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

FORM 10-K

(Mark One)

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

For the fiscal year ended **December 31, 2025**

OR

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

For the transition period from _____ to _____

Commission file number **001-38951**

Artelo Biosciences, Inc.

(Exact name of registrant as specified in its charter)

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

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

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**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of Common Stock, $0.001 par value per share (the "Common Stock"), held by non-affiliates of the registrant on June 30, 2025, was $9,288,602 based on a $13.27 average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

The registrant had 2,124,772 shares of Common Stock issued and outstanding as of February 20, 2026.

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FORWARD-LOOKING STATEMENTS

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

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

- our plans to obtain funding for our operations, including funding necessary to 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 I, Item 1A. "*Risk Factors*" of this Annual Report on Form 10-K. 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 Annual Report on Form 10-K. 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 audited 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 on Form 10-K. 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 on Form 10-K.

In this Annual Report on Form 10-K, unless otherwise specified, all dollar amounts are expressed in United States dollars ("USD") and all references to "common shares" refer to shares of our Common Stock.

As used in this Annual Report on Form 10-K, the terms "we", "us", "our" and the "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.

PART I

ITEM 1. BUSINESS

Corporate 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 novel, benzimidazole dual cannabinoid (CB) agonist that targets both the CB_1 and CB_2 peripheral receptors. This synthetic small molecule program is a G protein-coupled receptor ("GPCR") designated ART27.13 and was initially developed by AstraZeneca plc. We are developing ART27.13 as a potential treatment for cancer-related anorexia and it is currently in a Phase 1b/2a trial, titled the Cancer Appetite Recovery Study ("CAReS"). In an interim analysis of the on-going Phase 2a CAReS trial, patients with cancer anorexia receiving ART27.13 demonstrated a mean weight gain of over 6% compared to a 5% loss in the placebo group, while maintaining a safety profile similar to the Phase 1b despite doses up to twice the previous maximum. Currently there is no FDA approved treatment for cancer anorexia cachexia syndrome.

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 ("CIPN"). 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. In June 2025, we announced favorable results from our first-in-human study evaluating ART26.12. The Phase 1 Single Ascending Dose (SAD) study was designed to assess the safety, tolerability, and pharmacokinetics of ART26.12 in healthy volunteers and enrolled 49 subjects. All adverse events (AEs) were mild, transient, and self-resolving. No drug-related AEs were observed in the blinded dataset, and no tolerability issues or safety signals were detected across multiple assessments (vital signs, ECGs, clinical laboratory tests, physical examinations, and visual analogue mood scales). In addition, full dose-exposure profiles were successfully explored. Plasma analysis confirmed dose-dependent, linear absorption across the evaluated range. A wide safety margin was observed between estimated therapeutic plasma concentrations and the highest exposure levels achieved, supporting potential titration for maximum efficacy in future studies. In addition to ART26.12 in CIPN, our extensive library of small molecule inhibitors of Fatty Acid Binding Proteins ("FABPs") has shown therapeutic potential for the treatment of certain cancers, neuropathic and nociceptive pain, psoriasis, and anxiety disorders.

ART12.11 is our wholly owned, proprietary cocrystal composition of cannabidiol (CBD) and tetramethylpyrazine (TMP). Isolated as a single crystalline form, ART12.11 has exhibited better pharmacokinetics and improved efficacy compared to other forms of CBD in nonclinical studies. Greatly enhanced pharmaceutical properties, including physicochemical, pharmacokinetic, and pharmacodynamic advantages have been observed with ART12.11. We believe a more consistent and improved bioavailability profile may ultimately lead to increased safety and efficacy in humans, thus making ART12.11 a preferred CBD pharmaceutical composition. The U.S. issued composition of matter patent for ART12.11 is enforceable until December 10, 2038 and has now been granted or validated in 21 additional countries.

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 CB1 and CB2 full-receptor agonist, which was originally invented at AstraZeneca plc. 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 plc. 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 plc, 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 indicated 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 of 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 with 18 clinical sites across five countries.

As of December 31, 2025, 32 participants have been enrolled. On September 3, 2025, we announced interim results from the Phase 2a CAReS trial. In the interim analysis, 18 evaluable patients—primarily with lung and gastrointestinal cancers not receiving cyclic chemotherapy—were included. After 12 weeks of treatment in patients who were titrated to the top dose evaluated of 1300 micrograms (n=5), ART27.13 demonstrated compelling increases in mean body weight of 6.38% (Standard Deviation or SD 9.50) compared to patients on placebo (n=6) who lost -5.42% (SD 8.17). The maximum weight gain in the ART27.13 group reached 18.5%, versus only 0.4% in placebo. The maximum weight loss in the placebo arm was -17.4%, compared to just -3.0% in the ART27.13 group. Additional benefits were seen in lean body mass, with a +4.23% increase (SD 5.37) in the treatment group versus a -3.15% loss (SD 4.89) in placebo at one month, as well as qualitative improvements in total and weekly activity scores.

Safety results were consistent with prior findings. Among the 32 participants enrolled in the CAReS Phase 2 trial to date, 7 patients (22%) experienced adverse events that may be related to ART27.13. All were mild or moderate, with the exception of a single case of severe malaise, and no drug-related serious adverse events were reported. These data are aligned with safety outcomes observed in Phase 1 of CAReS, supporting ART27.13's overall favorable tolerability and acceptable safety profile.

Our second in-licensed patented program is being advanced from our platform of small-molecule inhibitors of FABPs, notably FABP5. 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. 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 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 June 10, 2024 and received a study may proceed notice from the FDA on July 8, 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 endocannabinoid system ("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.

Intellectual Property

We are a party to certain license agreements as described below and, going forward, we intend to license intellectual property from pharmaceutical and biotechnology companies and research institutions which would cover research stage and clinical stage assets to build a pipeline of product candidates that are associated with lipid signaling.

Patent Estate and Licenses

Product Candidate	Patent Status	License
ART27.13 – Synthetic GPCR CB_1 and CB_2 Receptor Agonist	Two (2) issued patents (U.S.) including composition of matter, terms of 11/3/25 and 5/31/28, eighteen (18) issued foreign patents, and one (1) Artelo-owned composition application with eighteen (18) pending National Phase filings, three (3) pending applications (Japan, Taiwan and U.S.) with composition claims, and one (1) pending provisional application in the U.S. for the treatment of eye-disorders, including glaucoma.	Worldwide exclusive license
ART26.12 – FABP5 inhibitor and FABP5 inhibitors platform	Six (6) patents issued (U.S.) and eleven (11) issued foreign patents. Covers the target, composition of matter, and utility claims. In addition, there are twenty-five (25) pending applications related to the ART26.12 program and related chemistries.	Worldwide exclusive license
ART12.11 – Synthetic CBD Cocrystal	Issued one (1) composition of matter patent (U.S.) and one (1) methods of use patent (U.S.). Both with a term through 12/10/38. Six (6) issued foreign patents and eight (8) pending applications (U.S. & Intl).	N/A (wholly owned by Artelo)

The NEOMED Relationship

On December 20, 2017, the Company entered into an agreement with NEOMED (the "NEOMED Agreement"), which provided the Company with up to twelve months from the date of receipt by the Company of the required materials to conduct certain non-clinical research studies, diligence and technical analyses with NEOMED's proprietary therapeutic compound NEO1940, now known as ART27.13 (the "Compound") and an option (the "NEOMED Option") for an exclusive worldwide license to develop and commercialize products comprising or containing the Compound. The NEOMED Agreement has an effective date of January 2, 2018 (the "NEOMED Effective Date"). On the NEOMED Effective Date, the Company issued 15,000 shares of its Common Stock (on a pre-reverse stock split basis) to NEOMED. Pursuant to the terms of the NEOMED Agreement, within 30 days after the NEOMED Effective Date, NEOMED, without additional consideration and at its sole cost, delivered to the Company certain technology transfer materials and the quantity of the Compound substance specified in a research plan, both as set out under the NEOMED Agreement.

On January 4, 2019, the Company entered into the First Amendment to Material and Data Transfer, Option and License Agreement (the "First Amendment to NEOMED Agreement"), pursuant to which the Company agreed to issue NEOMED shares of our Common Stock as consideration for the waiver by NEOMED of the cash payment of $100,000 that was due to NEOMED on October 1, 2018. The Company issued 61,297 shares of Common Stock (on a pre-reverse stock split basis) to NEOMED in connection with the Company's exercise of the NEOMED Option. The Company also issued 11,363 shares of Common Stock (on a pre-reverse stock split basis) to NEOMED pursuant to the terms of the First Amendment to NEOMED Agreement. Pursuant to the NEOMED Agreement, in July 2019, the Company completed a payment of $1,500,000 to NEOMED for the exercise of the NEOMED Option. Upon exercise of the NEOMED Option, NEOMED provided the Company with an exclusive worldwide license under all of NEOMED's intellectual property rights covering the Compound ("Licensed IP Rights") to research, develop, make, have made, use, offer for sale, sell, have sold and import products containing the Compound and otherwise exploit the Licensed IP Rights worldwide, in all fields.

In connection with the NEOMED Agreement, additional potential payments of up to $200.0 million will be due upon the achievement of certain regulatory, commercial, and sales milestones. Additionally, we will pay mid-to high-single digit royalties on annual net sales of any product successfully developed.

In clinical development studies with NEOMED's prior sponsor, ART27.13 was dosed in over 200 subjects. From 2007 to 2008, ART27.13 was evaluated in five phase 1 clinical trials under its original sponsor, AstraZeneca plc. ART27.13 was administered orally in 205 patients and its safety, tolerability, pharmacokinetics and pharmacodynamics were investigated. Four of these studies were single dose or Single Ascending Dose ("SAD") studies. An initial SAD study was conducted in the UK. The program was completed with another study performed in a Japanese population. The two other single dose studies aimed at measuring a pharmacodynamics effect (Proof-of-Principle or POP studies) on analgesia using the capsaicin test in one case, and the third molar extraction model in the other case. The last phase 1 study was a Multiple Ascending Dose ("MAD") study, where patients with chronic lower back pain received ART27.13 for a scheduled period of 12 days. Further details of the studies are found in Table 1.

Table 1 – Clinical studies performed with ART27.13 (formerly NEO1940)

Year	Full Title	Schedule	Primary Endpoint	Secondary Endpoints
2007	Phase 1, First Time in Man, Single-Centre, Randomised, Double-Blind (within panels), Placebo-Controlled Study to Investigate Safety, Tolerability and Pharmacokinetics of NEO1940 after Administration of Oral Single Ascending Doses in Healthy Volunteers	Single dose	Safety and tolerability	CNS effects; PK profile
2007-2008	A Phase 1, Single-Centre, Randomised, Double-Blind (within panels), Placebo-Controlled Study to Investigate Safety, Tolerability and Pharmacokinetics of NEO1940 after Administration of Oral Single Ascending Doses in Japanese Healthy Male Volunteers	Single dose	Safety and tolerability	CNS effects; PK profile
2007-2008	A Phase 1, Single-centre, Randomised, Double-blind, Placebo-controlled Crossover Study in Healthy Volunteers to Evaluate Effects of a Single Oral Dose of NEO1940 on Intradermal and Topical Capsaicin-evoked Pain Symptoms	Single dose	Effects on intradermal capsaicin injection-evoked pain response by assessment of pain intensity (continuous VAS rating) and to evaluate the effect on heat pain threshold in skin exposed to topical	Other pain parameters; safety and tolerability; CNS effects; PK profile, PK/PD effects
2008	A Randomised, Double Blind, Placebo-Controlled Study to Investigate the Analgesic Efficacy of a Single Dose of NEO1940, in Patients Undergoing Impacted Mandibular Third Molar Extraction	Single dose	To investigate the analgesic effect compared to placebo in dental surgery patients following impacted mandibular third molar extraction.	Safety and tolerability; CNS effects; PK profile, PK/PD effects
2008	A Phase 1, Multi-Centre, Randomised, Double-blind, Placebo-controlled Study to Investigate the Safety, Tolerability and Pharmacokinetics of NEO1940, Including an Interaction Study, After Administration of Oral Multiple Ascending Doses in Adult Subjects with Chronic Low Back Pain	Multiple dose	Safety and tolerability	CNS effects; PK profile, CYP450 induction

ART27.13 demonstrated, in general, an acceptable safety and tolerability profile in the safety endpoints. The profile of the observed safety effects was generally typical of cannabinoids and the majority of the adverse events were of mild or moderate intensity. A maximum tolerated dose was defined by the frequency and severity of adverse events. A dose dependent increase in body weight was observed in the MAD study. In three out of the five phase 1 studies, analgesia in acute pain models was also measured as an endpoint; no convincing analgesic efficacy was seen in any of these studies.

The Stony Brook University Relationship

On January 18, 2018, we entered into a license agreement (the "Stony Brook Agreement") with the Research Foundation at Stony Brook University (the "Foundation") which became effective on that same date (the "SBU Effective Date"). The Stony Brook Agreement provides us with an exclusive license under certain licensed patents of the Foundation to develop, make, manufacture, have made, use, sell, have sold, import, export, and offer for sale Patent Product(s) (as defined in the Stony Brook Agreement) and Other Product(s) (as defined in the Stony Brook Agreement) worldwide in all fields, including without limitation the field of human therapeutics.

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

We will also be required to pay a low-single digit royalty on net sales on any patent products (the "Royalties"). The Stony Brook Agreement provides for a reduction of the Royalties in certain cases. We will also pay to the Foundation, beginning in the first calendar year of the first commercial sales, an annual minimum royalty fee (the "Annual Minimum Royalty"). The Annual Minimum Royalty will be credited against the total Royalties due for the calendar year in which the Annual Minimum Royalty is paid.

We will also be required to make payments for the following milestones:

Milestone		Milestone Payment ($US)
Initiation of a Phase 2 Clinical Trial for the first Indication of each active pharmaceutical ingredient that results from the grant of rights in Section 2 to Licensed Subject Matter (as defined in the Stony Brook Agreement)	$	150,000
Initiation of a Phase 3 clinical trial for the first indication of each active pharmaceutical ingredient that results from the grant of rights in Section 2 to Licensed Subject Matter	$	250,000
Upon First Commercial Sale based upon FDA or European Medicines Agency ("EMA") regulatory approval for the first Indication of each active pharmaceutical ingredient that results from the grant of rights in Section 2 to Licensed Subject Matter	$	1,500,000
Receiving FDA or EMA approval for the second and each subsequent Indication of each active pharmaceutical ingredient that results from the grant of rights in Section 2 to Licensed Subject Matter	$	1,000,000
First time annual Net Sales (as defined in the Stony Brook Agreement) greater than $100,000,000	$	1,000,000
First time annual Net Sales greater than $500,000,000	$	5,000,000

The term of the Stony Brook Agreement commenced on the SBU Effective Date and will continue until the Stony Brook Agreement is terminated in accordance with its terms.

Research & Development

We intend to combine innovative science and accelerated clinical development to create and develop novel therapies using small molecule drug development strategies targeting lipid signaling pathways and the ECS. Our current research and development efforts have been limited to investigative work surrounding lipid signaling, including creating and developing novel and synthetic formulations, and evaluating potential opportunities to license technologies from pharmaceutical companies and leading research institutions. Our principal research efforts to date have been with the Stony Brook University, New York, University of Western Ontario, Canada, Trinity College Dublin, Ireland and with various clinical research organizations ("CROs") in the U.S., China, Spain, and UK.

Scientific Approach

We intend to create, acquire, and develop a broad spectrum of therapeutics, each of which has the potential to modulate lipid signaling for human health. The principal scientific platforms of our strategy are as follows:

- *New Chemical Entities.* We expect to license intellectual property rights for research stage platforms and new chemical entities developed within leading academic institutions under which we may develop programs that target lipid signaling pathways, including molecules that modulate the ECS. These programs may involve the use of compounds which are neither plant-based nor synthetically derived cannabinoids and are instead small molecules that have been shown to have promising potential in lipid signaling pathways. Our initiatives for this strategy led us to the license novel technology from Stony Brook University, which we expect to be a core platform for the Company. This platform comprises multiple inhibitors to FABPs and the lead program is designated ART26.12.

- *Novel Compounds.* We also plan to acquire rights to intellectual property for research and clinical stage assets developed within the pharmaceutical industry and leading research institutions for synthetic small molecules, new chemical entities or alternatives to plant-based cannabinoids. Our efforts to secure rights to synthetic novel compounds led us to the NEOMED Agreement with NEOMED for the Compound, ART27.13.

Our board of directors ("Board") and management have experience developing and commercializing ethical pharmaceutical products, including several first-in-class therapeutics. As we build our pipeline and advance our research and clinical development programs, we will evaluate partnerships with large pharmaceutical and biopharmaceutical companies where applicable. Based upon our management's current experience and the future talent we may attract, we plan to retain rights to develop and commercialize products on our own. However, we will seek to collaborate with biopharmaceutical partners should that strategy be believed to maximize the value for our stockholders.

Two of our development programs were licensed from established and respected organizations that have already conducted pre-clinical research and, in some cases, clinical research. Our science and regulatory teams are leveraging this research to speed development and commercialization timelines across our portfolio. Our current pipeline encompasses multiple mechanisms associated with lipid signaling. The specific programs that are currently in development are set forth below.

- *ART27.13* – ART27.13 is our name for the synthetic GPCR CB_1 and CB_2 receptor agonist compound formerly known as NEO1940 and AZD1940. We developed a synthetic oral formulation suitable for clinical evaluation for potential use in the treatment of anorexia/weight loss associated with cancer. ART27.13 has been administered to 205 subjects in prior phase 1 studies and 24 cancer patients in our Phase 1b stage of the Cancer Appetite Recovery Study (CAReS). On September 3, 2025, we announced interim results from the Phase 2a CAReS trial. In the interim analysis, 18 evaluable patients—primarily with lung and gastrointestinal cancers not receiving cyclic chemotherapy—were included. After 12 weeks of treatment in patients who were titrated to the top dose evaluated of 1300 micrograms (n=5), ART27.13 demonstrated compelling increases in mean body weight of 6.38% (Standard Deviation or SD 9.50) compared to patients on placebo (n=6) who lost -5.42% (SD 8.17). The maximum weight gain in the ART27.13 group reached 18.5%, versus only 0.4% in placebo. The maximum weight loss in the placebo arm was -17.4%, compared to just -3.0% in the ART27.13 group. Additional benefits were seen in lean body mass, with a +4.23% increase (SD 5.37) in the treatment group versus a -3.15% loss (SD 4.89) in placebo at one month, as well as qualitative improvements in total and weekly activity scores.

  Safety results were consistent with prior findings. Among the 32 participants enrolled in the CAReS Phase 2 trial to date, 7 patients (22%) experienced adverse events that may be related to ART27.13. All were mild or moderate, with the exception of a single case of severe malaise, and no drug-related serious adverse events were reported. These data are aligned with safety outcomes observed in Phase 1 of CAReS, supporting ART27.13's overall favorable tolerability and acceptable safety profile.

- *ART26.12* – ART26.12 is a small molecule and the lead product candidate from our chemical library of inhibitors of FABPs, notably FABP5. We received FDA clearance for our 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 CIPN. 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. In June 2025, we announced favorable results from our first-in-human study evaluating ART26.12. The Phase 1 Single Ascending Dose (SAD) study was designed to assess the safety, tolerability, and pharmacokinetics of ART26.12 in healthy volunteers and enrolled 49 subjects. All adverse events (AEs) were mild, transient, and self-resolving. No drug-related AEs were observed in the blinded dataset, and no tolerability issues or safety signals were detected across multiple assessments (vital signs, ECGs, clinical laboratory tests, physical examinations, and visual analogue mood scales). In addition, full dose-exposure profiles were successfully explored. Plasma analysis confirmed dose-dependent, linear absorption across the evaluated range. A wide safety margin was observed between estimated therapeutic plasma concentrations and the highest exposure levels achieved, supporting potential titration for maximum efficacy in future studies. In addition to ART26.12 in CIPN, our extensive library of small molecule inhibitors of FABPs has shown therapeutic potential for the treatment of certain cancers, neuropathic and nociceptive pain, psoriasis, and anxiety disorders.

- *ART12.11* – Our novel solid-state CBD composition co-formed with TMP is targeted for development in anxiety disorders and rare/orphan diseases. The anxiety strategy became a priority based upon results comparing ART12.11 to CBD in a stress-induced model of anxiety, where ART12.11 showed a treatment effect in all nine evaluations and CBD alone failed all tests. Our rare/orphan disease strategy is supported by commercial approval and sales of another company's product containing CBD. In addition, we have data demonstrating a similar pharmacokinetic profile to CBD formulated as a liquid with sesame seed oil, despite ART12.11's formulation being unoptimized and currently under development for administration as an oral solid.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and an emphasis on proprietary products. Any product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

We plan to compete in the segments of the pharmaceutical, biotechnological and other related markets with therapeutics that demonstrate clinical utility, have an acceptable safety profile and target commercially attractive indications characterized by previously unmet medical need.

Our potential competitors, which include pharmaceutical and biopharmaceutical companies such as Novartis International AG, Helsinn Therapeutics (U.S.), Inc., NGM Biopharmaceuticals Inc., Jazz Pharmaceuticals Inc., Skye Bioscience, Longboard Pharmaceuticals, and Pfizer Inc. may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved medicines than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain approval from the FDA or other regulatory agencies for their medicines more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Government Regulation

United States

Government authorities in the United States, at the federal, state and local levels, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

In the United States, the FDA approves and regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and the implementing regulations promulgated thereunder. The failure to comply with requirements under the FDCA and other applicable laws at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an Investigational New Drug ("IND") application, which must take effect before human clinical trials may begin;
- approval by an institutional review board representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices ("GCPs") to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of an NDA requesting marketing approval for one or more proposed indications, including the payment of application user fees;
- review by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practice ("cGMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of one or more clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy and the potential requirement to conduct post-approval studies.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the clinical trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which may review data and endpoints at designated check points, make recommendations or halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

Post-approval clinical trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a clinical trial may move forward at designated check points based on access to certain data from the clinical trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 clinical trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

NDA Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development nonclinical and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. It could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may offer conditional approval subject to, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on post-approval or Phase IV clinical studies, if applicable;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA permits patent term restoration of up to five years as compensation for a patent term lost during product development and FDA regulatory review process to the first applicant to obtain approval of an NDA for a new chemical entity in the United States. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2) ("505(b)(2) NDA"), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

Foreign Jurisdictions

In addition to regulations in the United States, a manufacturer is subject to a variety of regulations in foreign jurisdictions to the extent they choose to sell any drug products in those foreign countries. Even if a manufacturer obtains FDA approval of a product, it must still obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. For other countries, outside of the European Union, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary.

In the European Union, marketing authorizations for medicinal products may be obtained through different procedures founded on the same basic regulatory process. The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU Member States. The centralized procedure is compulsory for medicinal products produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases. On the other hand, a decentralized procedure provides for approval by one or more other concerned EU Member States of an assessment of an application for marketing authorization conducted by one EU Member State, known as the reference EU Member State. In accordance with the mutual recognition procedure, the sponsor applies for national marketing authorization in one EU Member State. Upon receipt of this authorization the sponsor can then seek the recognition of this authorization by other EU Member States.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (the "FCPA") prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. United States governmental authorities that enforce the FCPA, including the Department of Justice, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be "foreign officials" under the FCPA. Accordingly, when we interact with foreign health care professionals and researchers in testing and marketing our product candidates abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions.

International Laws

In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA. Violations of any of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

Other Healthcare Laws

Our business operations and current and future arrangements with healthcare professionals, consultants, customers and patients, may expose us to broadly applicable state and federal fraud and abuse and other healthcare laws and regulations. These laws constrain the business and financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;

- the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;

- in addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities may conclude that some of our business practices, including our promotional activities and interactions with our customers do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, additional integrity reporting and oversight obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

U.S. Healthcare Reform

In the U.S. and some non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the U.S., in March 2010, the Patient Protection and Affordable Care Act (the "ACA"), was passed, which substantially changed the way healthcare is financed by both the government and private insurers.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare measures promulgated by the government will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2032 unless additional Congressional action is taken.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Centers for Medicare & Medicaid Services ("**CMS**") may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, or 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 certain pharmaceutical companies 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, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. 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 if approved.

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, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. 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. Furthermore, there has been increased interest by third party payors and governmental authorities in reference to pricing systems and publication of discounts and list prices. 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.

The IRA became law in August 2022. The IRA includes new provisions related to health care, and prescription drug pricing in particular, which is expected to have far-reaching, long-term, and adverse effects on the pharmaceutical and biotech industry and its stakeholders. The prescription drug pricing provisions have already altered and terminated some pharmaceutical drug research and development strategies and going forward may impact patent litigation and market entry opportunities for competitor drugs.

Before the IRA became law, the Social Security Act prohibited the Secretary of Health and Human Services (HHS) from negotiating with drug manufacturers. The IRA now enables the Centers for Medicare & Medicaid Services (CMS) within HHS to negotiate a "maximum fair price" (MFP) for selected high-expenditure, single-source drugs annually. The price setting provisions of the IRA may also discourage further development of drugs that have already been approved to treat one rare disease.

A single-source small molecule drug generally qualifies for selection if at least seven years have passed since the date of approval from the FDA and there are no generic alternatives commercially available. Drug manufacturers are provided approximately 24 months advance notice for negotiation with CMS prior to the implementation of the negotiated price therefore the pharmaceutical companies are afforded at least nine years before they are required sell their product under Medicare Part B and Part D, as applicable, at the CMS-negotiated price. Pharmaceutical products covered by private insurance or paid for in cash by patients are not subject to the CMS price-negotiated MFP.

The small-molecule drug development pipeline has been impacted as many large and small pharmaceutical and biotech companies have already shifted their strategies to accommodate slightly more favorable treatment of biologics. Under the IRA, biologics are afforded more time on the market before becoming eligible for price-reduction negotiations. Specifically, compared to a small-molecules, biologics now have an extra four years to recoup investments before being subjected to CMS-negotiated MFP. Consequently, investors may view biotech more favorably than small-molecule drug innovation.

Because federal funding is one of many aspects CMS considers when negotiating the MFP under the IRA, a drug developed using government funding, such as from the National Institute of Health (NIH), risks lower MFP due to that collaboration. This risk may also discourage investment in drug manufacturers who have accepted funding from the U.S. government. Since the IRA is ambiguous with respect to what constitutes "prior" financial support leads to further uncertainty for both investors and innovators. As a consequence of the IRA both pharmaceutical companies and their investors may be disincentivized from pursuing development of scientific innovations associated with NIH collaboration.

While the IRA has created many uncertainties and potentially broad applications in the industry, many believe that the government's new pricing scheme may also impact patent infringement litigation. Patent litigation strategies may adjust for both the innovators and follow on manufacturers, depending on the timing, potential availability of generic drugs or biosimilar competitors, and cost versus benefit analysis of litigation. While we endeavor to monitor developments with the IRA and its resultant risks and consequences, especially with the companies with near-term impacts, we may not be able to anticipate all necessary alterations to our business strategies, actions by our potential competitors, or subsequent modifications of Congress.

Employees and Human Capital

As of December 31, 2025, we had seven (7) employees. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We also engage multiple contractors, consultants and advisors who provide services on a part-time basis. Our employees, contractors and consultants conduct or oversee all day-to-day operations of the Company including technical development, research, and administration. We currently have no material retainers or minimum financial commitments with any of our consultants, contractors or service providers. We consider relations with our employees, consultants, and contractors to be satisfactory.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate and Available Information

We were incorporated in Nevada in May 2011. Our principal executive offices are located at 505 Lomas Santa Fe, Suite 160, Solana Beach, CA 92075, and our telephone number is (858) 925-7049. Our investor relations website is located at ir.artelobio.com. Information contained on the website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the Securities and Exchange Commission ("SEC").

We use our investor relations website to post important information for investors, including news releases, analyst presentations, and supplemental financial information, and as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Accordingly, investors should monitor our investor relations website, in addition to following press releases, SEC filings and public conference calls and webcasts. We also make available, free of charge, on our investor relations website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports as soon as reasonably practicable after electronically filing or furnishing those reports to the SEC.

ITEM 1A. RISK FACTORS

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings, in evaluating our business. If any of the following risks actually occur, 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. The Company has 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. Effective for accounting periods starting on or after April 1, 2024, expenditures 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.
- The Company has no mature product candidates and may not be successful in licensing any.
- Even if the Company is 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 the Company 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 December 31, 2025, we had approximately $0.6 million in cash and cash equivalents and restricted cash, and working capital of negative $3.3 million, and we have incurred and expect to continue to incur significant costs in pursuit of our drug candidates. For the year ended December 31, 2025, we recorded a net loss of approximately $12.9 million and used cash in operations of approximately $8.5 million. Our financial statements for the year ended December 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 additional raises of capital.

These conditions raise substantial doubt about our ability to continue as a going concern. The Company has evaluated the significance of the uncertainty regarding the Company's financial condition in relation to its ability to meet its obligations, which has raised substantial doubt about the Company's ability to continue as a going concern. The Company believes if it is unable to obtain additional financing, existing cash resources will not be sufficient to enable it 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 the Company will be able to secure additional financing on acceptable terms. In the event the Company does not secure additional financing, the Company will be forced to delay, reduce, or eliminate some or all of its discretionary spending, which could adversely affect the Company's business prospects, ability to meet long-term liquidity needs and the ability to continue operations.

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

Since our inception, the Company has used substantial amounts of cash to fund our research and operations and we 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. The Company will also require a significant additional amount of capital to commercialize any products that may be approved in the future.

The Company will need to raise additional funds in the near future in order to satisfy our working capital and capital expenditure requirements. The Company 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. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company raises 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 the Company enters 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 the Company were to default on such indebtedness, the Company could lose such assets and intellectual property. If the Company raises additional funds through strategic partnerships and alliances and licensing arrangements with third parties, the Company may have to relinquish valuable rights to our product candidates. In addition, if the Company raises 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 the Company develops or acquires;
- 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 the Company is unable to raise additional capital when required or on acceptable terms, the Company 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. The Company also may be required to relinquish, license or otherwise dispose of rights to products or product candidates that the Company 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 II, Item 7 of this Annual Report on Form 10-K, "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," in January 2026 the Company 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 $25.0 million in shares of our Common Stock, which at the Company's sole discretion can be increased by an additional $25.0 million once the initial $25.0 million is exhausted, subject to the terms of the Equity Line. Though the Company has 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, the Company is 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 variable rate securities (as defined therein) during certain standstill periods (as defined therein), 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.

The Company is 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 likely 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 the Company is currently doing. The credits are paid in cash to loss-generating companies, which effectively reduces the costs, and the cash the Company uses, 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. the company will likely no longer meet the definition of a "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 would be delayed by 6 – 12 months.

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

The Company is a party to license agreements with NEOMED Institute and the Research Foundation at Stony Brook University, pursuant to which the Company in-licenses key patents and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty and other obligations on us. If the Company fails to comply with these obligations, our licensors may have the right to terminate the licenses, in which event the Company would not be able to develop or market the products covered by such licensed intellectual property. In particular, on April 24, 2019, the Company 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 the Company is 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 the Company fails to comply with any of our license obligations, our licensors may have the right to terminate these agreements, in which event the Company might not be able to develop and market any product candidate that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The Company may enter into additional licensing agreements in the future and if the Company fails to comply with obligations under those agreements, the Company 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 the Company 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 the Company experiences delays in completion of, or if the Company terminates 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 the Company may not be able to commence or complete our clinical trials as currently planned. The Company 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.

The Company faces 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. The Company has limited operating history as a medical research company engaged in biopharmaceutical research upon which an evaluation of our company and our prospects could be based. There can be no assurance that our management will be successful in being able to commercially exploit the results, if any, from our product development research projects or that the Company 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 the Company is unable to raise sufficient capital as needed, the Company 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, the Company anticipates incurring significant costs associated with commercializing any approved product candidate and the Company 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.

The Company does 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.

The Company currently does not have any therapeutic products that are approved for commercial sale. The Company has not received and does 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, the Company 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.

The Company has 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. The Company does 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 the Company has licensed;
- initiating preclinical, clinical or other required studies for future product candidates;
- adding manufacturers and suppliers required to advance our programs;
- obtaining regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- making milestone or other payments under any license agreements;
- expanding, maintaining and protecting our intellectual property portfolio;
- attracting and retaining skilled personnel; and
- creating and maintaining an infrastructure required to support our operations as a public company.

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

The Company expects 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 the approval of any of our product candidates, the Company will need to transition from a company with a research and development focus to a company capable of undertaking commercial activities. The Company may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

The Company may experience delays in providing sufficient product for future testing of our candidates due to prior and any future supply chain limitations caused by pandemics.

Due to prior and any future supply chain disruptions caused by pandemics, our contract manufacturing organizations may experience an inability to manufacture and produce sufficient quantities of our drug candidates as the Company progresses through our regulatory testing and/or approval. Should this happen, the Company 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 the Company 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, the Company 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 the Company is pursuing novel technologies may also exacerbate these risks with respect to our product candidates, and as a result the Company 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 the Company is 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 the Company has not planned or anticipated. The Company cannot assure you that the Company 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. The Company may also inadvertently fail to report adverse events the Company becomes aware of within the prescribed timeframe. The Company may also fail to appreciate that the Company has 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 the Company fails 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 the Company cannot be certain that the Company 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.

The Company does 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 the Company is investigating.

The Company 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 the Company experiences 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, the Company 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, the Company will have to decide to focus on developing a limited number of product candidates. As a result, the Company 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 the Company does not accurately evaluate the commercial potential or target market for a particular product candidate, the Company 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.

The Company 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.

The Company plans to rely on third-party CROs to conduct the majority of our preclinical research studies and our clinical trials. In addition, the Company plans 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 the Company can obtain the services the Company needs at commercially reasonable prices or within the timeframes the Company desires. Even though the Company will enter into agreements governing these third parties' activities, the Company will have limited influence over their actual performance, and the Company 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 the Company needs 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, the Company 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 the Company 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 the Company 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 the Company would if the Company 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, the Company 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.

The Company currently has no marketing and sales organization and has no experience in marketing products. If the Company is 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, the Company may not be able to generate product revenue.

The Company currently does not have sales, marketing or distribution capabilities and does not have experience as a company in commercializing products. If the Company develops internal sales, marketing, and distribution organization, this would require significant capital expenditures, management resources and time, and the Company would have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If the Company is unable or decides not to establish internal sales, marketing, and distribution capabilities, the Company expects to pursue collaborative arrangements regarding the sales, marketing, and distribution of our future products. However, the Company may not be able to establish or maintain such collaborative arrangements, or if the Company is able to do so, their sales forces may not be successful in marketing our future products. Any revenue the Company receives would depend upon the efforts of such third parties, which may not be successful. The Company 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 the Company had commercialized our product candidates ourselves. The Company also faces 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 the Company 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, the Company may be unable to complete our clinical trials on a timely basis, if at all.

The Company has entered into agreements with third parties to handle the manufacturing supply chain for our product candidates ART27.13 and ART26.12. If these manufacturers are unable or unwilling to provide us with sufficient quantities of our product candidates to meet its demands or fails to meet its standards of quality or other specification or to achieve drug cGMP compliance, the Company 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.

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

The Company 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 the Company requires or on terms acceptable to us, or at all, and the Company may not be able to locate alternative suppliers in a timely manner, or at all. If the Company is 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.

The Company may rely on a single supplier for certain of its supplies. If this supplier is unable to supply to us in the quantities the Company requires, or at all, or otherwise defaults on its supply obligations to us, the Company 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 the Company is required to vacate our facilities, our ability to pursue our research and development efforts may be jeopardized.

The Company currently does not have any manufacturing facilities. The Company also does not own any properties, laboratories, or manufacturing facilities. However, the Company has 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, water shortages, famines, pestilence, floods, hurricanes, typhoons, tornadoes, extreme weather conditions, medical epidemics, pandemics, such as the COVID-19 global pandemic, cyber warfare, national and international conflict, terrorism, climate change, and other natural or human-made disasters or other business interruptions, for which the Company is predominantly self-insured. Any of these may render it difficult or impossible for us to continue company operations. If any of our facilities is inoperable for even a short period of time, the interruption in research and development may result in harm to our reputation and increased costs, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment the Company uses to perform our research and development work.

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

Our commercial success is significantly dependent on intellectual property related to any product candidates and technologies the Company may either acquire, license, or develop internally. The Company is currently the licensee of multiple issued patents and pending patent applications and the Company intends to license additional technologies from pharmaceutical and biotechnology companies, and research institutions. In addition, the Company has 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, the Company 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 the Company licenses from third parties. Therefore, the Company 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 the Company has 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, the Company cannot be certain that the Company or our licensor were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that the Company 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. The Company 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 the Company complies with any required fee payment, documentary and/or procedural requirements as they might relate to any patents for which the Company is an assignee or co-assignee, the Company employs legal help and related professionals as needed to comply with those requirements. Failure to meet a required fee payment, document production or procedural requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances, the defect can be cured through late compliance, but there are situations where the failure to meet the required deadline cannot be cured. Such an occurrence could compromise the intellectual property protection around a preclinical or clinical product candidate and possibly weaken or eliminate our ability to protect our eventual market share for that product candidate.

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

In the United States, the DEA regulates the use of chemicals for medical research and/or commercial development, including the requirement of annual registrations to manufacture or distribute cannabinoid-based pharmaceuticals. The Company does not currently conduct manufacturing or repackaging/relabeling of any product candidates in the United States, however the Company intends 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 Substance Act of 1970 (“CSA”) by the DEA. The Company has 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, the Company has obtained laboratory certifications that its synthetic CBD product candidate, ART12.11 does not contain any levels of THC. The Company plans 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 the Company will be successful in obtaining the required licenses or that the Company will be successful identifying or engaging third party contractors who have the required registrations.

The Company is 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. The Company currently possesses 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 the Company is unable to conduct research at institutions that possess required licenses, or if those licenses are not obtained or renewed in the future, the Company 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, the Company will be required to obtain licenses to export from the U.S. or the UK, and to import into the recipient country. The Company may also conduct a portion of our research in Canada, where the Company is currently collaborating on certain research at the University of Western Ontario, and in Ireland, where the Company currently has multiple research collaborations with Trinity College Dublin.

To date, the Company has not obtained controlled substance import, export, or supply licenses in any countries, except the United Kingdom. The Company does not have an established track record of obtaining such required licenses and there is no assurance the Company 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 the Company develops may be subject to U.S. controlled substance laws and regulations and similar controls in territories outside the U.S. where the Company is 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 US Pharmaceutical products approved for use in the United States that comprise or contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances presenting the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs by licensed and DEA-registered health care providers is further restricted. For example, they may not be refilled without a new prescription.

Schedule I controlled substances once approved for medical use in the United States may be placed in Schedules II-V, since marketing approval by the FDA satisfies the "accepted medical use" requirement. If and when any of our product candidates receive FDA approval, the DEA will make a scheduling determination within ninety days, taking into account recommendations from the FDA controlled substances staff, in order to place the product in a schedule other than Schedule I so that it may be prescribed to patients in the US Furthermore, if the FDA, DEA, or any foreign regulatory authority subsequently determines that any approved and commercialized cannabinoid-based products may have potential for abuse, it may require us to generate more clinical or other data to establish whether or to what extent the substance has an abuse potential, which could result in a re-scheduling of the product and increase the costs associated with marketing that product. The Company has received guidance from the DEA that if a product does not contain any quantity of synthetically produced THC (or any other controlled substance), it is not controlled under the CSA. Additionally, the Company has 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 US, the DEA has removed it from the list of Schedule I chemicals and from the list of controlled substances.

DEA registration and inspection of facilities. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining the necessary registrations may result in delay of the importation, manufacturing, or distribution of any cannabinoid derived products the Company 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 the Company obtains federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. The Company 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 the Company develops 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 the Company 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. The Company does not currently conduct any clinical trials, clinical material manufacturing or repackaging/relabeling in the US; however, the Company is subject to similar laws and regulations in the UK and other countries where the Company is 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, the Company will not be allowed to import that drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. It is always possible the DEA could find that the active substance in a product, even if it is a plant derived substance, could be manufactured in the US. Moreover, Schedule I controlled substances, have never been registered with the DEA for importation commercial purposes, only for scientific and research needs. Therefore, if any of our future products could not be imported, that product would have to be wholly manufactured in the United States, and the Company 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, the Company 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, the Company 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. The Company 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. The Company cannot assure that any of our product candidates will achieve the expected market acceptance and revenue, if and when the Company obtains 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 the Company cannot be certain that the Company 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 the Company fails 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; the Company faces 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 the Company can derive any scientific conclusions or prove that our present assumptions for the current and planned research are scientifically compelling. While the Company is 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. The Company, 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.

The Company is partially dependent on initial and continued market acceptance and proliferation of cannabinoid-derived therapeutic treatments, and specifically ART12.11, our CBD cocrystal. The Company believes 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, the Company 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, the Company does 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, the Company 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. The Company has received guidance from the DEA that if a product does not contain any quantity of synthetically produced THC (or any other controlled substance), it is not controlled under the CSA. Additionally, the Company has 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, the Company 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, the Company 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 the Company decides to commence research based on plant-derived cannabinoids in the US, obtaining and maintaining necessary insurance coverage, for such things as workers compensation, general liability, product liability and directors' and officers' insurance, may be more difficult and expensive for us to find because of our research directions utilizing cannabinoids. There can be no assurance that the Company 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, the Company is compelled to operate without insurance coverage, the Company may be prevented from entering certain business sectors, experience inhibited growth potential and/or expose us to additional risks and financial liabilities.

The Company faces 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 the Company believes that demand for such products will continue to grow, there is no assurance that such increase in demand will happen, that the Company 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. The Company competes 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 the Company is 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.

The Company is highly dependent on our key personnel, and if the Company is not successful in attracting and retaining highly qualified personnel, the Company 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. The Company is highly dependent on our Chief Executive Officer, President, 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 the Company has 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. The Company maintains 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, the Company has 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 the Company is 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.

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

To execute our business plan, the Company will need to add other management, accounting, regulatory, and scientific staff. The Company currently has five employees and utilizes approximately twenty-five consultants and contractors. The Company 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. The Company also intends to add personnel in our research and development and regulatory departments as the Company expands our clinical trial and research capabilities. Moreover, the Company will need to hire additional accounting and other personnel and augment our infrastructure as the Company continues 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.

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

Due to our limited financial resources, the Company has engaged consultants to work on a part-time basis to oversee critical activities and perform services on behalf of the company. Even if the Company is successful in raising additional capital and require those activities and services be performed by full-time employees, there is no guarantee that the Company will be able to hire our current consultants or consultants with similar background and experience to oversee those functions or perform services on behalf of the company. The Company is also at risk that the consultants the Company uses 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 the Company does, 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.

The Company has incurred losses since inception and cannot assure that the Company will ever achieve or sustain profitability.

The Company has incurred losses since inception. The Company expects to continue to incur significant expenses and increasing operating and net losses for the foreseeable future. To date, the Company has 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.

The Company has never been profitable and does not expect to be profitable in the foreseeable future. The Company expects our expenses to increase significantly as the Company pursues our objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, and the Company expects 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. The Company cannot assure that the Company will ever be able to achieve profitability. Even if the Company achieves profitability, the Company may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, license additional programs, establish or maintain development efforts, obtain regulatory approvals, or continue operations.

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.

The Company is 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 the Company has 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. The Company has adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions the Company takes 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 the Company is 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.

The Company 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, the Company 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 the Company is 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 the Company 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, the Company 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, the Company cannot predict whether the patent applications the Company 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 the Company 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 the Company will fail to identify patentable aspects of our research and development output in time to file for or obtain patent protection. Although the Company enters 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, the Company may be open to competition. Further, if the Company encounters delays in our development efforts, the period of time during which the Company 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.

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

The Company 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, the Company 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 the Company or our licensors fail in defending any such claims, in addition to paying monetary damages, the Company 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 the Company 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 the Company may own or license from our licensors or that incorporate certain research in our product candidates that is in the public domain;
- the Company, 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 the Company or our licensors own now or in the future;
- the Company, 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 the Company 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 the Company 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;

- the Company may not develop additional proprietary product candidates that are patentable;
- the patents of others may harm our business if, for example, the Company 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
- the Company 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 the Company 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. The Company 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 the Company 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.

The Company 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 the Company tries to ensure that our employees do not use the proprietary information or know-how of others in their work for us, the Company may be subject to claims that the Company 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 the Company fails in defending any such claims, in addition to paying monetary damages, the Company may lose valuable intellectual property rights or personnel. Even if the Company is 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 the Company cannot maintain compliance with Nasdaq's continued listing requirements.

In order to maintain our listing on The Nasdaq Capital Market tier of The Nasdaq Stock Market LLC ("Nasdaq"), the Company is required to comply with the Nasdaq requirements, which includes maintaining minimum stockholders' equity.

On May 22, 2025, we received a notice from the Nasdaq staff notifying us that, because our stockholders' equity was below $2.5 million as reported on our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, we no longer meet the minimum stockholders' equity requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5550(b)(1). Pursuant to the notice and the Listing Rules of Nasdaq, we submitted a plan to regain compliance with the minimum stockholders' equity requirement within 45 calendar days of receiving the letter from the Staff. This plan was updated and resubmitted to Nasdaq on August 29, 2025. The Nasdaq staff determined that the Company has not completed the capital raising that was discussed in the materials submitted to Nasdaq on July 7, 2025, and August 29, 2025, which the Company expected would enable it to demonstrate compliance with the Listing Rule. As a result, on November 19, 2025, the Company received a delist determination letter from Nasdaq advising the Company that the Nasdaq staff had determined that the Company had not satisfied the conditions set forth in the May 22 letter to regain compliance. Additionally, because the Company's annual shareholder meeting on December 31, 2025, was adjourned due to a lack of a quorum, Nasdaq issued an additional deficiency notice related to the requirement for holding annual meetings. The Company appealed Nasdaq's determination to a hearing panel on January 15, 2026, to stay any further delisting actions. On February 2, 2026, the hearing panel issued an extension to March 30, 2026, for the Company to resolve the minimum shareholders' equity deficiency. The Company held its annual meeting on January 30, 2026, and cured the annual meeting deficiency. Following the hearing panel's extension, the Company's Common Stock will continue to trade on Nasdaq under the symbol "ARTL."

Although we intend to use all reasonable efforts to achieve compliance with all Nasdaq listing standards, there can be no assurance that we will be able to regain compliance with the listing standards or that we will otherwise be in compliance with other applicable Nasdaq listing criteria. Furthermore, Nasdaq may delist our Common stock for public interest concerns, even if we are able to regain compliance for continued listing on Nasdaq under the listing requirements.

If the Company is unable to maintain compliance with Nasdaq's continued listing requirements, 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 the Company is delisted, the Company 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. The Company 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 the Company sells securities in future financings our stockholders may experience immediate dilution and, as a result, our stock price may decline.

The Company 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, the Company may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or Common Stock. If the Company issues 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, the Company does 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, the Company was deemed a "shell company" under applicable SEC rules and regulations because the Company 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, the Company is 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 the Company was required to file such reports and materials), other than Form 8–K reports. The Company is currently subject to the reporting rules under the Exchange Act and expects to remain subject to the reporting requirements under the Exchange Act. However, sales may not be made under Rule 144 unless the Company is 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 the Company agrees 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 the Company 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.

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.

Certain of the outstanding shares of Common Stock may be "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.

The Company does not plan to declare or pay any dividends to our stockholders in the near future.

The Company has not declared any dividends in the past, and the Company does 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.

The Company incurs significant costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a public company, the Company will continue to incur significant legal, accounting, and other expenses. The Company is subject to the reporting requirements of the Exchange Act, which will require, among other things, that the Company files 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 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 the Company operates our business in ways the Company 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, the Company expects these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and the Company may be required to incur substantial costs to maintain the same or similar coverage. The Company cannot predict or estimate the amount or timing of additional costs the Company 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 the Company conducts business.

Our disclosure controls and procedures may not be effective to ensure that the Company makes all required disclosures.

As a public reporting company, the Company is 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 the Company files 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. The Company believes 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 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 the company to advance payment for defending pending or threatened claims;
- limiting the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board;
- controlling the procedures for the conduct and scheduling of board and stockholder meetings;
- limiting the determination of the number of directors on our board and the filling of vacancies or newly created seats on the board to our Board then in office; and
- providing that directors may be removed by stockholders at any time.

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

As a Nevada corporation, the Company is 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, the Company is 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.

The Company is a smaller reporting company, and the Company 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 the Company continues to be a smaller reporting company, the Company 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. The Company cannot predict if investors will find our securities less attractive because the Company 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. The Company does 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, the Company could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. We devote significant resources and designate key personnel, including our Chief Financial Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with human resources, IT, and management. Personnel at all levels and departments are expected to be in compliance with our cybersecurity policies.

We engage consultants and auditors in connection with our risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards. We require each third-party service provider to affirm that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

For additional information regarding whether any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, please refer to Item 1A, "*Risk Factors*," in this Annual Report on Form 10-K.

Governance

One of the key functions of our Board is the informed oversight of our risk management process, including risks from cybersecurity threats. Our Board is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our Board administers its cybersecurity risk oversight function through its Audit Committee.

Our Chief Financial Officer and members of our Audit Committee are primarily responsible to assess and manage our material risks from cybersecurity threats with assistance from third-party service providers that may bring more expertise regarding cybersecurity matters.

Our Chief Financial Officer and members of our Audit Committee oversee our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. The processes by which our Chief Financial Officer and members of our Audit Committee are informed about and monitor the prevention, detection, mitigation, and remediation of cybersecurity incidents includes the following:

Prevention: Our cyber security consultants operate a remote monitoring and management system which enables continuous monitoring of IT components, provides IT maintenance, and installs and maintains security and recovery capabilities, including patch management, antivirus, cloud data back up, and mobile device management.

Detection: Our cyber security consultants continuously monitor our environment for issues and alerts. The security tools that are installed in our systems and devices give them insight into possible suspicious behaviors. When warranted, the cyber security consultants will work with the IT support team to respond to possible security incidents as rapidly as possible.

Remediation: When necessary, our cyber security consultants are prepared to respond as a CIRT (Computer Incident Response Team). If necessary, security experts are prepared to perform DFS (Digital Forensics Sciences) on devices that might have been compromised.

Our Chief Financial Officer and key personnel provide quarterly briefings to the Audit Committee regarding our company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. Our Audit Committee provides regular updates to the Board on such reports.

ITEM 2. PROPERTIES

Our principal executive office is currently located at 505 Lomas Santa Fe, Suite 160, Solana Beach, California 92075, USA. Our United Kingdom subsidiary, Artelo Biosciences Limited maintains an office at the biohub located at Mereside, Alderly Park, Alderly Edge, Cheshire, SK10 4TG, UK. The Solana Beach facility is approximately 800 square feet and the United Kingdom facility is approximately 800 square feet. We do not currently own any real property, including laboratories or manufacturing facilities. We believe our current facilities are sufficient to meet our current needs.

ITEM 3. 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 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information for Common Stock and Warrants

Our Common Stock and warrants began trading on The Nasdaq Capital Market tier of Nasdaq on June 21, 2019, under the trading symbols "ARTL" and "ARTLW", respectively. On June 17, 2024, the warrants expired and were removed from trading.

Holders

As of February 20, 2026, there were approximately 167 registered stockholders of record of our Common Stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Equity Compensation Plan

Our equity plan information required by this Item is incorporated by reference to the information in Part III, Item 12 of this Annual Report on Form 10-K.

Dividend Policy

We have not paid any cash dividends to stockholders. The declaration of any future cash dividend will be at the discretion of our Board and will depend upon our earnings, if any, our capital requirements and financial position, our general economic conditions, and other pertinent conditions. It is our present intention not to pay any cash dividends in the foreseeable future, but rather to reinvest earnings, if any, in our business operations.

Recent Sales of Unregistered Securities

We did not sell any equity securities which were not registered under the Securities Act during the year ended December 31, 2025, that were not otherwise disclosed on our quarterly reports on Form 10-Q or our current reports on Form 8-K filed during the year ended December 31, 2025.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in Part I, Item 1A and elsewhere in this Annual Report on Form 10-K. See "Forward-Looking Statements."

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 novel, benzimidazole dual cannabinoid (CB) agonist that targets both the CB1 and CB2 receptors. This synthetic small molecule program is a G protein-coupled receptor ("GPCR") designated ART27.13 and was initially developed by AstraZeneca plc. We are developing ART27.13 as a potential treatment for cancer-related anorexia and it is currently in a Phase 1b/2a trial, titled the Cancer Appetite Recovery Study ("CAReS"). In an interim analysis of the on-going Phase 2a CAReS trial, patients with cancer anorexia receiving ART27.13 demonstrated a mean weight gain of over 6% compared to a 5% loss in the placebo group, while maintaining a safety profile similar to the Phase 1b despite doses up to twice the previous maximum. Currently there is no FDA approved treatment for cancer anorexia cachexia syndrome.

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 ("CIPN"). 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. In June 2025, we announced favorable results from our first-in-human study evaluating ART26.12. The Phase 1 Single Ascending Dose (SAD) study was designed to assess the safety, tolerability, and pharmacokinetics of ART26.12 in healthy volunteers and enrolled 49 subjects. All adverse events (AEs) were mild, transient, and self-resolving. No drug-related AEs were observed in the blinded dataset, and no tolerability issues or safety signals were detected across multiple assessments (vital signs, ECGs, clinical laboratory tests, physical examinations, and visual analogue mood scales). In addition, full dose-exposure profiles were successfully explored. Plasma analysis confirmed dose-dependent, linear absorption across the evaluated range. A wide safety margin was observed between estimated therapeutic plasma concentrations and the highest exposure levels achieved, supporting potential titration for maximum efficacy in future studies. In addition to ART26.12 in CIPN, our extensive library of small molecule inhibitors of Fatty Acid Binding Proteins ("FABPs") has shown therapeutic potential for the treatment of certain cancers, neuropathic and nociceptive pain, psoriasis, and anxiety disorders.

ART12.11 is our wholly owned, proprietary cocrystal composition of cannabidiol (CBD) and tetramethylpyrazine (TMP). Isolated as a single crystalline form, ART12.11 has exhibited better pharmacokinetics and improved efficacy compared to other forms of CBD in nonclinical studies. Greatly enhanced pharmaceutical properties, including physicochemical, pharmacokinetic, and pharmacodynamic advantages have been observed with ART12.11. We believe a more consistent and improved bioavailability profile may ultimately lead to increased safety and efficacy in humans, thus making ART12.11 a preferred CBD pharmaceutical composition. The U.S. issued composition of matter patent for ART12.11 is enforceable until December 10, 2038 and has now been granted or validated in 21 additional countries.

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 CB1 and CB2 full-receptor agonist. 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 plc. 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 plc, 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 of 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 eight 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 with 18 clinical sites across five countries.

As of December 31, 2025, 32 participants have been enrolled. On September 3, 2025, we announced interim results from the Phase 2a CAReS trial. In the interim analysis, 18 evaluable patients—primarily with lung and gastrointestinal cancers not receiving cyclic chemotherapy—were included. After 12 weeks of treatment in patients who were titrated to the top dose evaluated of 1300 micrograms (n=5), ART27.13 demonstrated compelling increases in mean body weight of 6.38% (Standard Deviation or SD 9.50) compared to patients on placebo (n=6) who lost -5.42% (SD 8.17). The maximum weight gain in the ART27.13 group reached 18.5%, versus only 0.4% in placebo. The maximum weight loss in the placebo arm was -17.4%, compared to just -3.0% in the ART27.13 group. Additional benefits were seen in lean body mass, with a +4.23% increase (SD 5.37) in the treatment group versus a -3.15% loss (SD 4.89) in placebo at one month, as well as qualitative improvements in total and weekly activity scores.

Safety results were consistent with prior findings. Among the 32 participants enrolled in the CAReS Phase 2 trial to date, seven patients (22%) experienced adverse events that may be related to ART27.13. All were mild or moderate, with the exception of a single case of severe malaise, and no drug-related serious adverse events were reported. These data are aligned with safety outcomes observed in Phase 1 of CAReS, supporting ART27.13's overall favorable tolerability and acceptable safety profile.

Our second in-licensed patented program is being advanced from our platform of small-molecule inhibitors of FABPs, notably FABP5. 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. 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 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 June 10, 2024 and received a study may proceed notice from the FDA on July 8, 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.

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 (expense)

Our other income (expense) consists of gain on investment, interest expense, interest expense – related party, loss on extinguishment of debt, loss on extinguishment of debt – related party, net change in fair value of digital assets and changes in fair value of the Company's trading marketable securities.

Results of Operations

Year ended December 31, 2025 compared to the year ended December 31, 2024

(In thousands)	Year ended December 31, 2025	2024	Change
Operating Expenses			
General and administrative	$ 5,981	$ 4,115	$ 1,866
Research and development	5,423	5,993	(570)
Total Operating Expenses	11,404	10,108	1,296
Loss from Operations	(11,404)	(10,108)	(1,296)
Other income (expense)	(1,475)	282	(1,757)
Net Loss	$ (12,879)	$ (9,826)	$ (3,053)

Our operating expenses for the year ended December 31, 2025, were $11.4 million compared to $10.1 million for the same period in 2024. The increase in operating expenses for the year ended December 31, 2025, was primarily the result of increased professional fees during the year related to our financing activities and increases in the service cost of stock-based compensation offset by a decrease in research and development activities compared to the prior year, due to the timing and level of the research being conducted.

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 $12.9 million for the year ended December 31, 2025.

In July 2023, we 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 us to sell, from time to time, up to $75,000 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 as of relevant measurement dates under applicable securities laws.

On May 1, 2025, we issued at-market, unsecured convertible notes with gross proceeds of $900. The convertible notes bore interest at 12.0% and had a maturity of 180 days. The convertible notes were subject to voluntary and automatic provisions for conversion into our common stock, as well as conversion into warrants to purchase our common stock for a five-year period at a price of $6.24 per share, as adjusted for the subsequent reverse stock split. Certain members of our board of directors, an officer and consultants to the Company acquired $350 of the convertible notes. On October 28, 2025, we entered into a subscription agreement pursuant to which it issued and sold to certain investors, and the investors purchased (by converting all or a portion of the unconverted voluntary conversion portion of unpaid principal balance and accrued interest due to such investors upon the maturity of the convertible promissory notes issued to the investors on May 1, 2025): (i) convertible notes to the investors in an aggregate principal amount of $692; and (ii) warrants (the “Warrants”) to purchase an aggregate of 438,182 shares of our common stock, par value $0.001 per share, at an exercise price of $3.40 per share. The Notes have a maturity of 180 days and bear interest at 12.0%.

On June 24, 2025, we entered into a securities purchase agreement with the purchasers named therein, for the private placement of (i) 136,843 shares of our common stock at $5.82 per share, (ii) pre-funded warrants to purchase 93,180 shares of common stock at an exercise price of $0.001 per share at $5.819 per pre-funded warrant, (iii) warrants to purchase 460,046 shares of common stock at an exercise price of $5.82 per share, and (iv) warrants to purchase 230,023 shares of common stock at an exercise price of $10.00 per share. Total gross proceeds were $1,425, net proceeds were $1,079 after transaction costs of $346.

On July 18, 2025, we entered into an At-The-Market Offering Agreement (the "Sales Agreement") with R.F. Lafferty & Co., Inc. ("R.F. Lafferty") under which we may offer and sell up to $6.5 million of shares of our common stock from time to time through an "at the market" offering program under which R.F. Lafferty will act as sales agent. Under the Sales Agreement, we will set the parameters for the sale of shares, including the number or dollar amount of shares to be issued, the time period during which sales are requested to be made, limitations on the number or dollar amount of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, R.F. Lafferty may sell the shares by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"). We have no obligation to sell any shares under the Sales Agreement and may at any time suspend solicitation and offers under the Sales Agreement. The shares will be issued pursuant to our shelf registration statement on Form S-3, including the prospectus supplement contained therein, which was declared effective by the SEC on July 14, 2023. During the quarter ended September 30, 2025, 50,858 shares were sold under the Sales Agreement for net proceeds of $442.

On August 4, 2025, we entered into a securities purchase agreement for an at-the market PIPE (private investment in public equity) for the purchase and sale of securities at a price of $10.45 per unit, consisting of: (a) 906,687 shares of common stock (or pre-funded warrants in lieu thereof); (b) three-year warrants to purchase 906,687 shares of common stock at an exercise price of $10.20 per share; and (c) three-year warrants to purchase 906,687 shares of common stock at an exercise price of $50.00 per share, for expected aggregate gross proceeds of approximately $9,475. The Company agreed that the net proceeds of the sale will be used to purchase Solana's native token, SOL. On August 19, 2025, this securities purchase agreement was terminated with mutual consent of us and investors and all proceeds received from investors were returned.

On September 4, 2025, we entered into an underwriting agreement (the "First Underwriting Agreement") with R.F. Lafferty & Co., Inc. ("Underwriter"), the sole book-running manager and underwriter, relating to an underwritten offering of (i) 640,924 shares of common stock at a price to the public of $4.40 per share, and (ii) pre-funded warrants to purchase up to 40,894 shares of common stock at an exercise price of $0.001 per share, at a price to the public of $4.399 per pre-funded warrant, for aggregate gross proceeds of approximately $3,000, before deducting underwriting discounts and commissions and other estimated offering expenses of $310 resulting in net proceeds of $2,690. The offering was closed on September 5, 2025. We delivered the securities to the Underwriter on the same day. Pursuant to the First Underwriting Agreement, we granted the Underwriter a 45-day option to purchase up to an additional 102,272 shares of common stock at the share purchase price per share and/or pre-funded warrants at the pre-funded warrant purchase price, less the underwriting discounts to cover overallotments, if any. The Underwriter purchased an additional 57,914 shares of common stock under this option for net proceeds of $237.

On September 30, 2025, we entered into an underwriting agreement (the "Second Underwriting Agreement") with the Underwriter, the sole book-running manager and underwriter, relating to an underwritten offering of (i) 441,210 shares (the "Shares") of our common stock, par value $0.001 per share, at a price to the public of $4.40 per share (the "Share Purchase Price"), and (ii) pre-funded warrants to purchase up to 13,335 shares of common stock at an exercise price of $0.001 per share at a price to the public of $4.399 per pre-funded warrant, for aggregate gross proceeds of approximately $2,000, before deducting underwriting discounts and commissions and the other estimated offering expenses of $240 resulting in net proceeds of $1,760. Pursuant to the Second Underwriting Agreement, the Company granted the Underwriter a 45-day option to purchase up to an additional 68,181 shares of common stock at the share purchase price per share and/or pre-funded warrants at the pre-funded warrant purchase price, less the underwriting discounts to cover over-allotments, if any. This option was not exercised by the Underwriter.

To continue operations, we 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 we will be successful in acquiring additional funding, that our 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 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.

As of December 31, 2025, we had cash, cash equivalents, and investments of $0.6 million.

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)	December 31, 2025	December 31, 2024	Change
Current Assets	$ 695	$ 2,557	$ (1,862)
Current Liabilities	4,044	1,772	2,272
Working Capital	$ (3,349)	$ 785	$ (4,134)

Our total current assets as of December 31, 2025, were $0.7 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 December 31, 2025, were $4.0 million as compared to total current liabilities of $1.8 million as of December 31, 2024. The increase in current liabilities was primarily due to slower payments to the Company's vendors due to cash constraints as well as the issuance of convertible notes of $0.6 million outstanding at December 31, 2025, for which there was no comparable outstanding balance in the prior year.

Historical Cash Flows

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

	Year ended December 31,		
(In thousands)	2025	2024	Change
Cash Flows used in operating activities	$ (8,520)	$ (8,350)	$ (170)
Cash Flows (used in) provided by investing activities	(62)	7,769	(7,831)
Cash Flows provided by financing activities	6,867	112	6,755
Effect of exchange rate changes on cash	(23)	(8)	(15)
Net change in cash and cash equivalent during period	$ (1,738)	$ (477)	$ (1,261)

Cash Flows from Operating Activities

During the year ended December 31, 2025, cash used in operating activities was $8.5 million compared to $8.4 million during the year ended December 31, 2024. Cash used in operating activities during the year ended December 31, 2025, was attributed to a net loss of $12.9 million, a non-cash loss of $1.2 million associated with the extinguishment of the convertible notes offset by decreases in operating assets and liabilities of $1.7 million and non-cash stock-based compensation of $1.1 million, and non-cash amortization of debt discounts and debt issuance costs of $0.3 million. Cash used in operating activities during the year ended December 31, 2024, was attributed to a net loss of $9.8 million and a non-cash gain of $0.3 million associated with our trading of marketable securities offset by decreases in operating assets and liabilities of $0.9 million and non-cash stock-based compensation of $0.8 million.

Cash Flows from Investing Activities

During the year ended December 31, 2025, cash used in investing activities was $0.1 million compared to cash provided by investing activities of $7.8 million during the year ended December 31, 2024. Cash flows used in investing activities in 2025 of $0.1 million were the result of $0.3 million from the purchase of Solana crypto currency offset by $0.2 million from its subsequent sale. Cash flows provided by investing activities in 2024 of $7.8 million were the result of $8.3 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 year ended December 31, 2025, cash flows provided by financing activities were the result of the net proceeds from the issuance of common shares of $6.2 million, net proceeds from the issuance of convertible notes of $0.6 million and proceeds from the exercise of warrants of $0.1 million. During the year ended December 31, 2024, cash flows provided by financing activities were 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 [11], "*Commitments and Contingencies*" to the financial statements in this Annual Report on Form 10-K.

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

During the year ended December 31, 2025, the Company adopted ASU 2023-08, Intangibles-Goodwill and Other-Crypto Assets (Subtopic 350-60): Accounting for and Disclosure of Crypto Assets ("ASU 2023-08"). The standard requires all entities holding cryptocurrency assets to measure these assets at fair value and disclose significant holdings. As the current reporting period was the first period in which the Company held cryptocurrency assets, there was no impact on any prior reporting periods as a result of the adoption of this standard.

ITEM 7A. 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ARTELO BIOSCIENCES, INC.
INDEX TO AUDITED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Artelo Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Artelo Biosciences, Inc. and its subsidiaries (collectively, the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2015.
Houston, Texas
February 23, 2026

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

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash and cash equivalents	$ 600	$ 2,338
Prepaid expenses and other current assets	95	219
Total Current Assets	695	2,557
Operating lease right-of-use assets	64	99
Intangible asset	2,039	2,039
Other assets	3	3
TOTAL ASSETS	$ 2,801	$ 4,698
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and accrued liabilities	$ 3,035	$ 1,676
Due to related parties	345	61
Operating lease liabilities - current portion	40	35
Accrued interest - convertible notes	11	-
Accrued interest – convertible notes – related party	4	-
Convertible notes	437	-
Convertible notes – related party	172	-
Total Current Liabilities	4,044	1,772
Operating lease liabilities	29	69
TOTAL LIABILITIES	4,073	1,841
STOCKHOLDERS' EQUITY		
Preferred Stock, par value $0.001, 69,444 shares authorized, 0 shares issued and outstanding as of December 31, 2025, and 2024	-	-
Common Stock, par value $0.001, 500,000,000 shares authorized and 2,018,746 and 567,582 shares issued and outstanding as of December 31, 2025, and 2024, respectively	2	1
Additional paid-in capital	62,013	53,194
Accumulated deficit	(63,015)	(50,136)
Accumulated other comprehensive loss	(272)	(202)
TOTAL STOCKHOLDERS' (DEFICIT) EQUITY	(1,272)	2,857
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 2,801	$ 4,698

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

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

	Year ended December 31,	
	2025	**2024**
OPERATING EXPENSES		
General and administrative	$ 5,981	$ 4,115
Research and development	5,423	5,993
Total Operating Expenses	11,404	10,108
Loss from Operations	(11,404)	(10,108)
OTHER INCOME (EXPENSE)		
Gain on investment	22	-
Interest expense	(194)	-
Interest expenses - related party	(83)	-
Loss on extinguishment of debt	(825)	-
Loss on extinguishment of debt - related party	(333)	-
Net change in fair value of digital assets	(62)	-
Net change in fair value of trading marketable securities	-	282
Total other (expense) income	(1,475)	282
Provision for income taxes	-	-
NET LOSS	$ (12,879)	$ (9,826)
OTHER COMPREHENSIVE INCOME (LOSS)		
Foreign currency translation adjustments	(70)	1
Total Other Comprehensive Income (Loss)	(70)	1
TOTAL COMPREHENSIVE LOSS	$ (12,949)	$ (9,825)
Basic and Diluted Loss per Common Share	$ (12.52)	$ (18.30)
Basic and Diluted Weighted Average Common Shares Outstanding	1,029	537

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

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

	Common stock		Additional paid-in capital	Accumulated Deficit	Accumulated Other Comprehensive Income (loss)	Total
	Shares	Amount				
Balance, December 31, 2023	552	$ 1	$ 52,264	$ (40,310)	$ (203)	$ 11,752
Common stock issued for cash, net of issuance costs	15	-	112	-	-	112
Stock based compensation	-	-	818	-	-	818
Net loss for the period	-	-	-	(9,826)	-	(9,826)
Other comprehensive loss	-	-	-	-	1	1
Balance, December 31, 2024	567	$ 1	$ 53,194	$ (50,136)	$ (202)	$ 2,857
Common stock issued for cash, net of issuance costs	1,329	1	6,150	-	-	6,151
Warrants exercised	123	-	132	-	-	132
Fair value of warrants issued upon extinguishment of debt	-	-	1,395	-	-	1,395
Stock-based compensation	-	-	1,142	-	-	1,142
Net loss for the period	-	-	-	(12,879)	-	(12,879)
Other comprehensive loss	-	-	-	-	(70)	(70)
Balance, December 31, 2025	2,019	$ 2	$ 62,013	$ (63,015)	$ (272)	$ (1,272)

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

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

	Year ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (12,879)	$ (9,826)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,142	818
Net change in fair value of trading marketable securities	-	(282)
Net change in fair value of digital assets	62	-
Non-cash lease expense	35	33
Loss on extinguishment of debt	825	-
Loss on extinguishment of debt - related party	333	-
Amortization of debt discounts and debt issuance costs	146	-
Amortization of debt discounts and debt issuance costs - related party	62	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	129	457
Accounts payable and accrued liabilities	1,308	449
Accounts payable - related parties	283	31
Accrued interest	48	-
Accrued interest – related party	21	-
Fixed cash payments related to operating leases	(35)	(30)
Net cash used in operating activities	(8,520)	(8,350)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of digital assets	(250)	-
Proceeds from disposition of digital assets	188	-
Investment in trading marketable securities	-	(481)
Proceeds from disposition of marketable securities	-	8,250
Net cash (used in) provided by investing activities	(62)	7,769
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common shares for cash, net	6,151	112
Proceeds from issuance of convertible notes, net	419	-
Proceeds from issuance of convertible notes, net – related party	189	-
Proceeds from exercise of warrants	132	-
Repayment of convertible note	(24)	-
Net cash provided by financing activities	6,867	112
Effect of exchange rate changes on cash	(23)	(8)
Net change in cash and cash equivalents	(1,738)	(477)
Cash and cash equivalents - beginning of period	2,338	2,815
Cash and cash equivalents - end of period	$ 600	$ 2,338
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

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

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 Solana Beach, 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, in the United Kingdom ("UK"), Trinity Research & Development Limited, on June 2, 2017 and in Canada, Artelo Biosciences Corporation, on March 18, 2020. On January 8, 2020, Trinity Research and Development Limited changed its name to Artelo Biosciences Limited. 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 $12,879 during the year ended December 31, 2025. As of December 31, 2025, we had cash and cash equivalents of $600.

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 as of relevant measurement dates under applicable securities laws.

On May 1, 2025, the Company issued at-market, unsecured convertible notes with gross proceeds of $900. The convertible notes bore interest at 12.0% and had a maturity of 180 days. The convertible notes were 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 $6.24 per share, as adjusted for the subsequent reverse stock split. Certain members of the Company's board of directors, an officer and consultants to the Company acquired $350 of the convertible notes. On October 28, 2025, Artelo Biosciences, Inc. (the "Company") entered into a Subscription Agreement (the "Subscription Agreement") pursuant to which it issued and sold to certain investors (the "Investors"), and the Investors purchased (by converting all or a portion of the unconverted "Voluntary Conversion" portion of unpaid principal balance and accrued interest due to such Investors upon the maturity of the convertible promissory notes issued to the Investors on May 1, 2025): (i) convertible notes (the "Notes") to the Investors in an aggregate principal amount of $692, of which $195 was to related parties; and (ii) warrants (the "Warrants") to purchase an aggregate of 438,182 shares of the Company's common stock, par value $0.001 per share ("Common Stock"), at an exercise price of $3.40 per share (collectively, the "Offering"). The Notes have a maturity of 180 days and bear interest at 12.0%.

On June 24, 2025, the Company entered into a securities purchase agreement with the purchasers named therein, for the private placement of (i) 136,843 shares of the Company's common stock at $5.82 per share, (ii) pre-funded warrants to purchase 93,180 shares of common stock at an exercise price of $0.001 per share at $5.819 per pre-funded warrant, (iii) warrants to purchase 460,046 shares of common stock at an exercise price of $5.82 per share, and (iv) warrants to purchase 230,023 shares of common stock at an exercise price of $10.00 per share. Total gross proceeds were $1,425, net proceeds were $1,079 after transaction costs of $346.

On July 18, 2025, the Company entered into an At-The-Market Offering Agreement (the "Sales Agreement") with R.F. Lafferty & Co., Inc. ("R.F. Lafferty") under which we may offer and sell up to $6.5 million of shares of our common stock from time to time through an "at the market" offering program under which R.F. Lafferty will act as sales agent. Under the Sales Agreement, the Company will set the parameters for the sale of shares, including the number or dollar amount of shares to be issued, the time period during which sales are requested to be made, limitations on the number or dollar amount of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, R.F. Lafferty may sell the shares by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"). We have no obligation to sell any shares under the Sales Agreement and may at any time suspend solicitation and offers under the Sales Agreement. The shares will be issued pursuant to the Company's shelf registration statement on Form S-3, including the prospectus supplement contained therein, which was declared effective by the SEC on July 14, 2023. During the year ended December 31, 2025, 50,858 shares were sold under the Sales Agreement for net proceeds of $442.

On August 4, 2025, the Company entered into a securities purchase agreement for an at-the market PIPE (private investment in public equity) for the purchase and sale of securities at a price of $10.45 per unit, consisting of: (a) 906,687 shares of common stock (or pre-funded warrants in lieu thereof); (b) three-year warrants to purchase 906,687 shares of common stock at an exercise price of $10.20 per share; and (c) three-year warrants to purchase 906,687 shares of common stock at an exercise price of $50.00 per share, for expected aggregate gross proceeds of approximately $9,475. The Company agreed that the net proceeds of the sale would be used to purchase Solana's native token, SOL. On August 19, 2025, this securities purchase agreement was terminated with mutual consent of the Company and investors and all proceeds received from investors were returned.

On September 4, 2025, the Company entered into an underwriting agreement (the "First Underwriting Agreement") with R.F. Lafferty & Co., Inc. ("Underwriter"), the sole book-running manager and underwriter, relating to an underwritten offering of (i) 640,924 shares of common stock at a price to the public of $4.40 per share, and (ii) pre-funded warrants to purchase up to 40,894 shares of common stock at an exercise price of $0.001 per share, at a price to the public of $4.399 per pre-funded warrant, for aggregate gross proceeds of approximately $3,000, before deducting underwriting discounts and commissions and other estimated offering expenses of $310 resulting in net proceeds of $2,690. The offering was closed on September 5, 2025. The Company delivered the securities to the Underwriter on the same day. Pursuant to the First Underwriting Agreement, the Company granted the Underwriter a 45-day option to purchase up to an additional 102,272 shares of common stock at the share purchase price per share and/or pre-funded warrants at the pre-funded warrant purchase price, less the underwriting discounts to cover overallotments, if any. The Underwriter purchased an additional 57,914 shares of common stock under this option for net proceeds of $237.

On September 30, 2025, the Company entered into an underwriting agreement (the "Second Underwriting Agreement") with the Underwriter, the sole book-running manager and underwriter, relating to an underwritten offering of (i) 441,210 shares (the "Shares") of common stock, par value $0.001 per share, of the Company at a price to the public of $4.40 per share (the "Share Purchase Price"), and (ii) pre-funded warrants to purchase up to 13,335 shares of common stock at an exercise price of $0.001 per share at a price to the public of $4.399 per pre-funded warrant, for aggregate gross proceeds of approximately $2,000, before deducting underwriting discounts and commissions and the other estimated offering expenses of $240 resulting in net proceeds of $1,760. Pursuant to the Second Underwriting Agreement, the Company granted the Underwriter a 45-day option to purchase up to an additional 68,181 shares of common stock at the share purchase price per share and/or pre-funded warrants at the pre-funded warrant purchase price, less the underwriting discounts to cover over-allotments, if any. This option was not exercised by the Underwriter.

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, 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.

Reverse Stock Split

On June 12, 2025, the Company filed with the Secretary of State of the State of Nevada a Certificate of Change, pursuant to Nevada Revised Statutes 78.209, to effect a one-for-six (1-for-6) reverse stock split (the "Reverse Split") of the Company's issued and outstanding common stock, par value $0.001 per share. The Reverse Split was effective as of 12:01 a.m. Eastern Time on June 13, 2025. Pursuant to the Nevada Revised Statutes 78.207, the Company's board of directors has the authority to effect a reverse stock split without stockholder approval if the number of authorized shares of common stock and the number of outstanding shares of common stock are proportionally reduced.

As a result of the Reverse Split, each six (6) pre-split shares of common stock outstanding were automatically combined into one (1) new share of common stock without any action on the part of the holders, and the number of outstanding shares of common stock was reduced from 3,280,000 to approximately 546,667. The number of authorized shares of common stock was reduced from 50,000,000 to 8,333,333, while the number of authorized shares of preferred stock was reduced from416,667 to 69,444. On August 28, 2025, the Company held a special meeting of stockholders in which the shareholders voted to increase the authorized number of shares of common stock from 8,333,333 shares to 500,000,000 shares.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The financial statements and related disclosures have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). The financial statements have been prepared using the accrual basis of accounting in accordance with GAAP. 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 R&D consultants. Clinical studies and outside services costs relate primarily to services performed by clinical research organizations associated with clinical trials 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 when received from the United Kingdom government for spending on R&D as an offset of R&D expenses. The Company received R&D tax credits of $704 and $1,349 during the years ended December 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 $600 and $2,338 in cash and cash equivalents at December 31, 2025, and 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 December 31, 2025, was approximately $171. 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.

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 December 31, 2025, and 2024.

Digital Assets

The Company's digital assets consisted solely of our investment in Solana's native token, SOL, which the Company divested prior to December 31, 2025. The cost basis of the Company's digital assets is calculated using the first-in, first-out (FIFO) method.

The Company initially records its digital assets at their cost, which includes the capitalization of any transaction costs or fees, which are subsequently, remeasured at fair value based on the SOL price quoted from its principal market at the end of each reporting period in accordance with ASC 820, Fair Value Measurement, with changes in fair value recognized on the consolidated statements of operations.

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 years ended December 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.

	December 31, 2025	December 31, 2024
Stock options	227,842	128,976
Warrants	1,398,741	23,315
	1,626,583	152,291

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

During the year ended December 31, 2025, the Company adopted ASU 2023-08, Intangibles-Goodwill and Other-Crypto Assets (Subtopic 350-60): Accounting for and Disclosure of Crypto Assets ("ASU 2023-08"). The standard requires all entities holding cryptocurrency assets to measure these assets at fair value and disclose significant holdings. As the current reporting period was the first period in which the Company held cryptocurrency assets, there was no impact on any prior reporting periods as a result of the adoption of this standard.

NOTE 3 – SEGMENT REPORTING

Operating segments are comprised of the components of an entity in which separate information is available for evaluation by the Company's CODM, 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 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.

	Year ended December 31,	
	2025	2024
General and administrative		
Employee and director compensation	$ 1,253	$ 1,173
Stock-based compensation	674	501
Professional fees	2,846	1,133
Other general and administrative [(a)]	1,208	1,308
Total general and administrative	$ 5,981	$ 4,115

	Year ended December 31,	
	2025	2024
Research and development		
Employee compensation	$ 1,278	$ 1,166
Stock-based compensation	467	317
Professional fees	3,666	5,169
Research and development tax credits	(704)	(1,349)
Other research and development [(b)]	716	690
Total research and development	$ 5,423	$ 5,993

(a) Consists of investor relations, travel and other office expenses.
(b) Consists of supplies and other items used in research and development activities.

NOTE 4 – DIGITAL ASSETS

During the year ended December 31, 2025, the Company purchased 1,524.69 units of Solana cryptocurrency at a cost of $250, which were subsequently sold with proceeds to the Company of $188 and a loss of $62 was recognized. The Company did not hold any digital assets as of December 31, 2025, and 2024.

NOTE 5 – RELATED PARTY TRANSACTIONS

During the years ended December 31, 2025, and 2024, a company owned by the Senior Vice President, European Operations, provided consulting services totaling $19 and $9, respectively. As of December 31, 2025, and 2024, there was $3 and $1, outstanding, respectively.

During the years ended December 31, 2025, and 2024, a company significantly influenced by a director of a subsidiary of the Company provided professional services totaling $79 and $100, respectively. As of December 31, 2025, and 2024, there was $8 and $36 outstanding, respectively.

During the years ended December 31, 2025, and 2024, a company controlled by a director of a subsidiary of the Company provided professional services totaling $84 and $78, respectively. As of December 31, 2025, and 2024, there was $0 and $24 outstanding, respectively.

As of December 31, 2025, and 2024, there was $333 and $0, respectively, payable to directors of the Company for unpaid board compensation.

NOTE 6 – CONVERTIBLE NOTES

Between April 27, 2025, and May 1, 2025, the Company entered into subscription agreements with various investors, pursuant to which the Company issued convertible notes (the "Notes") to the investors in an aggregate principal amount of $900 (collectively, the "Notes Offering"). A portion of the Notes was convertible into shares of the Company's common stock, at the election of each investor, pursuant to the Voluntary Conversion (defined below) and the remaining portion of each Note was to be converted into warrants to purchase shares of the Company's common stock. The sale and issuance of the Notes closed on May 1, 2025.

At the Maturity Date (defined below), the investor had the ability (at the investor's sole option) to convert all of that certain unpaid portion of principal and accrued interest of the investor's Note into shares of common stock (the "Voluntary Conversion"), specifically into that number of shares of common stock (the "Converted Shares") equal to the unpaid principal balance and any accrued interest of each Note divided by $7.74. The amount of principal balance and any accrued interest of each Note convertible pursuant to the Voluntary Conversion was equal to the number of Converted Shares multiplied by $6.24. Should the investor not elect Voluntary Conversion, such portion of the unpaid principal balance and any accrued interest of each Note subject to Voluntary Conversion became immediately due and payable in cash.

The Notes accrued interest at a rate of12% per annum, which would have adjusted to 20% upon an Event of Default (as defined in the Notes). All unpaid principal, together with any then unpaid and accrued interest and other amounts payable thereunder, became due and payable 180 days after the closing of the Notes Offering (the "Maturity Date"). Upon the closing of the Notes, the Company recorded deferred debt costs of $163 associated with transaction costs of the Notes.

Effective October 28, 2025, the Company entered into an agreement pursuant to which it issued and sold to certain investors, and the investors purchased (by converting all or a portion of the unconverted portion of unpaid principal balance and accrued interest due to such investors upon the maturity of the convertible promissory notes issued to the investors on May 1, 2025): (i) convertible notes in an aggregate principal amount of $692, of which $195 was for related parties; (ii) warrants to purchase an aggregate of 438,182 shares of the Company's common stock, par value $0.001 per share, at an exercise price of $3.40 per share; and (iii) warrants to purchase an aggregate of246,498 warrants of the Company's common stock, par value $0.001 per share, at an exercise price of $6.24 per share. The notes will accrue interest at a rate of12% per annum. All unpaid principal, together with any then unpaid and accrued interest and other amounts payable thereunder, shall be due and payable 180 days after the effective date. At any time prior to the Maturity Date, all or any portion of the outstanding principal amount of the Notes, together with the accrued and unpaid interest, shall be convertible, in whole or in part, into shares of Common Stock, at a conversion price of $3.40. Each warrant is immediately exercisable after issuance for five (5) years. The Company accounted for this transaction as an extinguishment of debt in accordance with ASC 470, Debt, and realized a loss on the extinguishment of debt of $1,158 during the year ended December 31, 2025 of which $333 was from related parties.

The Company utilizes the Black-Scholes model to value its warrants. During the year ended December 31, 2025, the Company utilized the following assumptions:

	Year ended December 31, 2025
Expected term	2.50 years
Expected average volatility	105%
Expected dividend yield	-
Risk-free interest rate	3.50%

As of December 31, 2025, the net carrying value of the Notes is $609 which includes principal of $692 and deferred debt costs of $83. During the year ended December 31, 2025, the Company recorded interest expense of $278 associated with the accretion of accrued interest of $69 and $209 amortization of deferred debt costs.

NOTE 7 - EQUITY

Preferred Stock

The Company has authorized 69,444 shares of preferred stock with a par value of $0.001 per share.

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

Common Stock

The Company has authorized 500,000,000 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 December 31, 2025, and 2024, there were2,018,746 and 567,582, respectively, shares of common stock issued and outstanding, respectively.

On June 26, 2025, the Company closed a private placement of (i)136,843 shares of the Company's common stock at $5.82 per share, (ii) pre-funded warrants to purchase 93,180 shares of common stock at an exercise price of $0.001 per share at $5.819 per pre-funded warrant, (iii) warrants to purchase460,046 shares of common stock at an exercise price of $5.82 per share, and (iv) warrants to purchase 230,023 shares of common stock at an exercise price of $10.00 per share. Each share or, at the election of the purchaser in lieu of shares, each pre-funded warrant, was issued and sold along with two (2) $5.82 warrants and one (1) $10.00 warrant. The combined purchase price for the securities was (i) $6.195 per share of common stock and three accompanying warrants and (ii) $6.194 per pre-funded warrant and three accompanying warrants. Total gross proceeds were $1,425, net proceeds were $1,079 after transaction costs of $346.

On July 18, 2025, the Company entered into a Sales Agreement with R.F. Lafferty under which we may offer and sell up to $6.5 million of shares of our common stock from time to time through an "at the market" offering program under which R.F. Lafferty will act as sales agent. Under the Sales Agreement, the Company will set the parameters for the sale of shares, including the number or dollar amount of shares to be issued, the time period during which sales are requested to be made, limitations on the number or dollar amount of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, R.F. Lafferty may sell the shares by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act. We have no obligation to sell any shares under the Sales Agreement and may at any time suspend solicitation and offers under the Sales Agreement. The shares will be issued pursuant to the Company's shelf registration statement on Form S-3, including the prospectus supplement contained therein, which was declared effective by the SEC on July 14, 2023. During the year ended December 31, 2025, 50,858 shares were sold under the Sales Agreement for net proceeds of $442.

On September 4, 2025, the Company entered into an underwriting agreement (the "First Underwriting Agreement") with R.F. Lafferty & Co., Inc. ("Underwriter"), the sole book-running manager and underwriter, relating to an underwritten offering of (i) 640,924 shares of common stock at a price to the public of $4.40 per share, and (ii) pre-funded warrants to purchase up to 40,894 shares of common stock at an exercise price of $0.001 per share, at a price to the public of $4.399 per pre-funded warrant, for aggregate gross proceeds of approximately $3,000, before deducting underwriting discounts and commissions and other estimated offering expenses of $310 resulting in net proceeds of $2,690. The offering was closed on September 5, 2025. The Company delivered the securities to the Underwriter on the same day. Pursuant to the First Underwriting Agreement, the Company granted the Underwriter a 45-day option to purchase up to an additional 102,272 shares of common stock at the share purchase price per share and/or pre-funded warrants at the pre-funded warrant purchase price, less the underwriting discounts to cover overallotments, if any. The Underwriter purchased an additional 57,914 shares of common stock under this option for net proceeds of $237.

On September 30, 2025, the Company entered into an underwriting agreement (the "Second Underwriting Agreement") with the Underwriter, the sole book-running manager and underwriter, relating to an underwritten offering of (i) 441,210 shares (the "Shares") of common stock, par value $0.001 per share, of the Company at a price to the public of $4.40 per share (the "Share Purchase Price"), and (ii) pre-funded warrants to purchase up to 13,335 shares of common stock at an exercise price of $0.001 per share at a price to the public of $4.399 per pre-funded warrant, for aggregate gross proceeds of approximately $2,000, before deducting underwriting discounts and commissions and the other estimated offering expenses of $240 resulting in net proceeds of $1,760. Pursuant to the Second Underwriting Agreement, the Company granted the Underwriter a 45-day option to purchase up to an additional 68,181 shares of common stock at the share purchase price per share and/or pre-funded warrants at the pre-funded warrant purchase price, less the underwriting discounts to cover over-allotments, if any. This option was not exercised by the Underwriter.

Warrants

A summary of activity of the warrants during the years ended December 31, 2025, and 2024 is as follows:

	Number of shares	Weighted Average Exercise Price	Weighted Average Life (years)
Outstanding, December 31, 2023	40,438	$ 264.42	1.10
Granted	-	-	-
Expired	(17,123)	602.88	-
Exercised	-	-	-
Outstanding, December 31, 2024	23,315	$ 67.50	0.79
Granted	1,522,158	5.26	5.00
Expired	(23,315)	67.50	-
Exercised	(123,417)	1.07	-
Outstanding, December 31, 2025	1,398,741	$ 5.63	4.84

The intrinsic value of the warrants as of December 31, 2025, is $57. All of the outstanding warrants are exercisable as of December 31, 2025.

2018 Equity Incentive Plan

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 80,693 shares of common stock.

As of December 31, 2025, the 2018 Plan permits the Company to issue up to an aggregate of 335,564 shares of common stock of which 107,722 shares are available to be issued.

Options granted during the year ended December 31, 2025

In July 2025, the Company granted options to certain employees, officers, and consultants to purchase a total of 53,366 shares of the Company's Common Stock with an exercise price of $11.03 and vesting as follows: one forty-eighth (1/48th) of the shares subject to the option shall vest each month following the Vesting Commencement Date on the same day of the month as the Vesting Commencement Date, such that the option shall be fully vested on the four (4) year anniversary of the Vesting Commencement Date. The vesting commencement date is January 1, 2025.

In July 2025, the Company granted options to certain employees, officers, and consultants to purchase a total of 45,500 shares of the Company's Common Stock with an exercise price of $11.03 and vesting as follows: fifty percent (50%) of the shares subject to the option shall vest January 1, 2026 and the remaining fifty percent (50%) of the shares subject to the option shall vest January 1, 2027. The vesting commencement date is January 1, 2025.

Options granted during the year ended December 31, 2024

In January 2024, the Company granted options to an officer of the Company to purchase an aggregate of 15,334 shares of the Company's Common Stock with an exercise price of $8.94 and vesting as follows: twenty-five (25%) of the shares subject to the option shall vest on the one-year anniversary of the vesting commencement date, and one forty-eighth ($1/48^{th}$) of the shares subject to the option shall vest each month thereafter on the same day of the month as the vesting commencement date. The vesting commencement date is January 5, 2024.

On March 5, 2024, the Company granted options to certain employees, officers and consultants to purchase a total of 25,342 shares of the Company's common stock with an exercise price of $8.82 and vesting as follows: twenty-five percent (25%) of the shares subject to the option shall vest on the one (1) year anniversary of the vesting commencement date, and one forty-eighth (1/48th) of the shares subject to the option shall vest each month thereafter on the same day of the month as the vesting commencement date. The vesting commencement date is March 5, 2024.

On December 20, 2024, the Company granted options to directors to purchase a total of 1,752 shares of the Company's common stock with an exercise price of $5.6856 and one hundred percent (100%) of the shares subject to the option shall vest on the earlier of (i) the one (1) year anniversary of the vesting commencement date, or (ii) the day prior to the date of the annual meeting of the Issuer's stockholders next following the vesting commencement date. The vesting commencement date is December 20, 2024.

The following is a summary of stock option activity during the years ended December 31, 2025 and 2024:

	Options Outstanding		Weighted Average Remaining life (years)
	Number of Options	Weighted Average Exercise Price	
Outstanding, December 31, 2023	86,559	$ 95.82	8.07
Granted	42,417	8.88	10.00
Exercised	-	-	-
Forfeited/canceled	-	-	-
Outstanding, December 31, 2024	128,976	$ 11.03	7.76
Granted	98,866	11.03	10.00
Exercised	-	-	-
Forfeited/canceled	-	-	-
Outstanding, December 31, 2025	227,842	$ 11.03	7.95
Exercisable options, December 31, 2025	87,204	$ 12.20	7.06

Valuation

The Company utilizes the Black-Scholes model to value its stock options. During the years ended December 31, 2025, and 2024, the Company utilized the following assumptions:

	Year ended December 31, 2025	Year ended December 31, 2024
Expected term	5.50 - 5.78 years	3.08 - 6.08 years
Expected average volatility	97 - 98%	87 - 110%
Expected dividend yield	-	-
Risk-free interest rate	3.87%	4.02 - 4.44%

During the year ended December 31, 2025, the Company granted98,866 options, valued at $849 of which 41,493 options, valued at $356, were for related parties. During the year ended December 31, 2024, the Company granted 42,417 options, valued at $307 of which 18,917 valued at $137 were for related parties. During the years ended December 31, 2025, and 2024, the Company recognized stock-based compensation expense of $1,142 and $818, respectively. As of December 31, 2025, $720 remains unamortized, of which $414 is for related parties. The intrinsic value of options outstanding as of December 31, 2025, and 2024, is $0 and $0, respectively.

NOTE 8– INCOME TAXES

The Company has not made provisions for income taxes for the years ended December 31, 2025, and 2024 since the Company has not generated taxable income and has the benefit of net operating losses in these periods.

Due to uncertainties surrounding the Company's ability to generate future taxable income to realize deferred income tax assets arising as a result of net operating losses carried forward, the Company has not recorded any deferred income tax assets as of December 31, 2025. The Company has incurred an aggregate net operating loss of $37,780; the net operating loss carry forwards will begin to expire in varying amounts beginning with the year ended December 31, 2034, subject to its eligibility as determined by respective tax regulating authorities. The Company's net operating loss carry forwards may be subject to annual limitations, which could eliminate, reduce or defer the utilization of the losses because of an ownership change as defined in Section 382 of the Internal Revenue Code. U.S. Federal tax returns are closed by statute for years through 2015. The status of state and non-U.S. tax examinations varies due to the numerous legal entities and jurisdictions in which the Company operates.

Net deferred tax assets consist of the following components as of:

	December 31, 2025	December 31, 2024
NOL Carryover	$ 7,817	$ 5,678
Valuation allowance	(7,817)	(5,678)
Net deferred tax asset	$ -	$ -

NOTE 9– INTANGIBLE ASSET

The Company 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 December 31, 2025, and 2024.

The amount capitalized consisted of a $1,500 payment and the fair value of 681 shares of common stock of $539. During the year ended December 31, 2025, no additional costs met the criteria for capitalization as an intangible asset.

NOTE 10 - 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 December 31, 2025:

	Years ended December 31,	
	2025	2024
Lease cost		
Operating lease cost	$ 35	$ 32
Other information		
Cash paid for operating cash flows from operating leases	$ 35	$ 30
Right-of-use assets obtained in exchange for new operating lease liability	$ -	$ 111
Weighted-average remaining lease term — operating leases (year)	1.58	2.58
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 December 31, 2025, as follows:

	Total
Year Ended December 31,	
2026	$ 43
2027	30
2028	-
2029	-
Thereafter	-
	73
Less: Imputed interest	(4)
Operating lease liabilities	69
Operating lease liability - current	40
Operating lease liability - non-current	$ 29

NOTE 11 – COMMITMENTS AND CONTINGENCIES

The Company has certain financial commitments relating to research and development contracts as of December 31, 2025, as follows:

- The Company is invoiced monthly 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, USA. 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 12 – SUBSEQUENT EVENTS

On January 30, 2026, the Company entered into an Equity Purchase Agreement, dated as of January 30, 2026 (the "Purchase Agreement"), with Square Gate Capital Master Fund, LLC – Series 5, ("Square Gate"), pursuant to which the Company has the right, but not the obligation, to direct Square Gate to purchase up to $25 million (the "Initial Commitment Amount") in shares of common stock, par value $0.001 per share, of the Company, which at the Company's sole discretion can be increased by an additional $25 million once the Initial Commitment Amount has been exhausted, subject to the terms and conditions contained in the Purchase Agreement.

In consideration for Square Gate's execution and delivery of the Purchase Agreement, the Company issued 106,026 shares of Common Stock to Square Gate (the "Commitment Shares") and 186,372 pre-funded warrants to purchase up to 186,372 shares of Common Stock at an exercise price of $0.001 per share (the "Pre-funded Warrants"), having an aggregate value, as of January 30, 2026, of $500,000, as shares and/or as pre-funded warrants. The Commitment Shares will be deemed fully earned on the date of the Purchase Agreement. In addition, the Company will be responsible for up to $35,000 of Square Gate's customary due diligence and legal fees in connection with the Purchase Agreement.

The Company will be prohibited from conducting any Variable Rate Transaction (as defined in the Purchase Agreement) without the prior written consent of Square Gate from any Put Date until the end of any Standstill Period (as defined in the Purchase Agreement); provided, however, that the Company may effect sales pursuant to a customary "at-the-market" facility with a FINRA-registered broker-dealer as sales agent.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our senior management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K (the "Evaluation Date"). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded as of the Evaluation Date that our disclosure controls and procedures were effective such that the information relating to us required to be disclosed in our SEC reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. With the participation of our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") 2013 Framework in Internal Control – Integrated Framework. Based upon such evaluation, our management concluded that we did maintain effective internal control over financial reporting as of December 31, 2025, based on the COSO framework criteria, as more fully described below.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to an exemption for non-accelerated filers from the internal control audit requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the quarter ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations in the Effectiveness of Controls

Management recognizes that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures 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 or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a 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 management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

We have no information to disclose that was required to be disclosed in a report on Form 8-K during the fourth quarter of fiscal year 2025 but was not reported.

None of our directors or "officers," as defined in Rule 16a-1(f) under the Exchange Act, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the fiscal quarter ended December 31, 2025.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our Board currently consists of seven directors, six of whom are independent under the listing standards of Nasdaq. Our Board is divided into three classes with staggered terms. Generally, directors in a staggered board will be elected for three-year terms; however, in order to implement the staggered board, at the 2023 annual meeting of stockholders, the Class I directors were elected for a one-year term, to serve until the 2024 annual meeting of stockholders, the Class II directors were elected for a two-year term, to serve until the 2025 annual meeting of stockholders, and the Class III directors were elected for a three-year term, to serve until the 2026 annual meeting of stockholders, and in each case, until their respective successor, if any, is duly elected and qualified.

The following table sets forth information for each of our current directors and executive officers:

Name	Position Held with the Company	Date first appointed	Age
Gregory D. Gorgas	President, Chief Executive Officer, Secretary and Director	April 3, 2017	63
Mark E. Spring	Chief Financial Officer and Treasurer	November 1, 2025	67
Connie Matsui[(1)(2)]	Director, Chairperson of the Board	May 2, 2017	72
Steven Kelly[(1)(3)]	Director	May 2, 2017	60
Douglas Blayney, M.D.[(2)]	Director	July 31, 2017	75
R. Martin Emanuele, Ph. D.[(2)]	Director	September 20, 2017	71
Gregory R. Reyes, M.D., Ph. D.[(3)]	Director	November 30, 2020	72
Tamara A. Favorito[(1)(3)]	Director	March 3, 2021	67

(1) Member of the Audit Committee
(2) Member of the Corporate Governance and Nominating Committee
(3) Member of the Compensation Committee

Gregory D. Gorgas was appointed president, chief executive officer, secretary and director of our Company in April 2017. From April 2017 until November 2025, Mr. Gorgas also served as our Chief Financial Officer and Treasurer. Prior to joining our Company, Mr. Gorgas was Senior Vice President, Commercial, and Corporate Officer at Mast Therapeutics from July 2011 to January 2017 with commercial leadership accountability and business development responsibilities for the hematology, oncology and cardiovascular development programs. In addition, he performed a key role in helping Mast Therapeutics raise over $50M in new capital. From November 2009 to July 2011, Mr. Gorgas was Managing Director at Theragence, Inc., a privately held company he co-founded, that applied proprietary computational intelligence to mine and analyze clinical data. From November 2008 to July 2011, Mr. Gorgas also served as an independent consultant, providing commercial and business development consulting services to pharmaceutical, biotechnology and medical device companies. From 1997 to October 2008, Mr. Gorgas held several positions with Biogen Idec Inc., most recently, from March 2006 to October 2008, as Senior Director, Global and U.S. Marketing with responsibility for the strategic vision and operational commercialization of the company's worldwide cancer business. In this role, he hired and led the team in marketing, operations, project management, and business development in Europe and the US. Before such time, he had increasing responsibilities in marketing, sales, commercial operations, and project team and alliance management. He holds an MBA from the University of Phoenix and a BA in economics from California State University, Northridge. We believe Mr. Gorgas is qualified to serve as a member of our Board because of his extensive experience and accomplishments in the biopharmaceutical industry and his past leadership positions at successful public companies.

Mark E. Spring was appointed chief financial officer and treasurer of our Company in November 2025. Mr. Spring also served as a consultant to us from December 2024 to October 2025. Mr. Spring brings 30 years of experience in life sciences to his role, including financial leadership of private and public, domestic and multinational, commercial and development stage companies. Mr. Spring most recently was a fractional/interim CFO for Danforth Advisors from 2023 to 2025, including serving as interim chief financial officer for LENZ Therapeutics through its reverse merger transaction. Mr. Spring was co-founder and chief financial officer of Secura Bio from 2019 to 2023, a commercial-stage oncology therapeutics company. Mr. Spring also held the role of chief financial officer for Hyperion Therapeutics, Prometheus Laboratories, Veracyte, Sotera Wireless and Genoptix. Mr. Spring has extensive M&A experience with significant roles in transactions at Caremark, Dade Behring, Baxter, MedImmune, Prometheus and Genoptix. Mr. Spring holds a BA in Business Administration from Monmouth College, completed post-graduate studies at the University of Texas, Dallas and is a Certified Public Accountant (active).

Connie Matsui was elected to our Board in May 2017. Ms. Matsui brings to her role over 16 years of general management experience in the biotechnology industry. Ms. Matsui retired from Biogen Idec in January 2009 as Executive Vice President, Knowledge and Innovation Networks. She served as an Executive Committee member at both Biogen Idec and IDEC Pharmaceuticals, a predecessor of Biogen Idec. Among the major roles she held after joining IDEC in November 1992 were: Senior Vice President, overseeing investor relations, corporate communications, human resources, project management and strategic planning; Collaboration Chair for the late stage development and commercialization of rituximab (tradenames: Rituxan ®, MabThera ®) in partnership with Roche and Genentech; and Project Leader for Zevalin®, the first radioimmunotherapy approved by the FDA. Prior to entering the biotechnology industry, Ms. Matsui worked for Wells Fargo Bank in general management, marketing and human resources. Ms. Matsui currently serves as the Chair of the Board at Sutro Biopharma. She previously served as a Board member for Halozyme Therapeutics from July 2006 to May 2025. She also has been active on a number of not-for-profit boards at the local, national and global level. Ms. Matsui earned BA and MBA degrees from Stanford University. We believe Ms. Matsui is qualified to serve as a member of our Board because of her extensive management experience and deep familiarity with the biotechnology industry.

Steven Kelly was elected to our Board in May 2017. Mr. Kelly brings over thirty years of experience in Pharma/Biotech at all phases of the business across multiple therapeutic categories. From 2018 to 2025, Mr. Kelly was CEO at Carisma Therapeutics (NASDAQ: CARM), a biotech pioneering the development of CAR macrophages, a disruptive approach to immunotherapy in cancer. From 2012 to 2018, Mr. Kelly was the principal of KellyBioConsulting, LLC, and served as an independent consultant providing strategic direction and guidance to a variety of life sciences companies. Previously, Mr. Kelly was the founding CEO of Pinteon Therapeutics, an early stage oncology and CNS development company. Prior to this he held a number of leadership positions in the biotechnology industry including: CEO, Theracrine; CCO, BioVex; CEO, Innovive Pharmaceuticals; as well as various commercial and manufacturing roles at Sanofi, IDEC Pharmaceuticals and Amgen. Mr. Kelly holds a BS from University of Oregon and an MBA from Cornell University. We believe Mr. Kelly is qualified to serve as a member of our Board because of his entrepreneurial background and extensive knowledge of the biopharmaceutical and biotechnology industries.

Douglas Blayney, M.D. was elected to our Board in July 2017. Dr. Blayney is a Professor of Medicine (Oncology), Emeritus at Stanford University and former Medical Director of Stanford Cancer Center. Dr. Blayney is a past president of the American Society of Clinical Oncology (ASCO) and a founder of the ASCO Quality Symposium. He was previously a Professor of Internal Medicine and Medical Director of the Comprehensive Cancer Center at the University of Michigan, and prior to that practiced and led Wilshire Oncology Medical Group, Inc. a physician owned multidisciplinary oncology practice in southern California. Dr. Blayney served on the Food and Drug Administration's Oncologic Drugs Advisory Committee and is Founding Editor-in-Chief and Editor-in-Chief Emeritus of ASCO's Journal of Oncology Practice. He has over 120 scientific publications with expertise on clinical trial development, use of oncology drugs in clinical practice, and information technology use. Dr. Blayney earned a degree in electrical engineering from Stanford, is a graduate of the University of California, San Diego (UCSD) School of Medicine, and received post graduate training at UCSD and at the National Cancer Institute in Bethesda, Maryland. We believe Dr. Blayney is qualified to serve as a member of our Board because of his expertise in biopharmaceutical matters and deep familiarity with clinical trials and the FDA.

R. Martin Emanuele, Ph.D. was elected to our Board in September 2017. Dr. Emanuele is currently co-founder and Chief Executive Officer of Visgenx. Inc, a private bio-pharmaceutical company. He is also currently co-founder and Executive Chairman of Lucina Biotherapeutics, a private biopharmaceutical company. From May 2011 to October 2016, he served as Senior Vice President, Development at Mast Therapeutics Inc. (now Savara, Inc., a biopharmaceutical company), from April 2010 to April 2011, Dr. Emanuele was Vice President, Pharmaceutical Strategy at DaVita, Inc., and leading provider of dialysis and other healthcare services in the United States. Prior to DaVita, from June 2008 to April 2010, Dr. Emanuele was a co-founder and CEO of SynthRx, Inc. a private biopharmaceutical company that was acquired by Mast Therapeutics (Savara, Inc) in April 2011. From November 2006 to May 2008, Dr. Emanuele was Senior Vice President, Business Development at Kemia, Inc., a venture-backed privately held company focused on discovering and developing small molecule therapeutics. From 2002 to 2006, Dr. Emanuele held various senior-level positions with Avanir Pharmaceuticals, Inc., most recently as Vice President, Corporate Development and Portfolio Management, and from 1988 to 2002, Dr. Emanuele held positions of increasing responsibility at CytRx Corporation, most recently as Vice President, Research and Development and Business Development. He earned a Ph.D. in pharmacology and experimental therapeutics from Loyola University of Chicago, Stritch School of Medicine and a BS in biology from Colorado State University. He also holds an MBA with an emphasis in healthcare and pharmaceutical management from the University of Colorado. We believe that Dr. Emanuele is qualified to serve as a member of our Board because of his professional background experience in the biopharmaceutical industry.

Gregory R. Reyes, M.D., Ph.D., was elected to our Board in November 2020. Dr. Reyes has served as a Pharmaceutical and Biotech Industry Advisor and Consultant to various companies from June 2016 to present. Dr. Reyes has served as the Co-Founder and scientific advisor of OROX Biosciences, Inc. from June 2017 to present and has also served as scientific advisor to Yatiri Bio and Multiverse Pharma from June 2016 to present. Prior to that, Dr. Reyes served as the Senior Vice President, Drug Discovery & San Diego Site Head, overseeing drug discovery at Celgene from June 2011 to June 2016. Prior to that, Dr. Reyes served as Senior Vice President & San Diego Site Head, leading the oncology franchise at Biogen Idec from October 2008 to June 2011. Dr. Reyes served as an advisor to Cancer Research UK's New Agents Committee and previously served on NIH's National Advisory General Medical Sciences Council, and the Standing Review Committee for the Research Centers in Minority Institutions, National Center for Research Resources. Dr. Reyes obtained his M.D. and Ph.D. at The Johns Hopkins School of Medicine and trained in medicine at Stanford University Hospital. Dr. Reyes received his bachelor's degree in Biology from the University of California, Santa Cruz. We believe Dr. Reyes is qualified to serve as a member of our Board because of his extensive experience serving in leadership positions for biopharmaceutical companies.

Tamara A. Favorito was elected to our Board in March 2021. Ms. Favorito has more than 30 years of life sciences industry experience including 20 years as Chief Financial Officer. Ms. Favorito currently serves as Chairman of the Board and chairman of the audit committee of Zevra Therapeutics, Inc. (NASDAQ: ZVRA), a publicly-traded commercial-stage rare disease therapeutics company. Ms. Favorito served as Interim CFO of Immunic Therapeutics, Inc. (NASDAQ: IMUX), a publicly-traded clinical-stage drug development company in 2019. She served as CFO of several companies including Signal Genetics, Inc., a then publicly-traded molecular diagnostics company which was acquired by Viridian Therapeutics Inc., from 2014 to 2017, HemaQuest Pharmaceuticals, Inc. (now known as Viracta Therapeutics, Inc. (NASDAQ: VIRX)), a clinical-stage drug development company, from 2010 to 2014 and Favrille, Inc. (now known as MMR Global, Inc.), a clinical-stage drug development company, from 2001 to 2009. While at these companies, Ms. Favorito led multiple private and public financings, including Favrille's IPO. In addition, Ms. Favorito was instrumental in M&A transactions and led the finance, investor relations, human resources, administration and managed care and payor reimbursement functions. Earlier in her career, Ms. Favorito spent eight years in public accounting with Deloitte & Touche LLP and PricewaterhouseCoopers LLP, including three years as audit manager. Ms. Favorito is a Certified Public Accountant (inactive). Ms. Favorito received an MBA, emphasis in Finance, from Georgia State University, and a BBA, emphasis in Accounting, from Valdosta State University. Ms. Favorito served on the Board of Directors of Beacon Discovery, Inc. from 2018 until their acquisition in 2021and served as a board member and audit committee chair of Kintara Therapeutics, Inc. a publicly-traded clinical-stage drug development company from 2021 until its merger with TuHura Biosciences, Inc. (NASDAQ: HURA) in 2024. We believe Ms. Favorito is qualified to serve as a member of our Board because of her experience leading public companies, her financial expertise and her familiarity with the biopharmaceutical industry.

Attendance at Board and Stockholder Meetings

For the fiscal year ending December 31, 2025, our Board held twelve meetings. Each director attended at least 75% of the aggregate number of meetings of the Board and of the committees on which they served during the past fiscal year, in each case during the period that he or she served as a director.

Although we do not have a formal policy regarding attendance by members of our Board at the annual meetings of stockholders, we encourage, but do not require, directors to attend. Three members of our Board attended our 2025 annual meeting of stockholders.

Director Independence

Our Common Stock is listed on Nasdaq. As a company listed on Nasdaq, we are required under Nasdaq listing rules to maintain a board comprised of a majority of independent directors as determined affirmatively by our Board. Under Nasdaq listing rules, a director will only qualify as an independent director if, in the opinion of that listed company's board of directors, the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of our audit, compensation and corporate governance and nominating committees be independent.

Audit Committee members must also satisfy the additional independence criteria set forth in Rule 10A-3 under the Exchange Act and Nasdaq listing rules applicable to audit committee members. Compensation Committee members must also satisfy the additional independence criteria set forth in Rule 10C-1 under the Exchange Act and Nasdaq listing rules applicable to compensation committee members.

Our Board has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our Board has determined that Ms. Matsui, Dr. Blayney, Mr. Kelly, Dr. Emanuele, Dr. Reyes, and Ms. Favorito representing six of our seven directors, are "independent directors" as defined under the rules of the Nasdaq. Mr. Gorgas is not considered independent due to his service as an executive officer of the Company.

In determining whether directors were independent under Nasdaq rules, the Board considered the matters discussed in the section entitled "*Related Party Transactions*" in Part III, Item 13 below. There are currently no legal proceedings, and during the past ten years there have been no legal proceedings, that are material to the evaluation or the ability or integrity of any of our directors or director nominees.

Family Relationships

There are no family relationships between any of our directors or executive officers.

Leadership Structure of the Board of Directors

The Board has the following general leadership structure:

- The positions of Chief Executive Officer and Chair of the Board are separate but may be held by the same individual. The positions of Chief Executive Officer and Chair of the Board are currently held by Mr. Gorgas and Ms. Matsui, respectively.
- The Chair of the Board presides at meetings of the Board and, so long as the Chair of the Board is an independent director, also presides at executive sessions of the non-management and/or independent directors.
- If the Chair of the Board is not an independent director, the independent directors will appoint one independent director to serve as "lead independent director." In that scenario, the lead independent director will preside at executive sessions of the non-management and/or independent directors, preside at meetings of the Board in the absence of the Chair of the Board, review agendas for meetings of the Board with the Chief Executive Officer and Chair of the Board, and assume such other functions as the Board may deem appropriate.
- The Chief Executive Officer and the Chair of the Board jointly establish the agenda for each meeting of the Board, though any director may request the inclusion of items on the agenda.

Ms. Matsui currently serves as Chair of the Board and is an independent director, thus, the Board does not currently have a lead independent director. The Board has determined that this leadership structure, specifically the separation of the Chief Executive Officer and Chair of the Board positions, is appropriate for our Company because, in the judgment of the Board, an independent Chair of the Board (or lead independent director, if the Chair of the Board is not an independent director) is best positioned to express to management the views of the Board (and, particularly, the independent directors) and to provide constructive feedback to the Chief Executive Officer regarding management's performance.

Role of the Board of Directors in Risk Oversight

Management is responsible for day-to-day risk management at our company. The role of the Board is to provide oversight of the processes designed to identify, assess and monitor key risks and risk mitigation activities. The Board fulfills its risk oversight responsibilities through (i) the receipt of reports directly from management and (ii) the receipt of reports from each committee chair regarding such committee's oversight of specific risk topics.

Delegation of Risk Oversight

The Board has delegated oversight of specific risk areas to its committees. For example, the Audit Committee is tasked with overseeing risk management at our company with respect to financial matters and the adequacy of our internal control over financial reporting. Pursuant to its charter, the Audit Committee is required, among other things, to discuss with management our policies with respect to risk assessment and risk management, including guidelines and procedures to govern the process by which risk assessment and risk management are handled, and to review our major risk exposures and the steps management has taken to monitor, control and report such exposures. The Audit Committee typically has these discussions with management at least once per quarter, and the Chair of the Audit Committee subsequently reports on these discussions to the full Board. Similarly, the Compensation Committee assists the Board in overseeing risks arising from our compensation policies and practices, and the Corporate Governance and Nominating Committee assists the Board in overseeing risks associated with corporate governance, director and executive officer succession planning, board membership and board structure. The Board then discusses significant risk management issues with the Chief Executive Officer and recommends appropriate action.

Board Committees

The Board has an Audit Committee, a Compensation Committee, and a Corporate Governance and Nominating Committee. Each of these committees operate under written charters, each of which are available on our website at http://www.artelobio.com under "Investors—Governance." The Board has determined that all members of these committees satisfy the applicable independence requirements under Nasdaq rules.

Audit Committee

Our Audit Committee is currently comprised of Tamara A. Favorito, Steven Kelly, and Connie Matsui. Ms. Favorito serves as the chairperson of our Audit Committee. Our Board has determined that each member of our Audit Committee meets the requirements for independence and financial literacy under the applicable rules and regulations of the SEC and the listing standards of Nasdaq. Our Board has also determined that Ms. Favorito is an "audit committee financial expert" as defined in the rules of the SEC and has the requisite financial sophistication as defined under the listing standards of Nasdaq. The responsibilities of our Audit Committee include, among other things:

- selecting and hiring the independent registered public accounting firm to audit our financial statements;
- overseeing the performance of the independent registered public accounting firm and taking those actions as it deems necessary to satisfy itself that the accountants are independent of management;
- reviewing financial statements and discussing with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews, and the reports regarding internal control over financial reporting and disclosure controls;
- preparing the audit committee report that the SEC requires to be included in our annual proxy statement;
- reviewing the adequacy and effectiveness of our internal controls and disclosure controls and procedures;
- overseeing our policies on risk assessment and risk management;
- reviewing related party transactions; and
- approving or, as required, pre-approving, all audit and all permissible non-audit services and fees to be performed by the independent registered public accounting firm.

Our Audit Committee operates under a written charter which satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq, a copy of which can be found on our website at http://www.artelobio.com under "Investors—Governance.".

Compensation Committee

Our Compensation Committee is currently comprised of Steven Kelly, Gregory R. Reyes, M.D., Ph.D., and Tamara A. Favorito. Mr. Kelly serves as the chairperson of our Compensation Committee. Our Board has determined that each member of our Compensation Committee meets the requirements for independence under the applicable rules and regulations of the SEC and listing standards of Nasdaq. Each member of the Compensation Committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. The purpose of our Compensation Committee will be to oversee our compensation policies, plans and benefit programs and to discharge the responsibilities of our Board relating to compensation of our executive officers. The responsibilities of our Compensation Committee include, among other things:

- reviewing and approving or recommending to the Board for approval compensation of our executive officers and directors;
- overseeing our overall compensation philosophy and compensation policies, plans and benefit programs for service providers, including our executive officers;
- reviewing, approving, and making recommendations to our Board regarding incentive compensation and equity plans; and
- administering our equity compensation plans.

Our Compensation Committee operates under a written charter, which satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq, a copy of which can be found on our website at http://www.artelobio.com under "Investors—Governance.".

Corporate Governance and Nominating Committee

Our Corporate Governance and Nominating Committee is currently comprised of Douglas Blayney, M.D., R. Martin Emanuele, Ph.D., and Connie Matsui. Dr. Blayney serves as chairperson of our Corporate Governance and Nominating Committee. Our Board has determined that all members of our Corporate Governance and Nominating Committee meet the requirements for independence under the applicable rules and regulations of Nasdaq listing standards. The responsibilities of our Corporate Governance and Nominating Committee include, among other things:

- identifying, evaluating, and selecting, or making recommendations to our Board regarding, nominees for election to our Board and its committees;
- evaluating the performance of our Board and of individual directors;
- considering and making recommendations to our Board regarding the composition of our Board and its committees; and
- developing and making recommendations to our Board regarding corporate governance guidelines and matters.

Our Corporate Governance and Nominating Committee operates under a written charter, which satisfies the listing standards of Nasdaq, a copy of which can be found on our website at http://www.artelobio.com under "Investors—Governance."

Insider Trading Policy and Prohibition on Hedging or Pledging of Securities

We maintain an insider trading policy that applies to our officers and directors that prohibits trading our securities during certain established periods and when in possession of material non-public information.

Under our insider trading policy, our directors, officers, employees and agents are prohibited from, directly or indirectly, among other things, (1) engaging in short sales, (2) trading in publicly-traded options, such as puts and calls, and other derivative securities with respect to our securities (other than stock options, stock appreciation rights and other securities issued pursuant to Company benefit plans or other compensatory arrangements with the Company), (3) pledging any of our securities as collateral for any loans and (4) holding our securities in a margin account.

Communications with the Board of Directors

The Company's contact information is available on our website at https://artelobio.com/ under the "Investors" tab. Interested parties may send communications to the non-management members of the Board. Communications to the Board must be in writing and sent care of the Secretary by mail to our principal executive offices at 505 Lomas Santa Fe, Suite 160, Solana Beach, CA 92075. This centralized process will assist the Board in reviewing and responding to stockholder and interested party communications in an appropriate manner. The name of any specific intended recipient should be noted in the communication. All communications must be accompanied by the following information:

- if the person submitting the communication is a security holder, a statement of the type and amount of securities of our company the person holds;
- if the person submitting the communication is not a security holder and is submitting the communication to the non-management directors as an interested party, the nature of the person's interest in our company;
- any special interest, meaning an interest not in the capacity of a stockholder of our company, of the person in the subject matter of the communication; and
- the address, telephone number and e-mail address, if any, of the person submitting the communication.

Communications should be addressed to the attention of the Secretary and should not exceed 500 words in length, excluding the information required to accompany the communication as described above. The Board has instructed the Secretary to forward such correspondence to the Board.

Consideration of Director Nominees

Director Qualifications

The Corporate Governance and Nominating Committee evaluates all incumbent, replacement or additional nominees for election as directors, taking into account (i) all factors the committee considers appropriate, which may include career specialization, relevant technical skills or financial acumen, diversity of viewpoint and industry knowledge, and (ii) the following minimum qualifications:

- Each director nominee must have displayed the highest personal and professional ethics, integrity and values, and sound business judgment;
- Each director must be highly accomplished in his or her respective field, with superior credentials and recognition and broad experience at the administrative and/or policy making level in business, government, education, technology or public interest;
- Each director must have relevant expertise and experience, and be able to offer advice and guidance to the Chief Executive Officer based on that expertise and experience;
- Each director must be able to represent all of our stockholders and be committed to enhancing long-term stockholder value; and
- Each director must have sufficient time available to devote to activities of the Board and to enhance his or her knowledge of our business.

In determining whether to recommend a director for re-election to the Board, the Corporate Governance and Nominating Committee also considers the director's past attendance at meetings and participation in and contributions to the activities of the Board and any applicable committees of the Board.

The Corporate Governance and Nominating Committee does not have a formal policy governing the consideration of diversity in identifying nominees for director but does take diversity into consideration on an informal basis.

Stockholder Recommendations and Nominees

Our Corporate Governance and Nominating Committee will consider recommendations and nominations for candidates to our Board from stockholders in the same manner as candidates recommended to the committee from other sources, so long as such recommendations and nominations comply with our articles of incorporation and bylaws, all applicable company policies and all applicable laws, rules and regulations, including those promulgated by the SEC. Our Corporate Governance and Nominating Committee will evaluate such recommendations in accordance with its articles of incorporation, our bylaws and corporate governance principles and the director nominee criteria described above. Stockholders wishing to recommend a candidate for director should write to our Secretary at Artelo Biosciences, Inc., Attn: Secretary, 505 Lomas Santa Fe, Suite 160, Solana Beach, CA 92075.

To be considered, the recommendation of a director candidate must include the following written information as to each person whom the stockholder proposes to nominate for election as a director: (i) such person's name, age, business address, residence address and principal occupation or employment; (ii) the class and number of shares of the Company that are held of record or are beneficially owned by such person and any (x) derivative instruments (as defined in the Company's bylaws) held or beneficially owned by such person, including the full notional amount of any securities that, directly or indirectly, underlie any derivative instrument; and (y) other agreement, arrangement or understanding the effect or intent of which is to create or mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of such person with respect to the Company's securities; (iii) all information relating to such person that is required to be disclosed in connection with solicitations of proxies for the contested election of directors, or is otherwise required, in each case pursuant to the Section 14 of the Exchange Act; (iv) such person's written consent (x) to being named as a nominee of such stockholder, (y) to being named in the Company's form of proxy pursuant to Rule 14a-19 under the Exchange Act and (z) to serving as a director of the Company if elected; (v) any direct or indirect compensatory, payment, indemnification or other financial agreement, arrangement or understanding that such person has, or has had within the past three years, with any person or entity other than the Company (including, without limitation, the amount of any payment or payments received or receivable thereunder), in each case in connection with candidacy or service as a director of the Company (such agreement, arrangement or understanding, a "Third-Party Compensation Arrangement"); and (vi) a description of any other material relationships between such person and such person's respective affiliates and associates, or others acting in concert with them, on the one hand, and such stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made, and their respective affiliates and associates, or others acting in concert with them, on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K if such stockholder, beneficial owner, affiliate or associate were the "registrant" for purposes of such rule and such person were a director or executive officer of such registrant.

Identification and Evaluation of Nominees for Director

The Corporate Governance and Nominating Committee uses a variety of methods for identifying and evaluating nominees for director. The Corporate Governance and Nominating Committee regularly assesses the appropriate size and composition of the Board, the needs of the Board and each committee of the Board, and the qualifications of candidates in light of these needs. Candidates may come to the attention of the Corporate Governance and Nominating Committee through stockholders, management, current members of the Board or search firms. The evaluation of these candidates may be based solely upon information provided to the Corporate Governance and Nominating Committee or may also include discussions with persons familiar with the candidate, an interview of the candidate or other actions the Corporate Governance and Nominating Committee deems appropriate, including the use of third parties to review candidates.

Code of Ethics

The Board has adopted a Code of Business Conduct and Ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and agents and representatives, including consultants. A copy of the Code of Business Conduct and Ethics is available on our website at www.artelobio.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified above.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table for the Fiscal Years Ended December 31, 2025 and 2024

The following table shows the compensation earned by our named executive officers for the fiscal years ended December 31, 2025 and 2024:

Name and Principal Position[1]	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Gregory D. Gorgas, President, CEO, Secretary, and Director and Former CFO and Treasurer	2025	540,000	270,000	-	346,532	-	-	66,923[3]	1,223,455
	2024	520,000	242,450[4]	-	240,016[5]	-	-	58,004[6]	1,060,470
Mark E. Spring, CFO and Treasurer	2025	41,667	-	-	64,555	-	-	184,313[7]	290,535
	2024	-	-	-	-	-	-	813[8]	813

(1) For the year ended December 31, 2025, our sole named executive officer until November 1, 2025, was Gregory D. Gorgas, our President, Chief Executive Officer, Chief Financial Officer, Treasurer and Secretary. Mr. Spring joined us as Chief Financial Officer and Treasurer effective November 1, 2025.
(2) In accordance with SEC rules, the amounts shown reflect the aggregate grant date fair value of stock awards granted to Non-Employee Directors during the applicable year, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 ("FASB ASC 718"). The grant date fair value for stock options is measured based on the Black-Scholes Model. See [Note 7 – Equity] to our audited financial statements included in this Annual Report on Form 10-K.
(3) This is comprised of health insurance premiums of $57,238 and life insurance premiums of $9,685.
(4) 2024 bonus has been granted but not yet paid.
(5) New option awards granted in 2024 totaled $115,834. On February 28, 2024, previously issued options were repriced to $9.30 and had their vesting schedules modified. As per ASC 718 the changes were treated as modifications to the options. This modification resulted in an additional option award in the amount $124,182.
(6) This is comprised of health insurance premiums of $52,173 and life insurance premiums of $5,831.
(7) For the year ended December 31, 2025, Mr. Spring received consulting fees of $184,313.
(8) For the year ended December 31, 2024, Mr. Spring received consulting fees of $813.

Outstanding Equity Awards at Fiscal Year-End December 31, 2025

The following table sets forth certain information regarding equity awards granted to our named executive officer that remained outstanding as of December 31, 2025.

Name	Number of Securities Underlying Unexercised Options: Exercisable	Number of Securities Underlying Unexercised Options: Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested
Gregory D. Gorgas	510	324(1)	-	$ 9.30	August 29, 2029	-	-	-	-
President, CEO,					February 12, 2031				
Secretary,	5,667	3,606(2)	-	$ 9.30		-	-	-	-
and Director,	3,905	2,485(3)	-	$ 9.30	March 5, 2031	-	-	-	-
and Former	9,201	5,855(4)	-	$ 9.30	December 3, 2031	-	-	-	-
CFO and Treasurer	8,658	5,509(5)	-	$ 9.30	February 1, 2033	-	-	-	-
	7,348	7,986(6)	-	$ 8.94	January 5, 2034	-	-	-	-
	4,674	15,719(7)	-	$ 11.03	July 2, 2035	-	-	-	-
	-	20,000(8)	-	$ 11.03	July 2, 2035	-	-	-	-
Mark E. Spring	1,145	3,855(9)	-	$ 11.03	July 2, 2035	-	-	-	-
CFO and Treasurer	-	2,500(10)	-	$ 11.03	July 2, 2035	-	-	-	-

(1) 24 Options vesting each month until February 2027.
(2) 258 Options vesting each month until February 2027.
(3) 178 Options vesting each month until February 2027.
(4) 419 Options vesting each month until February 2027.
(5) 394 Options vesting each month until February 2027.
(6) 320 Options vesting each month until January 2028.
(7) 425 Options vesting each month until January 2029.
(8) 10,000 Options vesting in each of January 2026 and January 2027.
(9) 104 Options vesting each month until January 2029.
(10) 1,250 Options vesting in each of January 2026 and January 2027.

Executive Employment Agreement with our Named Executive Officers

On August 30, 2019, and effective as of June 20, 2019, the Company and Mr. Gorgas entered into an amended and restated employment agreement (the "Employment Agreement").

Mr. Gorgas' annual base salary for 2025 was $540,000 per year, less applicable withholdings, and he is eligible to earn an annual target bonus of up to 50% of his base salary upon achievement of performance objectives to be determined by the Board or its Compensation Committee. Mr. Gorgas is also eligible to participate in any employee benefit plans sponsored by us.

The Employment Agreement also provides that the Company shall pay the premiums for a life insurance policy for Mr. Gorgas for coverage of up to $1,000,000, and Mr. Gorgas shall be entitled to select personal beneficiaries for 100% of the proceeds of such policy. Mr. Gorgas may also choose to pay any additional premiums to increase the coverage of this life insurance policy.

The Employment Agreement also provides benefits in connection with a termination of employment under specified circumstances. Under the terms of the Employment Agreement, if we terminate Mr. Gorgas' employment other than for Cause, death, or Disability, or Mr. Gorgas terminates his employment for Good Reason (as such terms are defined in the Employment Agreement), Mr. Gorgas will be entitled to receive, subject to his timely execution and non-revocation of a release of claims, non-disparagement and his continued adherence to the non-solicitation provision of the Employment Agreement the following benefits: (A) if his termination of service occurs within the period 3 months prior to and 12 months after a change of control of the Company, (i) a lump sum severance payment equal to (x) 12 months of his then-current base salary and (y) his prorated annual bonus at the target level of achievement for the year in which the termination occurs, (ii) reimbursements for Mr. Gorgas and his eligible dependents' COBRA premiums for up to 12 months; and (iii) accelerated vesting as to 100% of Mr. Gorgas' then-outstanding time-based and performance-based equity awards; or (B) if his termination of service occurs outside of the period 3 months prior to and 12 months after a change of control of the Company, (i) continuing monthly payments of his then-current base salary for 12 months, (ii) a lump sum payment equal to a pro-rata portion of his then-current year target bonus, (iii) reimbursements for Mr. Gorgas and his eligible dependents' COBRA premiums for up to 12 months; and (iv) accelerated vesting as to (x) 100% of Mr. Gorgas' then-outstanding time-based equity awards and (y) that portion of Mr. Gorgas' then-outstanding performance based equity awards for the performance goals that had been satisfied at the time of termination or are expected to be satisfied.

On October 26, 2025, we entered into an Amendment to Mr. Gorgas' Employment Agreement (the "Employment Agreement Amendment"). Based in part on evaluation from the Compensation Committee's outside compensation consultant, the Employment Agreement Amendment amended Mr. Gorgas' existing Employment Agreement to align Mr. Gorgas' severance benefits with current market practice and make other updates for compliance with applicable laws and intended to align with good governance practices. The Employment Agreement Amendment reflects Mr. Gorgas' current base salary and target bonus and includes the following changes to the Employment Agreement: (1) extends Mr. Gorgas' eligibility to receive severance benefits upon a constructive termination whereby Mr. Gorgas may resign for Good Reason (as such term is defined in the Employment Agreement Amendment) outside of the period of time beginning three months before, and ending twelve months following, a change in control (the "CIC Protection Period"); (2) provides that severance benefits are subject to recoupment in accordance with the Company's clawback policy; and (3) adjusts severance benefits upon an involuntary termination (a termination by the Company without Cause or a resignation for Good Reason, as such terms are defined in the Employment Agreement Amendment) to (a) increase the cash severance Mr. Gorgas is eligible for from twelve (12) months of annual base salary to twenty-four (24) months of annual base salary and target bonus (increased to thirty-six (36) months if the involuntary termination occurs during the CIC Protection Period); (b) increase the COBRA reimbursements Mr. Gorgas is eligible for from twelve (12) months to twenty-four (24) months (increased to thirty-six (36) months if the involuntary termination occurs during the CIC Protection Period); (c) provide that the pro-rated bonus payment due for the year of termination will be calculated based on actual achievement of the applicable performance goals for such year (or if such involuntary termination occurs in the CIC Protection Period, a pro-rated annual target bonus, if greater); (d) remove the provision for full equity vesting acceleration upon an involuntary termination outside of the CIC Protection Period and replace it, effective for equity awards granted after the Effective Date, with partial vesting acceleration of awards scheduled to vest within the twenty-four (24) months following termination; and (e) provide for an extended time to exercise vested stock options of up to twelve (12) months after an involuntary termination.

If any of the severance and other benefits provided for in the Employment Agreement or otherwise payable to Mr. Gorgas constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code and could be subject to excise tax under Section 4999 of the Internal Revenue Code, then such payments will be delivered in full or delivered as to such lesser extent which would result in no portion of such benefits being subject to excise tax, whichever results in the greater amount of after-tax benefits to Mr. Gorgas.

In connection with Mr. Spring's appointment as Chief Financial Officer and Treasurer in October 2025 (effective November 1, 2025), the Company entered into an Employment Agreement with Mr. Spring, dated as of October 26, 2025, and effective as of November 1, 2025 (the "Spring Employment Agreement"). Pursuant to the terms of the Spring Employment Agreement, Mr. Spring is entitled to: (i) an initial annual base salary of $250,000 (the "Base Salary"); (ii) an annual target bonus of 35% of the Base Salary less applicable withholdings, upon achievement of performance objectives to be determined by the compensation committee of the Board in its sole discretion, effective beginning in 2026; (iii) equity awards determined from time to time by the Board or compensation committee; and (iv) certain employee benefits, paid-time off and business expense reimbursements, as set forth in the Spring Employment Agreement.

Additionally, the Spring Employment Agreement provides for the following benefits upon an involuntary termination (a termination by the Company without Cause or a resignation for Good Reason, as such terms are defined in the Spring Employment Agreement) which are subject to the execution, delivery and effectiveness of a customary release of claims in the Company's favor: (1) 12 months of annual base salary (increased to 18 months if such involuntary termination occurs in connection with a change in control); (2) a pro-rated annual bonus payment for the year in which the termination occurs, based on actual achievement of the applicable performance goals for such year (or if such involuntary termination occurs in connection with a change in control, a pro-rated annual target bonus, if greater); (3) reimbursement for COBRA premium payments for a period of up to 12 months following termination (increased to 18 months if such involuntary termination occurs in connection with a change in control); and (4) if such involuntary termination occurs in connection with a change in control, full vesting acceleration of equity awards and an extended time to exercise vested stock options of up to twelve (12) months involuntary termination.

Director Compensation

The following table presents compensation information for our non-employee directors for the fiscal year ended December 31, 2025.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)[1]	Incentive Plan Compensation ($)	Deferred Compensation Earnings ($)	Other Compensation ($)	Total ($)
Connie Matsui[2]	76,500	-	-	-	-	-	76,500
Douglas Blayney, M.D.[3]	48,000	-	-	-	-	-	48,000
Gregory R. Reyes, M.D., Ph.D.[4]	45,000	-	-	-	-	-	45,000
R. Martin Emanuele, Ph.D.[5]	44,000	-	-	-	-	-	44,000
Steven Kelly[6]	59,500	-	-	-	-	-	59,500
Tamara A. Favorito[7]	60,000	-	-	-	-	-	60,000

(1) In accordance with SEC rules, the amounts shown reflect the aggregate grant date fair value of stock awards granted to non-employee directors during 2025, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 ("FASB ASC 718"). The grant date fair value for stock options is measured based on the Black-Scholes Model. See Note 7 – Equity to our audited financial statements included in this Annual Report on Form 10-K:

(2) 2,877 option awards outstanding as of December 31, 2025.

(3) 2,267 option awards outstanding as of December 31, 2025.

(4) 2,143 option awards outstanding as of December 31, 2025.

(5) 2,190 option awards outstanding as of December 31, 2025.

(6) 2,663 option awards outstanding as of December 31, 2025.

(7) 1,143 option awards outstanding as of December 31, 2025. Fees earned or paid in cash were paid to Favorito Financial Consulting LLC.

Outside Director Compensation Policy

The Outside Director Compensation Policy, which was in effect for 2025, provides for the following cash compensation program for our non-employee directors:

- $40,000 per year for service as a non-employee director;
- $25,000 per year additionally for service as chairperson of our board of directors;
- $15,000 per year additionally for service as chairperson of the Audit Committee;
- $7,500 per year additionally for service as an Audit Committee member;
- $12,000 per year additionally for service as chairperson of the Compensation Committee;
- $5,000 per year additionally for service as a Compensation Committee member;
- $8,000 per year additionally for service as chairperson of the Corporate Governance and Nominating Committee; and
- $4,000 per year additionally for service as a Corporate Governance and Nominating Committee member.

The terms of our Outside Director Compensation Policy also allow for new non-employee directors to receive, upon becoming a non-employee director, an initial award of stock options to purchase 417 shares of our common stock at a per-share exercise price equal to the fair market value of a share of our common stock on the first trading date on or after the date on which such individual first becomes a non-employee director. The initial award shall vest in three (3) equal installments on each anniversary of the date the applicable non-employee director's service commenced, in each case subject to the non-employee director continuing to be a service provider through the applicable vesting date.

Our Outside Director Compensation Policy, also provides for an annual award (the "Annual Award") to continuing non-employee directors who have served as a non-employee director for at least six (6) months on the date of each annual meeting of stockholders of stock options to purchase 292 shares of our common stock at a per-share exercise price equal to the fair market value of a share of our common stock on the date of each annual meeting; provided, however, that the Board may make exceptions to this requirement of being an outside director for six (6) months to receive an Annual Award. Beginning fiscal year 2025, the Annual Award for continuing non-employee directors who have served as a non-employee director for at least six (6) months on the date of each annual meeting of stockholders was increased to stock options to purchase 409 shares of our common stock. The Annual Award shall vest on the earlier of the one-year anniversary of the date the annual award is granted, or the day prior to the date of the annual meeting next following the date the annual award is granted, in each case, subject to the non-employee director continuing to be a service provider through the applicable vesting date.

We also reimburse our directors for expenses associated with attending meetings of our Board and committees of our Board. Directors who are also our employees receive no additional compensation for their service as a director.

Our Outside Director Compensation Policy further provides that in any given fiscal year, a non-employee director may not receive cash compensation and equity awards with an aggregate value greater than $750,000 (determined in accordance with accounting principles generally accepted in the United States of America). Any cash compensation paid or awards granted to an individual for his or her services as an employee or a consultant (other than as a non-employee director) will not count for purposes of this limitation.

Our 2018 Equity Incentive Plan, as amended, or the 2018 Plan, provides that in the event of a merger or change in control, as defined in our 2018 Plan, each outstanding equity award granted under our 2018 Plan that is held by a non-employee director will fully vest, all restrictions on the shares subject to such award will lapse, and with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels, and all of the shares subject to such award will become fully exercisable, if applicable.

Compensation Recovery Policy

We have adopted a compensation recovery policy, effective as of October 2, 2023, that complies with the new SEC rules under the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Clawback Policy"). Subject to the terms of the Clawback Policy, the Clawback Policy requires us to recover certain cash or equity-based incentive compensation payments or awards made or granted to an executive officer in the event we are required to prepare an accounting restatement due to our material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

Benefits and Perquisites

We provide benefits to our executive officers on the same basis as provided to all of our employees, including health, dental and vision insurance; life insurance; accidental death and dismemberment insurance. We do not maintain any executive-specific benefit or perquisite programs except we do pay for the life insurance benefits and the health benefits reflected in the "Summary Compensation Table" above for our named executive officers.

2018 Equity Incentive Plan

Our Board has adopted a 2018 Equity Incentive Plan (the "2018 Plan"), and our stockholders have approved it. Our 2018 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and any parent and subsidiary corporations' employees, and for the grant of non-statutory stock options, restricted stock, restricted stock units, and stock appreciation rights to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants.

Authorized Shares. On January 1, 2024, the 2018 Plan was increased to permit the issuance of an additional 478,344 shares of Common Stock awards. On February 28, 2025, an additional 484,155 shares of our Common Stock were reserved for issuance pursuant to the 2018 Plan. On January 29, 2026, an additional 302,812 shares of our Common Stock were reserved for issuance pursuant to the 2018 Plan.

As of December 31, 2025, 335,564 shares of our Common Stock have been reserved for issuance pursuant to the 2018 Plan, of which options to purchase 227,842 shares of Common Stock are issued and outstanding.

Plan Administration. Our Board or one or more committees appointed by our Board will administer the 2018 Plan. Our Compensation Committee currently administers our 2018 Plan. In addition, if we determine it is desirable to qualify transactions under the 2018 Plan as exempt under Rule 16b-3 of the Exchange Act, or Rule 16b-3, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2018 Plan, the administrator has the power to administer the plan, including but not limited to, the power to determine the fair market value of our Common Stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2018 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2018 Plan and awards granted under it, prescribe, amend and rescind rules relating to our 2018 Plan, including creating sub-plans, modify or amend each award, including but not limited to the discretionary authority to extend the post-termination exercisability period of awards (except no option or stock appreciation right will be extended past its original maximum term) and allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award). The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type and/or cash or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants.

Stock Options. We may grant stock options under the 2018 Plan. The exercise price of options granted under our 2018 Plan will at least be equal to 100% of the fair market value of our Common Stock on the date of grant. The term of an option may not exceed 10 years. With respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option, to the extent vested as of the termination date, for the period of time stated in his or her option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 6 months. In all other cases, in the absence of a specified time in an award agreement, the option will generally remain exercisable for 30 days following the termination of service. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 2018 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights. We may grant stock appreciation rights under our 2018 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our Common Stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director, or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for 6 months. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for 30 days following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2018 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our Common Stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. We may grant restricted stock under our 2018 Plan. Restricted stock awards are grants of shares of our Common Stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2018 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever vesting conditions it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), except the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. We may grant restricted stock units under our 2018 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our Common Stock. Subject to the provisions of our 2018 Plan, the administrator determines the terms and conditions of restricted stock units, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit or individual goals (including, but not limited to, continued employment or service) or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, in shares or in some combination thereof. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2018 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments. In the event of any dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of our shares or other securities, or other change in our corporate structure affecting our shares, to prevent diminution or enlargement of the benefits or potential benefits available under our 2018 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2018 Plan and/or the number, class and price of shares covered by each outstanding award and the numerical share limits set forth in our 2018 Plan.

Dissolution or Liquidation. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and, to the extent not exercised, all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control. Our 2018 Plan provides that in the event of a merger or change in control, as defined under our 2018 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant or all awards of the same type, similarly.

If a successor corporation does not assume or substitute for any outstanding award, then the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, all restrictions on restricted stock and restricted stock units will lapse, and for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If an option or stock appreciation right is not assumed or substituted, the administrator will notify the participant in writing or electronically that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

Clawback. Awards will be subject to our Clawback Policy, a copy of which is filed as Exhibit 97.1 to this Annual Report on Form 10-K.

Amendment; Termination. The administrator has the authority to amend, alter, suspend or terminate our 2018 Plan, provided such action does not materially impair the rights of any participant. Our 2018 Plan automatically will terminate in 2028, unless we terminate it sooner.

Grants of Plan-Based Awards

During the year ended December 31, 2025, we granted stock options to purchase a total of 98,866 shares of Common Stock.

Option Exercises and Stock Vested

During the year ended December 31, 2025, there were no options exercised by our directors or executive officers.

Pension, Retirement or Similar Benefit Plans

There are no arrangements or plans in which we provide pension, retirement or similar benefits for directors or executive officers.

Indebtedness of Directors, Senior Officers, Executive Officers and Other Management

None of our directors or executive officers or any associate or affiliate of our company during the last two fiscal years, is or has been indebted to our company by way of guarantee, support agreement, letter of credit or other similar agreement or understanding currently outstanding.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth, as of February [20], 2026, certain information with respect to the beneficial ownership of our common shares by each shareholder known by us to be the beneficial owner of more than 5% of our common shares, as well as by each of our named executive officers and our directors, and all of our current directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security. Under those rules, beneficial ownership includes securities that the individual or entity has the right to acquire, such as through the exercise of stock options, within 60 days of February [20], 2026. Shares subject to options that are currently exercisable or exercisable within 60 days of February [20], 2026 are considered outstanding and beneficially owned by the person holding such options for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as noted by footnote, and subject to community property laws where applicable, based on the information provided to us, we believe that the persons and entities named in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them. The percentage of beneficial ownership of Artelo is calculated based on [20] shares of Common Stock outstanding as of February [20], 2026.

Except as otherwise noted below, the address of each of the individuals and entities named in the table below is c/o Artelo Biosciences, Inc., 505 Lomas Santa Fe, Suite 160, Solana Beach, California 92075.

Name and Address of Beneficial Owner	Number of Shares of Common Stock Held	Percent of Common Stock %
Directors and Named Executive Officers		
Gregory D. Gorgas[(1)]	96,406	4.5
Connie Matsui[(2)]	146,105	6.9
Steven Kelly[(3)]	2,005	*
Douglas Blayney, M.D.[(4)]	2,082	*
R. Martin Emanuele, Ph.D.[(5)]	2,062	*
Gregory R. Reyes M.D., Ph.D.[(6)]	1,638	*
Tamara A. Favorito[(7)]	26,505	12.3
Mark E. Spring[(8)]	1,666	*
All Current Directors and Executive Officers as a Group	276,803	13.0
5% Stockholders		
None		

* Less than 1%

(1) Consists of (i) 3,007 common shares held directly by Gregory D. Gorgas, (ii) 400 common shares held indirectly by Gorgas Family Trust, (iii) 57,176 shares of Common Stock issuable pursuant to options held directly by Gregory D. Gorgas exercisable within 60 days, (iv) 8,644 common shares issued on the conversion of an outstanding note payable, (v) 9,586 warrants representing 9,586 shares of Common Stock which have an exercise price of $6.24 per common share and expire in October 2030, and (vi) 17,592 warrants representing 17,592 shares of Common Stock which have an exercise price of $3.40 per common share and expire in October 2030.

(2) Consists of (i) 629 common shares held directly by Connie Matsui, (ii) 2,175 shares of Common Stock issuable pursuant to options held directly by Connie Matsui exercisable within 60 days, (iii) 34,578 common shares issued on the conversion of an outstanding note payable, (v) 38,346 warrants representing 38,346 shares of Common Stock which have an exercise price of $6.24 per common share and expire in October 2030, and (vi) 70,376 warrants representing 70,376 shares of Common Stock which have an exercise price of $3.40 per common share and expire in October 2030.

(3) Consists of (i) 139 common shares held by Steven Kelly, and (ii) 1,866 shares of Common Stock issuable pursuant to options held directly by Steven Kelly exercisable within 60 days.

(4) Consists of (i) 139 common shares held by Douglas Blayney, M.D., and (ii) 1,943 shares of Common Stock issuable pursuant to options held directly by Douglas Blayney, M.D., exercisable within 60 days.

(5) Consists of (i) 139 common shares held by R. Marty Emanuele, Ph.D., and (ii) 1,923 shares of Common Stock issuable pursuant to options held directly by R. Marty Emanuele, Ph.D., exercisable within 60 days.

(6) Consists of 1,638 shares of Common Stock issuable pursuant to options held directly by Gregory R. Reyes M.D., Ph.D., exercisable within 60 days.

(7) Consists of (i) 919 shares of Common Stock issuable pursuant to options held directly by Tamara A. Favorito exercisable within 60 days, (ii) 6,174 common shares issued on the conversion of an outstanding note payable, (iii) 6,846 warrants representing 6,846 shares of Common Stock which have an exercise price of $6.24 per common share and expire in October 2030, and (vi) 12,566 warrants representing 12,566 shares of Common Stock which have an exercise price of $3.40 per common share and expire in October 2030.

(8) Consists of 1,666 shares of Common Stock issuable pursuant to options held directly by Mark E. Spring, exercisable within 60 days.

Equity Compensation Plan Information

The following table summarizes information about our equity compensation plans as of December 31, 2025. All outstanding option awards relate to our Common Stock.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders:			
2018 Equity Incentive Plan[1]	227,842	$ 11.03	107,722
Equity compensation plans not approved by security holders	-	-	-
Total	227,842	$ 11.03	107,722

(1) Our Board adopted, and our stockholders approved, our 2018 Plan. The 2018 Plan provides that the number of shares available for issuance under the 2018 Plan will be increased on the first day of each fiscal year beginning with the 2021 fiscal year, in an amount equal to the least of (i) 7,500,000 shares (subject to the reverse stock split), (ii) fifteen (15%) of the outstanding shares on the last day of the immediately preceding fiscal year or (iii) such other amount of shares determined by our Board.

Changes in Control

We are unaware of any contract or other arrangement or provisions of our Articles or Bylaws the operation of which may at a subsequent date result in a change of control of our company.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

Described below are any transactions occurring since January 1, 2024 and any currently proposed transactions to which we were a party and in which:

- the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years; and
- a director, executive officer, holder of more than 5% of the outstanding capital stock of us, or any member of such person's immediate family had or will have a direct or indirect material interest.

None.

Indemnification of Directors and Officers

The Company's Articles of Incorporation and Bylaws provide that, to the fullest extent permitted by the laws of the State of Nevada, any officer or director of the Company, who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he/she is or was or has agreed to serve at the request of the Company as a director, officer, employee or agent of the Company, or while serving as a director or officer of the Company, is or was serving or has agreed to serve at the request of the Company as a director, officer, employee or agent (which, for purposes hereof, shall include a trustee, partner or manager or similar capacity) of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity. For the avoidance of doubt, the foregoing indemnification obligation includes, without limitation, claims for monetary damages against the indemnitee to the fullest extent permitted under Section 78.7502 of the Nevada Revised Statutes.

The indemnification provided shall be from and against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the indemnitee or on the indemnitee's behalf in connection with such action, suit or proceeding and any appeal therefrom, but shall only be provided if the indemnitee acted in good faith and in a manner indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action, suit or proceeding, had no reasonable cause to believe the indemnitee's conduct was unlawful.

In the case of any threatened, pending or completed action or suit by or in the right of the Company to procure a judgment in its favor by reason of the fact that he/she is or was a director, officer, employee or agent of the Company, or while serving as a director or officer of the Company, is or was serving or has agreed to serve at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, no indemnification shall be made in respect of any claim, issue or matter as to which the indemnitee shall have been adjudged to be liable to the Company unless, and only to the extent that, the Nevada courts or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, the indemnitee is fairly and reasonably entitled to indemnity for such expenses which the Nevada courts or such other court shall deem proper.

The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that he/she did not act in good faith and in a manner which the indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the indemnitee's conduct was unlawful.

To the extent that indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. If a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of our company in the successful defense of any action, suit or proceeding) is asserted by any of our directors, officers or controlling persons in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

Director Independence

Our Board has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our Board has determined that Ms. Matsui, Dr. Blayney, Mr. Kelly, Dr. Emanuele, Dr. Reyes and Ms. Favorito representing six of our seven directors, are "independent directors" as defined under the rules of the Nasdaq. Mr. Gorgas is not considered independent due to his service as an executive officer of the Company.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth the aggregate fees for audit services provided by MaloneBailey, LLP for the years ended December 31, 2025 and 2024:

	Year ended December 31,	
Fee Category	**2025**	**2024**
Audit Fees	$ 123,600	$ 123,593
Audit-Related Fees	129,265	4,120
Tax Fees	7,725	7,725
All Other Fees	-	-
Total Fees	$ 260,590	$ 135,438

Policy on Audit Committee Pre-Approval of Services Performed by Independent Registered Public Accounting Firm

Consistent with the requirements of the SEC and the Public Company Accounting Oversight Board (PCAOB) regarding auditor independence, our Audit Committee has responsibility for appointing, setting compensation, and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, our Audit Committee has established a policy for the pre-approval of all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services, and other services. The Audit Committee generally pre-approves particular services or categories of services on a case-by-case basis. The independent registered public accounting firm and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with these pre-approvals, and the fees for the services performed to date.

Our Audit Committee pre-approves all services provided by our independent auditors. All of the above services and fees were reviewed and approved by the Audit Committee either before or after the respective services were rendered.

Our Board has considered the nature and amount of fees billed by our independent auditors and believes that the provision of services for activities unrelated to the audit is compatible with maintaining our independent auditors' independence.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Financial Statements

(1) Financial statements for our company are listed in the index under Item 8 of this document.

(2) All financial statement schedules are omitted because they are not applicable, not material or the required information is shown in the financial statements or notes thereto.

(b) Exhibits

Exhibit No.	Description
3.1	Articles of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed on May 11, 2023)
3.2	Certificate of Change (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on June 13, 2025)
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 21, 2023)
3.4	Certificate of Amendment to Bylaws (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 10, 2025)
3.5	Certificate of Amendment to Bylaws (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 14, 2025)
4.1*	Description of Securities
4.2	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 filed on December 16, 2020)
10.1	Securities Purchase Agreement by and between the Company and Gregory D. Gorgas dated April 3, 2017 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on April 7, 2017)
10.2†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on May 8, 2017)
10.3	Stock Purchase Agreement dated May 4, 2017 (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on May 8, 2017)
10.4	Form of Private Placement Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 4, 2017)
10.5	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on August 4, 2017)
10.6	Stock Purchase Agreement dated August 1, 2017 (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed on August 4, 2017)
10.7#	Material and Data Transfer, Option and License Agreement dated as of December 20, 2017 by and between the Company and NEOMED Institute (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on January 16, 2018)
10.8#	First Amendment to Material and Data Transfer, Option and License Agreement by and between the Company and NEOMED Institute, dated as of January 4, 2019 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on April 15, 2019)
10.10#	License Agreement with Stony Brook University, by and between the Company and Stony Brook University, dated January 18, 2018 (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-1/A filed on April 17, 2018)
10.11†	2018 Equity Incentive Plan, as amended, and Forms of Award Agreement thereunder (incorporated by reference to Exhibit 99.1 to the Registration Statement on Form S-8 filed on December 16, 2020)

10.12†	Amended and Restated Employment Agreement by and between the Company and Gregory D. Gorgas dated August 30, 2019 (incorporated by reference to Exhibit 10.3 to the Annual Report on Form 10-K filed on November 25, 2019)
10.13†	Amendment to Amended and Restated Employment Agreement by and between the Company and Gregory D. Gorgas dated October 26, 2025 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on October 27, 2025)
10.14	Form of Note and Warrant Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on May 1, 2025)
10.15	Form of Convertible Note (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on May 1, 2025)
10.16	Form of Warrant (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on May 1, 2025)
10.17	Form of Securities Purchase Agreement by and between Artelo Biosciences Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 26, 2025)
10.18	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on June 26, 2025)
10.19	Form of $5.82 Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed on June 26, 2025)
10.20	Form of $10.00 Warrant (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed on June 26, 2025)
10.21	At-The-Market Offering Agreement by and among the Company and R.F. Lafferty & Co., Inc., dated as of July 18, 2025 (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed on July 18, 2025)
10.22	Form of Securities Purchase Agreement by and between Artelo Biosciences, Inc. and the investors named therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 4, 2025)
10.23	Form of Prefunded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on August 4, 2025)
10.24	Form of Market Priced Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed on August 4, 2025)
10.25	Form of $50.00 Warrant (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed on August 4, 2025)
10.26	Form of Termination and Mutual Release Agreement by and between Artelo Biosciences, Inc. and the investors named therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 20, 2025)
10.27#	Common Stock Warrant issued to ABK Labs, Inc., dated August 1, 2025 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on August 7, 2025)
10.28	Consulting Agreement by and between Artelo Biosciences, Inc. and ABK Labs, Inc., dated August 1, 2025 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 7, 2025)
10.29	Termination Agreement by and between Artelo Biosciences, Inc. and ABK Labs, Inc., dated August 19, 2025 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on August 20, 2025)
10.30	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on September 5, 2025)
10.31	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on October 1, 2025)
10.32	Cooperation Letter Agreement dated October 15, 2025, among the Company and the Farb Parties (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 17, 2025)
10.33†	Employment Agreement by and between the Company and Mark E. Spring dated October 26, 2025 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 27, 2025)

10.34	Form of Subscription Agreement by and between Artelo Biosciences Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 31, 2025)
10.35	Form of Convertible Note (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on October 31, 2025)
10.36	Form of Warrant (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on October 31, 2025)
19.1	Insider Trading Policy, as amended (incorporated by reference to Exhibit 19.1 to the Annual Report on Form 10-K filed on March 3, 2025)
21.1	List of subsidiaries (incorporated by reference to Exhibit 21.1 to the Quarterly Report on Form 10-Q filed on November 8, 2023)
23.1*	Consent of MaloneBailey, LLP
31.1*	Section 302 Certification of Principal Executive Officer
31.2*	Section 302 Certification of Principal Financial and Accounting Officer
32.1**	Section 906 Certification of Principal Executive Officer
32.2**	Section 906 Certification of Principal Financial and Accounting Officer
97.1†	Compensation Recovery Plan (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K filed on March 25, 2024)
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)

* Filed herewith.

† Management contracts or compensatory plans, contracts or arrangements.

Certain portions of this exhibit have been omitted.

** The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Annual Report, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Artelo Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report, irrespective of any general incorporation language contained in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

ARTELO BIOSCIENCES, INC.

Dated: February 24, 2026

By: */s/ Gregory D. Gorgas*
Gregory D. Gorgas
President, Chief Executive Officer,
Secretary and Director
(Principal Executive Officer)

By: */s/ Mark E. Spring*
Mark E. Spring
Chief Financial Officer and Treasurer
(Principal Financial Officer and
Principal Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints each of Gregory D. Gorgas and Mark E. Spring as his or her true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: February 24, 2026

/s/ Gregory D. Gorgas
Gregory D. Gorgas
President, Chief Executive Officer,
Secretary and Director
(Principal Executive Officer)

Dated: February 24, 2026

/s/ Mark E. Spring
Mark E. Spring
Chief Financial Officer and Treasurer
(Principal Financial Officer and
Principal Accounting Officer)

Dated: February 24, 2026

/s/ Connie Matsui
Connie Matsui
Director

Dated: February 24, 2026

/s/ Steven Kelly
Steven Kelly
Director

Dated: February 24, 2026

/s/ Douglas Blayney
Douglas Blayney
Director

Dated: February 24, 2026

/s/ R. Martin Emanuele
R. Martin Emanuele
Director

Dated: February 24, 2026

/s/ Gregory R. Reyes
Gregory R. Reyes
Director

Dated: February 24, 2026

/s/ Tamara A. Favorito
Tamara A. Favorito
Director

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Artelo Biosciences, Inc. has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our common stock.

Description of Capital Stock

The following description of our capital stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Articles of Incorporation, as amended (our "Articles of Incorporation") and our Bylaws, as amended (our "Bylaws"), copies of which are included as exhibits to our Annual Report on Form 10-K. We encourage you to read our Articles of Incorporation, our Bylaws and the applicable provisions of the Nevada Corporate Law, for additional information.

General

Our authorized capital stock consists of 500,069,444 shares of capital stock, of which 500,000,000 shares are common stock, par value $0.001 per share and 69,444 shares are preferred stock, par value $0.001 per share.

Common Stock

The holders of our common stock (i) have equal ratable rights to dividends from funds legally available, therefore, when, as and if declared by our board of directors (the "Board"); (ii) are entitled to share in all of our assets available for distribution to holders of common stock upon liquidation, dissolution or winding up of our affairs; (iii) do not have preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights; and (iv) are entitled to one non-cumulative vote per share on all matters submitted to a vote of stockholders. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Non-cumulative Voting

Our Articles of Incorporation and our Bylaws do not provide for cumulative voting rights. At any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise required by law. The presence in person or by proxy of the holders of at least 35% of the votes entitled to be cast on a matter at a meeting shall constitute a quorum of shareholders for that matter. All directors hold office until the expiration of their term for which they are elected and until their successors have been elected and qualified or until their earlier death, resignation, disqualification or removal.

Election of Directors and Vacancies; Board of Directors

Our Bylaws provide the number of members of our Board, unless and until changed by resolution of the Board shall be not less than one nor more than twelve. The Board may increase or decrease this number by resolution. Our Board currently consists of seven directors, which are divided into three classes, designated Class I, Class II and Class III. The election of each director requires the affirmative vote of a majority of the shares present in person or by proxy and entitled to vote at a meeting at which a quorum is present.

Except as otherwise provided by law, vacancies in the Board, whether caused by resignation, death, retirement, disqualification, removal, increase in the number of directors, or otherwise, may be filled for the remainder of the term by the Board, by the shareholders, or, if the directors in office constitute less than a quorum of the Board, by an affirmative vote of a majority of the remaining directors. The term of a director elected to fill a vacancy expires at the next shareholders' meeting at which directors are elected. A vacancy that will occur at a specific later date may be filled before the vacancy occurs, but the new director(s) may not take office until the vacancy occurs.

Our Bylaws provide that any director may be removed at any time by a two-thirds shareholder vote at a special meeting called for that purpose.

Anti-Takeover Effects of Nevada Law and our Articles of Incorporation and Bylaws.

Nevada law, our Articles of Incorporation, and our Bylaws contain certain provisions that may have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Classified Board. Our amended and restated certificate of incorporation provides that our board of directors is divided into three classes, designated Class I, Class II, and Class III. Each class will be an equal number of directors, as nearly as possible, consisting of one third of the total number of directors constituting the entire board of directors. The term of Class I directors shall terminate on the date of the 2027 annual meeting, the term of the Class II directors shall terminate on the date of the 2025 annual meeting, and the term of the Class III directors shall terminate on the date of the 2026 annual meeting. At each annual meeting of stockholders, successors to the class of directors whose term expires at that annual meeting will be elected for a three-year term.

Stockholder Meetings. Our Bylaws provide that a special meeting of stockholders may be called only by our president, by all of the directors provided that there are no more than three directors, or if more than three, by any three directors, or by the holder of a majority share of our capital stock.

Stockholder Action by Written Consent. Our Bylaws allow for any action that may be taken at any annual or special meeting of the stockholders to be taken without a meeting and without prior notice, if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding shares having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

Stockholders Not Entitled to Cumulative Voting. Our Bylaws do not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Nevada Business Combination Statutes. The "business combination" provisions of Sections 78.411 to 78.444, inclusive, of the Nevada Revised Statutes, (the "NRS"), generally prohibit a Nevada corporation with at least 200 stockholders of record from engaging in various "combination" transactions with any interested stockholder for a period of two years after the date of the transaction in which the person became an interested stockholder, unless the transaction is approved by the Board prior to the date the interested stockholder obtained such status or the combination is approved by the Board and thereafter is approved at a meeting of the stockholders by the affirmative vote of stockholders representing at least 60% of the outstanding voting power held by disinterested stockholders, and extends beyond the expiration of the two-year period, unless:

- the combination was approved by the Board prior to the person becoming an interested stockholder or the transaction by which the person first became an interested stockholder was approved by the Board before the person became an interested stockholder or the combination is later approved by a majority of the voting power held by disinterested stockholders; or

- if the consideration to be paid by the interested stockholder is at least equal to the highest of: (a) the highest price per share paid by the interested stockholder within the two years immediately preceding the date of the announcement of the combination or in the transaction in which it became an interested stockholder, whichever is higher, (b) the market value per share of common stock on the date of announcement of the combination and the date the interested stockholder acquired the shares, whichever is higher, or (c) for holders of preferred stock, the highest liquidation value of the preferred stock, if it is higher.

A "combination" is generally defined to include mergers or consolidations or any sale, lease exchange, mortgage, pledge, transfer, or other disposition, in one transaction or a series of transactions, with an "interested stockholder" having: (a) an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation, (b) an aggregate market value equal to 5% or more of the aggregate market value of all outstanding voting shares of the corporation, (c) more than 10% of the earning power or net income of the corporation, and (d) certain other transactions with an interested stockholder or an affiliate or associate of an interested stockholder.

In general, an "interested stockholder" is a person who, together with affiliates and associates, beneficially owns (or within two years, did own) 10% or more of the voting power of the outstanding voting shares of a corporation. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Nevada Control Share Acquisition Statutes. The "control share" provisions of Sections 78.378 to 78.3793, inclusive, of the NRS apply to "issuing corporations" that are Nevada corporations with at least 200 stockholders of record, including at least 100 stockholders of record who are Nevada residents, and that conduct business in Nevada directly or through an affiliated corporation. The control share statute prohibits an acquirer, under certain circumstances, from voting its shares of a target corporation's stock after crossing certain ownership threshold percentages, unless the acquirer obtains approval of the target corporation's disinterested stockholders. The statute specifies three thresholds: one-fifth or more but less than one-third, one-third or more but less than a majority, and a majority or more, of the outstanding voting power. Generally, once an acquirer crosses one of the above thresholds, those shares in an offer or acquisition and acquired within 90 days thereof become "control shares" and such control shares are deprived of the right to vote until disinterested stockholders restore the right. These provisions also provide that if control shares are accorded full voting rights and the acquiring person has acquired a majority or more of all voting power, all other stockholders who do not vote in favor of authorizing voting rights to the control shares are entitled to demand payment for the fair value of their shares in accordance with statutory procedures established for dissenters' rights.

A corporation may elect to not be governed by, or "opt out" of, the control share provisions by making an election in its articles of incorporation or bylaws, provided that the opt-out election must be in place on the 10th day following the date an acquiring person has acquired a controlling interest, that is, crossing any of the three thresholds described above. We have not opted out of the control share statutes, and will be subject to these statutes if we are an "issuing corporation" as defined in such statutes.

The effect of the Nevada control share statutes is that the acquiring person, and those acting in association with the acquiring person, will obtain only such voting rights in the control shares as are conferred by a resolution of the stockholders at an annual or special meeting. The Nevada control share law, if applicable, could have the effect of discouraging takeovers of us.

Amendment of Charter and Bylaw Provisions. The amendment of any of the above provisions would require approval by holders of at least a majority of the total voting power of all of our outstanding voting stock, except in certain circumstances.

The provisions of Nevada law, our Articles of Incorporation, and our Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "ARTL."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. The transfer agent and registrar's address is 48 Wall Street, 23rd Floor, New York, NY 10043. The transfer agent's telephone number is (800) 937-5449.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File Nos. 333-288653, 333-264967, 333-291597), Form S-3 (File No. 333-273153), and Form S-8 (File No. 333-285934) of our report dated February 23, 2026, with respect to the audited consolidated financial statements of Artelo Biosciences, Inc. (the "Company") appearing in this Annual Report on Form 10-K.

/s/ MaloneBailey, LLP
www.malonebailey.com
Houston, Texas
February 23, 2026

EXHIBIT 31.1

CERTIFICATION

I, Gregory D. Gorgas, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: February 24, 2026

/s/ Gregory D. Gorgas
Gregory D. Gorgas
President, Chief Executive Officer,
Secretary and Director
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Mark E. Spring, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: February 24, 2026

/s/ Mark E. Spring
Mark E. Spring
Chief Financial Officer and Treasurer
(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 Annual Report of Artelo Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), the undersigned, in the capacities and on the dates indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his 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.

Date: February 24, 2026

/s/ Gregory D. Gorgas
Gregory D. Gorgas
President, Chief Executive Officer,
Secretary and Director
(Principal Executive Officer)

EXHIBIT 32.2

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 Annual Report of Artelo Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), the undersigned, in the capacities and on the dates indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his 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.

Date: February 24, 2026

/s/ Mark E. Spring
Mark E. Spring
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal
Accounting Officer)