 2025, we recorded a net loss of approximately $2.4 million and used cash in operations of approximately $1.6 million. Our financial statements for the three months ended March 31, 2025 have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. To date, we have not generated substantial product revenues from our activities and have incurred substantial operating losses. We expect that we will continue to generate substantial operating losses for the foreseeable future until we complete development and approval of one of our product candidates. We expect to continue to fund our operations primarily through utilization of our current financial resources and additional raises of capital.

These conditions raise substantial doubt about our ability to continue as a going concern. We have evaluated the significance of the uncertainty regarding our financial condition in relation to our ability to meet our obligations, which has raised substantial doubt about our ability to continue as a going concern. While it is very difficult to estimate our future liquidity requirements, we believe if we are unable to obtain additional financing, existing cash resources will not be sufficient to enable us to fund the anticipated level of operations through one year from the date the accompanying financial statements are issued. There can be no assurances that we will be able to secure additional financing on acceptable terms. In the event we do not secure additional financing, we will be forced to delay, reduce, or eliminate some or all of its discretionary spending, which could adversely affect our business prospects, ability to meet long-term liquidity needs and the ability to continue operations.

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 and completing clinical trials will require substantial amounts of capital. We will also require a significant additional amount of capital to commercialize any products that may be approved in the future.

We will need to raise additional funds in the near future in order to satisfy our working capital and capital expenditure requirements. We may raise additional funds through public or private equity offerings, debt financings, strategic partnerships or alliances, receivables or royalty financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership 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, 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 U.S. 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;
- changes in economic conditions, including recessionary effects and inflationary pressures;
- 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.

As described in Part I, Item 2 of this Quarterly Report on Form 10-Q, "Management's Discussion and Analysis of Financial Condition and Results of Operations," we entered into the Equity Line with an institutional investor which provides, among other things, for the sale by us to the institutional investor of up to $20.0 million in shares of our Common Stock, subject to the terms of the Equity Line. Though we have the right, but not the obligation, to sell to the institutional investor shares of our Common Stock under the Equity Line, market conditions may not be favorable for us to sell shares of our Common Stock to the institutional investor.

Under the terms of the Equity Line, we are prohibited from effecting or entering into an agreement to effect any issuance by us or our subsidiaries of shares of our Common Stock involving the issuance of any floating conversion rate or variable priced equity-like securities, not including the prohibition of the issuance and sale of shares of our Common Stock pursuant to an "at-the-market offering" by us exclusively through a registered broker-dealer acting as our agent pursuant to a written agreement between us and such registered broker-dealer.

We are currently receiving Research and Development ("R&D") tax credits from the UK in connection with its activities in the UK. The value of these will decrease and there is an increased risk payments may be significantly delayed.

The UK government grants R&D tax credits to companies conducting preclinical research and clinical trials in the UK, as we are currently doing. The credits are paid to loss making companies, which effectively reduces the costs, and the cash we use, for our current trials. The value of R&D tax credits has decreased for all companies due to legislative changes affecting expenditure incurred after April 1, 2023. As a result of this and because of the increase in R&D activities in the U.S. we will likely no longer meet the definition of an "R&D intensive" company in the UK and will therefore only be eligible for payable credits at the lower rate of 10%. Furthermore, increased compliance activity by the UK tax authorities over the last year has resulted in a significantly higher number of claims being selected for enquiry. In the event of an inquiry the payment of the R&D credit could be delayed by 6-12 months.

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 have in-licensed 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. Further, changes in regulatory requirements and policies can impact our clinical trials, including due to public health concerns, such as the COVID-19 pandemic. For example, stresses on healthcare systems and our clinical trial sites may have a material impact on our ability to recruit participants for our clinical trials and we may not be able to commence or complete our clinical trials as currently planned. We may also be required to significantly modify our study protocol, policies and procedures in order to address or accommodate patients and study site needs. 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. Recently, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

Geopolitical tensions, including the war in Ukraine and the Israel-Hamas war or other regional conflicts may disrupt investment in our business, supply chains carrying required materials and the movement of people globally. Such disruptions may adversely affect our clinical trials, scope of potential partners and our business generally. In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

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 us 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 areas.

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 pre-clinical 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. Upon approval of any of our product candidates, we will need to transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

We may experience delays in providing sufficient product for future testing of our candidates due to prior and any future supply chain limitations caused by COVID-19 or other pandemics.

Due to prior and any future supply chain disruptions caused by COVID-19, or other pandemics, 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.

After submitting Investigational New Drug applications, 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. Although we have commenced clinical trials, 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.

Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrolment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

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 desires. 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 develops 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.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce an alternative formulation of one or more of our product candidates during the course of our clinical trials. Such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

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, financial institution collapses, mass deportations or migrations, water shortages, famines, pestilence, floods, hurricanes, typhoons, tornadoes, extreme weather conditions, medical epidemics, pandemics, such as the COVID-19 global pandemic, cyber warfare, tariffs, 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 our 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 U.S. patent, one U.S. 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 fees, 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 candidate 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 its synthetic cannabidiol (“CBD”) cocrystal drug candidate. Cannabinoids, including naturally-occurring cannabinoids, are currently considered Schedule 1 controlled substances under the Controlled Substances Act of 1970 (“CSA”) by the DEA. We have received guidance from the DEA that if a product does not contain any quantity of synthetically produced tetrahydrocannabinol (“THC”) (or any other controlled substance), it is not controlled by the CSA. Additionally, we have obtained laboratory certifications that its synthetic CBD product candidate, ART12.11 does not contain any levels of THC. 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 U.S. 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 multiple research collaborations 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 U.S. controlled substance laws and regulations and similar controls in territories outside the U.S. 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 CSA in the U.S. 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 U.S. 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. We have received guidance from the DEA that if a product does not contain any quantity of synthetically produced tetrahydrocannabinol ("THC") (or any other controlled substance), it is not controlled under the CSA. Additionally, we have obtained laboratory certifications that its synthetic CBD product candidate, ART12.11 does not contain any levels of THC. 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 U.S,, 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 U.S.; 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 U.S. 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 candidates, 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 lipid-signaling modulators and cannabinoid-based product candidates are novel with very limited or non-existing history; we face a significant risk that the trials will not result in commercially viable products and treatments.

At present, there is only a very limited documented clinical trial history related to lipid-signaling modulators and cannabinoids 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 or Ethics Committee approvals, licenses required for obtaining and using cannabinoids for research, either before or after a trial is commenced;
- unfavorable results from ongoing non-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 U.S. 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. We have received guidance from the DEA that if a product does not contain any quantity of synthetically produced tetrahydrocannabinol (“THC”) (or any other controlled substance), it is not controlled under the CSA. Additionally, we have obtained laboratory certifications that its synthetic CBD product candidate, ART12.11 does not contain any levels of THC. Before conducting testing in humans in the U.S. of a drug that has not been approved by the FDA, we will need to submit an IND application to the FDA. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications (“NDAs”), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

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

The constant evolution of laws and regulations affecting the research and development of cannabinoid-based pharmaceutical products and treatments could detrimentally affect our business. Laws and regulations related to the therapeutic uses of cannabinoids are subject to changing interpretations. These changes may require us to incur substantial costs associated with legal and compliance fees and ultimately require us to alter our business plan. Furthermore, violations or alleged 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 U.S., obtaining and maintaining necessary insurance coverage, for such things as workers compensation, general liability, product liability and directors' and officers' insurance, may be more difficult and 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 U.S. and other governments and/or health administrations provide coverage and/or reimbursements for our products. The ongoing efforts of governments, insurance companies, and other participants in the health care services industry to reduce health care costs may adversely affect our ability to achieve profitability. For example, in August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single-source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges as well as future litigation in view of the Supreme Court's overturn of the *Chevron* doctrine, legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. Further, uncertainties created by the IRA and additional government constraints on drug pricing could reduce valuation of companies and decrease funding in new drug development, which can have a material impact on our business. In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, restrictions on certain product access and marketing cost disclosure and transparency measures. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Further, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

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 significantly 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 add other management, accounting, regulatory, and scientific staff. We currently have five employees and utilize approximately twenty-five 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. 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 our behalf. 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 our behalf. 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 and 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 our value 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.

If our information technology systems or data, or those of third parties upon which we depend, are compromised, adverse consequences may follow. These consequences include business operation disruptions, litigation, regulatory investigations or actions, fines and penalties, reputational harm, and financial losses.

The operation of our business is dependent on information technology systems and infrastructure. We may process confidential, and sensitive, including personal data (such as health-related data), intellectual property, and proprietary business information (collectively, sensitive information) in the ordinary course of our business. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We have also outsourced some of our operations (including parts of our information technology infrastructure) to a number of third-party service providers who may have, or could gain, access to sensitive information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are increasing in frequency, persistence, sophistication and intensity. These threats come from a variety of sources, including personnel (such as through theft or misuse), computer "hackers," and sophisticated nation states. Some actors now engage and are expected to continue to engage in cyberattacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. We and the third parties upon which we rely may be subject to a variety of evolving threats, including, but not limited to, personnel misconduct or error, supply-chain attacks, ransomware attacks, malware, malicious code (such as viruses), denial-of-service attacks, social engineering attacks (including "phishing"), server malfunctions, telecommunication failures, software or hardware failures, loss of data or other technology assets, adware, earthquakes, fires, floods, and other similar threats. We have been the target of events of this nature and expect them to continue.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. Additionally, many of our employees who work from home at least part of the time, utilizing network connections outside our locations, which may increase risks to our information technology systems and data. Moreover, the prevalent use of mobile devices by our employees and third-party service providers to access confidential information increases the risk to our information technology systems and data. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our proprietary or sensitive information. A security incident or other interruption could disrupt our ability to conduct our business operations and divert significant resources. Though we have insurance that may cover some of the costs and fees resulting from a cyberattack, data security incident, or data breach, that insurance may not be sufficient to cover all of the costs, fees, losses, damages, fines, and penalties that may arise from a data security incident.

We may allocate substantial resources and/or adjust our business operations to safeguard against security incidents. Our data privacy and security obligations necessitate the implementation and maintenance of targeted security protocols and tools. These measures adhere to industry standards and are designed to protect our information technology systems, as well as our proprietary and sensitive information.

While we have implemented security measures to safeguard our information technology systems and infrastructure, there is no absolute guarantee that these measures will completely thwart cyberthreats, attacks, security incidents, data breaches, malware, ransomware, and other disruptions that could harm our business. The dynamic nature of threats and their sophistication means that vulnerabilities may elude detection until after an incident occurs. Despite our diligent efforts to identify and address vulnerabilities, success is not assured. Additionally, delays in implementing remedial measures to tackle identified vulnerabilities may occur. Furthermore, inadequate internal accounting controls related to security incidents and cybersecurity could impact the accuracy and timeliness of our financial statements, potentially leading to regulatory scrutiny.

Compliance with data privacy and security obligations, including data breach notification laws in the U.S. and other jurisdictions, may necessitate notifying relevant stakeholders about security incidents. Such disclosures come at a significant cost, and failure to comply with these requirements could have adverse consequences. If we (or a third party on whom we rely) encounter a security incident or are perceived to have experienced one, we may face various negative outcomes. These include government enforcement actions (such as investigations, fines, penalties, audits, and inspections), additional reporting obligations, restrictions on processing sensitive information (including personal data), litigation (including class-action claims), financial liabilities to third parties, indemnification responsibilities, negative publicity, reputational damage, diversion of monetary funds, operational disruptions (including data availability), financial losses, and other similar harms. Security incidents and their associated consequences may disrupt our operations significantly and potentially lead to material program disruptions. For instance, the loss of clinical trial or nonclinical study data for our product candidates could cause delays in regulatory approval efforts and substantially increase costs due to the additional time and resources required for data recovery, verification, or potential reproduction.

Our contractual agreements may lack adequate limitations of liability, and even when present, there is no guarantee that these provisions sufficiently shield us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot definitively ascertain that our insurance coverage will adequately protect us or mitigate liabilities arising from our privacy and security practices. The availability of such coverage on commercially reasonable terms remains uncertain, as does its ability to cover future claims.

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

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our product candidates or utilize similar science or technology but that are not covered by the claims of the patents that we may own or license from our licensors or that incorporate certain research in our product candidates that is in the public domain;
- we, or our licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we or our licensors own now or in the future;
- we, or our licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our or our licensors' current or future pending patent applications will not lead to issued patents;
- issued patents that we or our licensors hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- 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 maintain 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 include maintaining a minimum bid price and a minimum public float. For example, we are required to maintain a minimum bid price of $1.00 per share, and our Common Stock 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 our 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. On August 24, 2022, we received a formal notification via letter from Nasdaq confirming that we had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2), which requires that our Common Stock maintain a minimum bid price of at least $1.00 per share, and that the matter is now closed.

On April 23, 2025, 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 our Common Stock. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we will be afforded an initial period of 180 calendar days, or until October 20, 2025, to regain compliance with the Minimum Bid Price Rule.

Additionally, as of March 31, 2025 we were not in compliance with Nasdaq Listing Rule 5550 (b)(1) which requires minimum stockholders' equity of $2.5 million. Our stockholders' equity as of that date was $0.7 million.

If we are unable to maintain compliance with Nasdaq's continued listing requirements in the future, 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, including potential sales of our equity to an institutional investor as described above. 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 continue 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 continue, 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 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, 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 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. Wd 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:

- classifying our board of directors (“Board”) into three classes of directors with staggered 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 us 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 (which expired June 17, 2024) have been and 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 product development 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 in part 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

Securities Trading Plans of Directors and Executive Officers

During our last fiscal quarter, none of our directors or officers, as defined in Rule 16a-1(f), adopted and/or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408.

Item 6. Exhibits

Exhibit Number	Description	Form	File No.	Filing Date	Filed Herewith
3.1	Articles of Incorporation, as amended	10-Q	001-38951	05/11/2023	
3.2	Amended and Restated Bylaws	8-K	001-38951	04/21/2023	
31.1	Section 302 Certification				*
32.1 **	Section 906 Certification				*
101. INS	Inline XBRL Instance Document				
101. SCH	Inline XBRL Taxonomy Extension Schema Document				
101. CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101. DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101. LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101. PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover page Interactive Data File (embedded with the Inline XBRL document)				

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** The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q, is deemed furnished and not filed with the Securities and Exchange Commission and is 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 Quarterly Report on Form 10-Q, 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 13, 2025

/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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

5. 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 13, 2025

/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

In connection with the Quarterly Report of Artelo Biosciences, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gregory D. Gorgas, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: May 13, 2025

/*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)