

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, 2022

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

(State or other jurisdiction of incorporation or organization)

33-1220924

(I.R.S. Employer Identification No.)

505 Lomas Santa Fe, Suite 160,
Solana Beach, CA USA

(Address of principal executive offices)

92075

(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
Warrants	ARTLW	The Nasdaq Stock Market, LLC

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

N/A

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of 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 last 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
Non-accelerated Filer

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 held by non-affiliates of the Registrant on June 30, 2022, was \$3,685,251 based on a \$4.75 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 2,855,688 shares of common stock issued and outstanding as of March 27, 2023.

Explanatory note: The Company changed its fiscal year end from August 31 to December 31 on September 17, 2021. Due to the change in fiscal year end we are reporting the financial statements and other disclosures as of and for the year ended December 31, 2022, four months ended December 31, 2021, and year ended August 31, 2021.

TABLE OF CONTENTS

PART I

<u>ITEM 1.</u>	<u>BUSINESS</u>	5
<u>ITEM 1A.</u>	<u>RISK FACTORS</u>	15
<u>ITEM 1B.</u>	<u>UNRESOLVED STAFF COMMENTS</u>	45
<u>ITEM 2.</u>	<u>PROPERTIES</u>	45
<u>ITEM 3.</u>	<u>LEGAL PROCEEDINGS</u>	45
<u>ITEM 4.</u>	<u>MINE SAFETY DISCLOSURES</u>	45

PART II

<u>ITEM 5.</u>	<u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	46
<u>ITEM 6.</u>	<u>[RESERVED]</u>	47
<u>ITEM 7.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	47
<u>ITEM 7A.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	52
<u>ITEM 8.</u>	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	F-1
<u>ITEM 9.</u>	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	53
<u>ITEM 9A.</u>	<u>CONTROLS AND PROCEDURES</u>	53
<u>ITEM 9B.</u>	<u>OTHER INFORMATION</u>	53
<u>ITEM 9C.</u>	<u>DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTION</u>	53

PART III

<u>ITEM 10.</u>	<u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	54
<u>ITEM 11.</u>	<u>EXECUTIVE COMPENSATION</u>	59
<u>ITEM 12.</u>	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	66
<u>ITEM 13.</u>	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	68
<u>ITEM 14.</u>	<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	68

PART IV

<u>ITEM 15.</u>	<u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	69
<u>ITEM 16.</u>	<u>FORM 10-K SUMMARY</u>	69
<u>SIGNATURES</u>		70

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 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;
- any impact of the global COVID-19 pandemic, or responses to the pandemic, on our business, clinical trials or personnel;
- geopolitical tensions, including the war in Ukraine, 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 US 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;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- potential claims related to our intellectual property;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to 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 United States Dollars ("USD") and are prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). The following discussion should be read in conjunction with our financial statements and the related notes that appear elsewhere in this annual report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below and elsewhere in this annual report.

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

As used in this annual report, the terms "we", "us", "our" and "our company" mean Artelo Biosciences, Inc., and our wholly-owned subsidiaries, Trinity Reliant Ventures Limited, in Ireland, Artelo Biosciences Limited, in England and Wales, and Artelo Biosciences Corporation, in Canada, unless otherwise indicated.

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 of therapeutics that target lipid-signaling pathways, including the endocannabinoid system (the “ECS”), a family of receptors and neurotransmitters that form a biochemical communication network throughout the body.

Our product candidate pipeline broadly leverages leading scientific methodologies and balances risk across mechanism of action and stages of development. Our programs represent a comprehensive approach in utilizing the power and promise of lipid signaling to develop pharmaceuticals for patients with unmet healthcare needs. We are currently developing a dual cannabinoid agonist. This synthetic small molecule program is a G protein-coupled receptor (“GPCR”) designated ART27.13. We are developing ART27.13 as a potential treatment for anorexia associated with cancer in a Phase 1b/2a trial, titled the Cancer Appetite Recovery Study (“CAREs”). Our second program, ART26.12 is a small molecule and the lead product candidate from our chemical library of inhibitors of fatty acid binding proteins, notably Fatty Acid Binding Protein 5 (“FABP5”), undergoing pre-clinical research as a potential treatment for painful neuropathies. In addition, ART26.12 may have broad applications as a cancer therapeutic, a treatment for pain and inflammation, and potential use in anxiety-related disorders, including post-traumatic stress disorder. We are also developing our own invention ART12.11 (the “CBD cocrystal”). ART 12.11 is our patented solid-state composition of cannabidiol (“CBD”).

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-restricted high-potency dual CB₁ and CB₂ receptor full-receptor agonist, which was originally invented at AstraZeneca plc (“AstraZeneca”). We exercised our option to exclusively license this GPCR 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. In Phase 1, single dose studies in healthy volunteers and a multiple ascending dose study in individuals with chronic low back pain conducted by AstraZeneca, ART27.13 exhibited an attractive pharmacokinetic and absorption, distribution, metabolism, and excretion profile and was well tolerated within the target exposure range. It also exhibited dose-dependent and potentially clinically meaningful increases in body weight. Importantly, the changes in body weight were not associated with fluid retention or other adverse effects and occurred at exposures without central nervous system (“CNS”) side effects. Discussions with UK, US and Canadian regulators indicate there is a potential pathway for development of ART27.13 for the treatment of cancer-related anorexia, which affects approximately 60% of advanced stage cancer patients.

We commenced enrollment and dosed the first patient in CAREs, our Phase 1b/2a clinical study of cancer-related anorexia with ART27.13 in April 2021. We have been enrolling patients steadily since that time. The results of the Phase 1b stage are intended to determine the most effective and safe dose recommended for the Phase 2a portion of CAREs. After we completed enrollment of the planned first three dosing cohorts, per the approved protocol, we elected to enroll a fourth cohort of six patients at a higher dose before making a determination as to which dose is selected for the Phase 2a stage of CAREs. We experienced minor delays due to COVID-19; however, we do not foresee significant ongoing impacts, and anticipate commencing enrollment in the stage two portion of CAREs during the first half of 2023. We are aware the situation could change and we are working to mitigate any adverse effects that may materialize due to the pandemic or its aftermath or any other global disruption.

Our second in-licensed patented program is from our platform of small-molecule inhibitors of fatty acid binding proteins, notably FABP5 acquired from Stony Brook University (“SBU”), and our lead program is designated ART26.12. To date, SBU has received approximately \$8.0 million in funding from the National Institutes of Health to develop these candidates including a \$4.2 million grant in 2020 to advance research of FABP5 inhibition in prostate cancer. Fatty acid binding proteins (“FABPs”) are attractive therapeutic targets, however, the high degree of sequence and structural similarities among family members have made the creation of drugs targeting specific FABPs challenging. FABP5 is believed to specifically target and regulate one of the body’s endogenous cannabinoids, anandamide (“AEA”). While searching for a FABP5 inhibitor to regulate AEA, researchers at SBU discovered the chemistry for creating a large library of compounds which we believe to be highly specific and potent small molecule inhibitors of FABP5 and other isoforms. In addition to its potential as a synthetic endocannabinoid modulator with development targeting pain, inflammation, and anxiety, FABP5 plays an important role in lipid signaling and is believed to be an attractive strategy for cancer drug development. 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. We licensed exclusive world-wide rights to these inhibitors from SBU in all fields. Through our sponsored research we have subsequently identified a potential role for FABP5 inhibition to treat anxiety disorders, such as Post Traumatic Stress Disorder (“PTSD”). We have also been awarded a research grant in Canada to expand on our earlier research at the University of Western Ontario in this new development area. Based upon recently disclosed positive pre-clinical evidence of promising activity and a differentiated mechanism-of-action for the prevention and treatment of Chemotherapy Induced Peripheral Neuropathy (“CIPN”), we have prioritized CIPN as the initial indication for development of our lead product candidate, ART26.12. CIPN is a significant unmet need, often resulting in anti-cancer treatment delays or discontinuations, and there are currently no approved treatments for CIPN from the regulatory authorities in the US, UK or EU. The ART26.12 program is in the beginning stages of regulatory-enabling studies. We anticipate first-in-human studies could begin in the middle of 2024 depending, in part, on the ongoing impact of the COVID-19 global pandemic, the ability of selected contract research organizations to source materials and resources, including animals, in order to perform required studies, and the review and approval process with the regulatory authorities, such as the US Food and Drug Administration (the “FDA”). The COVID-19 pandemic has created uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as us, and because of such uncertainties, we are unable to predict our expected timelines with any degree of certainty at this time.

[Table of Contents](#)

In addition to our in-licensed programs, we have internal discovery research initiatives which resulted in ART12.11, a proprietary cocrystal composition of CBD. The crystal structure of CBD is known to exhibit solid polymorphism, or the ability to manifest in different forms. Polymorphism can adversely affect stability, dissolution, and bioavailability of a drug product and thus may affect its quality, safety, and efficacy. Based upon our research, we believe our 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. Anticipated advantages of this single crystal structure include improved stability, solubility, and a more consistent absorption profile. We believe these features will result in more consistent and improved bioavailability and may lead to improved safety and efficacy.

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

We are developing our product candidates in accordance with traditional regulated drug development standards and expect to make them available to patients via prescription or physician orders only after obtaining marketing authorization from a regulatory authority, such as the 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 expect to retain rights to internally develop and commercialize products; however, we may seek collaborations with partners in the biopharmaceutical industry when that strategy serves to maximize value for our stockholders.

Product Candidate Pipeline:

Product Candidate	Target Indications	Development Phase	Estimated Market Size
ART27.13 – Synthetic Dual Cannabinoid GPCR Agonist	Anorexia associated with cancer	Clinical	Cancer anorexia cachexia syndrome: >\$2 billion
ART26.12 – FABP5 inhibitor	Chemotherapy Induced Peripheral Neuropathy, Prostate cancer and Breast cancer, pain, and anxiety disorders	Pre-clinical	CIPN: >\$1 billion Prostate cancer: approximately \$9 billion Breast cancer: approximately \$18 billion PTSD: approximately \$7 billion
ART12.11 – Synthetic CBD Cocrystal	Inflammatory Bowel Disease (IBD), Post-Traumatic Stress Disorder (PTSD), and other potential indications including cancer	Pre-clinical	IBD: approximately \$7 billion PTSD: approximately \$7 billion

Background

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

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

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

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

Business Strategy

Our objective is to develop and commercialize ethical pharmaceutical products that provide physicians access to the therapeutic potential lipid signaling of modulators, including modulating the ECS. We intend to pursue technologies and compounds that offer promising therapeutic approaches to known and validated signaling pathways, specifically lipid signaling which includes compounds that promote the effectiveness of the ECS. While many of our programs are directed towards improving the lives of people suffering with cancer and cancer treatments, the Company’s portfolio may ultimately be used to treat a wide range of diseases and conditions where leveraging the ECS is particularly useful.

Corporate Information

Our website address is www.artelobio.com. The contents of our website are not incorporated by reference into this Form 10-K. We provide, free of charge through a link on our website access to our Transition Reports on Form 10-KT, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as amendments to those reports, as soon as reasonably practical after the reports are electronically filed with, or furnished to, the Commission.

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 products that modulate the ECS.

Patent Estate and Licenses

Product Candidate	Patent Status	License
ART27.13 – Synthetic GPCR Agonist	Two (2) issued patents (US) including composition of matter, terms 11/3/24 and 9/22/25, not including any patent term extension, or PTE; 31 issued (Intl) patents, and one (1) pending (Intl) application.	Worldwide exclusive license
ART26.12 – FABP5 inhibitor	Three (3) patents issued (US), terms 6/18/31 (includes PTA) and 7/19/33, not including any PTE. Covers the target, composition of matter, and utility claims. One (1) pending (US) and eleven (11) pending (Intl) applications, and three (3) pending (US) provisional applications	Worldwide exclusive license
ART12.11 – Synthetic CBD Cocrystal	Issued (1) composition of matter patent (US) with a term through 12/10/38. Pending applications (US & 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 provides 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 by and between us and NEOMED (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 two hundred million dollars will be due upon the achievement of certain regulatory, commercial, and sales milestones. Additionally, we may 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. 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 ⁽¹⁾	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 ⁽²⁾	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 ⁽³⁾	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 agreement became effective on that same 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. The Stony Brook Agreement has an effective date of January 18, 2018 (the “SBU Effective Date”).

Table of Contents

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)	\$ 150,000.00
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	\$ 250,000.00
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	\$ 1,500,000.00
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	\$ 1,000,000.00
First time annual Net Sales (as defined in the Stony Brook Agreement) greater than \$100,000,000.00	\$ 1,000,000.00
First time annual Net Sales greater than \$500,000,000.00	\$ 5,000,000.00

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 US, China, Spain, and UK.

Scientific Approach

We intend to create, acquire, and develop a full 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 endogenous 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, but are instead compounds that have been shown to have promising potential in 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. We currently designate this program ART26.12. 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 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 serve 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 growing portfolio. Our current pipeline encompasses multiple mechanisms for endocannabinoid system modulation. The specific programs that are currently in development are set forth below.

- *ART27.13* – ART27.13 is our name for the synthetic GPCR agonist compound formerly known as NEO1940 and AZD1940. We intend to develop a synthetic formulation suitable for treatment of anorexia/weight loss associated with cancer. ART27.13 has been in 205 subjects in prior clinical studies and is currently enrolling in a Phase 1b/2a study in anorexia associated with cancer.
- *ART26.12* – Our FABP5 inhibitor program is intended for treatment of breast cancer, prostate cancer, neuropathic and nociceptive pain and anxiety disorders, including PTSD. Our near-term goal is to develop our lead development compound and assess its activity in models of cancer and pain. While advancing our lead, additional compound(s) may be identified and selected for advancement in regulatory-enabling studies.
- *ART12.11* – Our novel solid-state CBD composition cofomed with tetramethylpyrazine (“TMP”) is targeted for development in Inflammatory Bowel Disease, Post-Traumatic Stress Disorder (“PTSD”), and rare/orphan diseases. The rare/orphan disease strategy is supported by recent FDA actions with other company programs containing CBD, however, we intend to prioritize pain conditions associated with inflammation and neurologic conditions such as epilepsy and PTSD. In addition, interesting data was observed in anti-cancer models and the Company is continuing to explore this potential development strategy.

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., Pfizer Inc., and Tetra Bio-Pharma 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.

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) 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 by the current administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In December of 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the individual mandate had been repealed, and on December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether other reforms enacted as part of the ACA but not specifically related to the individual mandate or health insurance could be severed from the rest of the ACA so as not to be declared invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, heard oral arguments on November 10, 2020 and issued a decision on June 17, 2021, effectively upholding the constitutionality of the ACA. It is unclear how this result, similar litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. 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 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was signed into law on March 27, 2020 and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020 and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs, as well as several recent Executive Orders signed by President Trump. Additionally, individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs.

Employees

We currently have seven (7) employees. 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 have no unionized employees. We currently have no 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.

ITEM 1A. RISK FACTORS

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

Risk Factor Summary

Risks Related to our Business and Product Candidates:

- We will need to raise additional financing to support our business objectives. We cannot be sure we will be able to obtain additional financing on terms favorable to us when needed, or at all. If we are unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated.
- We are currently receiving Research and Development, or R&D, tax credits from the United Kingdom (“UK”) in connection with our clinical trials being conducted in the UK. With effect from April 2024 if expenditure is incurred in connection with activities which take place outside the UK as part of our clinical trials, such credits are not expected to be available.
- If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are vital to our business.
- Changes in regulatory requirements or other unforeseen circumstances may impact the timing of the initiation or completion of our clinical trials.
- We face many of the risks and difficulties frequently encountered by relatively new companies with respect to our operations.
- We have no mature product candidates and may not be successful in licensing any.
- Even if we are successful in licensing lead product candidates, resource limitations may limit our ability to successfully develop them.

Risks Related to our Intellectual Property:

- If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to our product candidates, and our ability to successfully commercialize any product candidates we may develop, and our science may be adversely affected.
- Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- We may be subject to claims challenging the inventorship of our patents and other intellectual property.
- Intellectual property rights do not necessarily address all potential threats.
- Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Risks Related to our Securities:

- Our Common Stock may be delisted from The Nasdaq Capital Market if we cannot maintain compliance with Nasdaq’s continued listing requirements.
- If we sell securities in future financings stockholders may experience immediate dilution and, as a result, our stock price may decline.
- The price of our securities may be volatile, and you could lose all or part of your investment. Further, we do not know whether an active, liquid and orderly trading market will continue for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of our securities.
- Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(I) which apply to a former “shell company.”
- Sales of our currently issued and outstanding stock may become freely tradable pursuant to Rule 144 and sales of such shares may have a depressive effect on the share price of our Common Stock.

RISKS RELATED TO OUR BUSINESS AND PRODUCT CANDIDATES

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

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

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

- the costs related to initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- any change in the clinical development plans for these product candidates;
- the number and characteristics of product candidates that we develop or acquire;

Table of Contents

- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the events related to the outcome, timing and cost of meeting regulatory requirements established by the US Drug Enforcement Agency (the “DEA”), the FDA or other comparable foreign regulatory authorities;
- the potential costs of filing, prosecuting, defending and enforcing our patent claims and other intellectual property;
- changes in economic conditions, including recessionary effects and inflationary pressures;
- the costs associated with attracting and retaining skilled personnel;
- the costs associated with being a public company;
- the cost of defending intellectual property disputes; and
- the cost of marketing and generating revenues for any of our product candidates.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts, or other aspects of our business plan. We also may be required to relinquish, license or otherwise dispose of rights to products or product candidates that we would otherwise seek to commercialize or develop ourselves on terms that are less favorable than might otherwise be available. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

As described in Part I, Item 7. of this Annual Report on Form 10-K, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” we entered into the Lincoln Park Agreements with Lincoln Park Capital Fund LLC (“Lincoln Park”) which provide, among other things, for the sale by us to Lincoln Park of up to \$20.0 million in shares of our Common Stock, subject to the terms of the Lincoln Park Agreements. Though we have the right, but not the obligation, to sell to Lincoln Park shares of our Common Stock under the Lincoln Park Agreements, market conditions may not be favorable for us to sell shares of our Common Stock to Lincoln Park.

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

We are currently receiving Research and Development (“R&D”), tax credits from the UK in connection with our clinical trials being conducted in the UK. With effect from April 2024 if expenditure is incurred in connection with activities which take place outside the UK as part of our clinical trials, such credits are not expected to be available.

The UK government grants R&D tax credits to companies conducting clinical trials in the UK, as we are currently doing. This effectively reduces the costs, and the cash we use, for our current trials. With effect from April 2024 if expenditure is incurred in connection with activities which take place outside the UK as part of our clinical trials, such credits are not expected to be available. In addition, if the rate of relief changes or the regime is altered in scope, our production costs could increase significantly. Based on announcements made as part of the UK Budget on March 15, 2023 and which have yet to be enacted, the rate of relief from April 2023 will depend on whether the company incurs

40% of its total expenditure on R&D. If it does, the value of the relief will only reduce marginally from April 2023. Otherwise, the rate of repayable credit will reduce materially and this will significantly adversely affect the cost of product development.

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

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

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

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

The full impact of the COVID-19 pandemic on our clinical trial plans, product development, and how a regulatory body reviews study data is difficult to predict, but the pandemic may have a material adverse impact on our business operations, clinical trial plans, and product development, including delays in clinical trial and study participant recruitment, delays in regulatory approval of our product candidates, and the need to expend additional costs and resources. The pandemic’s impact on the US and global economy and drug product manufacturing and supply chain may also adversely affect our clinical trial plans and drug development. Additionally, depending on the duration of impacts of the COVID-19 pandemic, including stresses on healthcare systems and our clinical trial sites, our ability to recruit participants for our clinical trials may be significantly impacted, and we may not be able to commence or complete our clinical trials as currently planned. We may also be required to significantly modify our study protocol, policies and procedures in order to address or accommodate patients and study site needs. Such changes can include modification to protocol inclusion and exclusion criteria, extending the time for patient follow up visits, using telemedicine, phone interviews and other technology to monitor patient safety, all of which will need to be approved by applicable IRBs, ethics committees, and regulatory authorities.

Geopolitical tensions, including the war in Ukraine, 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 and our business generally.

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

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

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

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

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

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

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

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

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

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

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

- our research and development efforts, including preclinical studies and clinical trials of our product candidates;
- developing sustainable, scalable, reliable and cost-effective manufacturing and distribution processes for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own cGMPs, manufacturing facilities and processes;
- addressing any competing technological and industry developments;
- identifying, assessing, acquiring and/or developing new technology platforms and product candidates across numerous therapeutic areas;
- obtaining regulatory approvals and marketing authorizations for product candidates;
- launching and commercializing any approved products, either directly or with a collaborator or distributor;
- obtaining market acceptance of and acceptable reimbursement for any approved products;
- completing collaborations, licenses and other strategic transactions on favorable terms, if at all;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

We have very limited operating history and capabilities.

Although our company was formed in 2011, our current business focus and operations in pharmaceutical development began in 2017. We do not currently have the ability to perform all the functions necessary to develop and commercialize any product candidates. The successful development of any product candidates will require us to perform a variety of functions including, but not limited to:

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

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

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

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

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

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

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

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

Prior to commencing clinical trials in territories with a regulatory authority we must obtain the necessary approvals to commence the clinical studies. For example, before initiating a clinical trial in the United States for any of our product candidates, we may be required to have an IND in effect for each product candidate. Submission of an IND may not result in the FDA allowing clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials. Once an IND is submitted, the sponsor must wait 30 calendar days before initiating the clinical trial, during which FDA will review the IND and either provide comments or allow the trial to proceed. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a clinical trial application (the equivalent of an IND in foreign jurisdictions), these regulatory authorities may change their requirements in the future. The fact that we are pursuing novel technologies may also exacerbate these risks with respect to our product candidates, and as a result we may not meet our anticipated clinical development timelines.

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

As with most biopharmaceutical products, use of our product candidates could be associated with side effects or adverse events which can vary in severity and frequency. Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval or market our product candidates. Side effects such as toxicity or other safety issues associated with the use of our product candidates could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business if we are found liable.

The emergence of unforeseen safety issues or adverse events may lead to regulatory agencies requiring us to conduct additional preclinical or clinical trials regarding the safety and efficacy of our product candidates, which we have not planned or anticipated. We cannot assure you that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition. We may also inadvertently fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

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

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

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

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on clinical trial design, to commence a clinical trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtain and maintain IRB, approval at each clinical trial site;
- identify, recruit, and enroll suitable patients to participate in a clinical trial;
- have a sufficient number of patients complete a clinical trial or return for post-treatment follow-up;
- ensure clinical investigators observe clinical trial protocol or continue to participate in a clinical trial;
- address any patient safety concerns that arise during the course of a clinical trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- timely manufacture sufficient quantities of a product candidate for use in clinical trials; or
- raise sufficient capital to fund a clinical trial.

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

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

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

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

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

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

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

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

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

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

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

If we are unable or decide not to establish internal sales, marketing, and distribution capabilities, we expect to pursue collaborative arrangements regarding the sales, marketing, and distribution of our future products. However, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, their sales forces may not be successful in marketing our future products. Any revenue we receive would depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the sales, marketing, and distribution efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales, marketing, and distribution efforts of our product candidates, if approved. There can be no assurance that we will be able to develop internal sales, marketing distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

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

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

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

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

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

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

We currently do not have any manufacturing facilities. We also do not own any properties, laboratories, or manufacturing facilities. However, we have leased office space in Solana Beach, California and a location near Manchester, United Kingdom. Our facilities could be harmed or rendered inoperable by natural or human-made disasters, including earthquakes, fires, power shortages, nuclear, and radiation accidents, telecommunications failures, 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 we are predominantly self-insured. Any of these may render it difficult or impossible for us to continue company operations. If any of our facilities is inoperable for even a short period of time, the interruption in research and development may result in harm to our reputation and increased costs, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work.

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

Our commercial success is significantly dependent on intellectual property related to any product candidates and technologies we may either acquire, license, or develop internally. We are currently the licensee of multiple issued patents and pending patent applications and we intend to license additional technologies from pharmaceutical and biotechnology companies, and research institutions. In addition, we have one US patent, one US patent application, and two foreign patent applications directed to a solid-state CBD composition.

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

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

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

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

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

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

In the United States, the DEA regulates the use of chemicals for medical research and/or commercial development, including the requirement of annual registrations to manufacture or distribute cannabinoid-based pharmaceuticals. We do not currently conduct manufacturing or repackaging/relabeling of any product candidates in the United States, however we intend to conduct research on cannabinoids, including naturally-occurring cannabinoids, which are currently considered Schedule I controlled substances. We plan to obtain the required licenses in the territories regulating the possession and supply of cannabinoids and to utilize third party contractors to conduct research who have the required registrations, however there is no assurance that we will be successful in obtaining the required licenses or that we will be successful identifying or engaging third party contractors who have the required registrations.

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

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

Any product candidates we develop may be subject to US controlled substance laws and regulations and similar controls in territories outside the US where we are conducting research. Failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition.

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

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

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

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

Clinical trials. It is possible some compounds we develop may contain cannabinoids, which may be designated as Schedule I substances, therefore, to conduct clinical trials in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our lead products, as applicable, and to obtain the product from our importer. If the DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import. We do not currently conduct any clinical trials, clinical material manufacturing or repackaging/relabeling in the US; however, we are subject to similar laws and regulations in the UK and other countries where we are conducting a clinical trial and have contracted for clinical material manufacturing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are substantially dependent on initial and continued market acceptance and proliferation of cannabinoid-derived therapeutic treatments, and specifically ART12.11, our CBD cocrystal. We believe that as cannabinoid-derived products become more widely accepted by the medical and scientific communities and the public at large, stigma associated with cannabinoid-derived products and treatments will moderate and, as a result, consumer demand is likely to continue to grow. However, we cannot predict the future growth rate and size of the market, assuming that the regulatory framework is favorable of which there can be no assurance. Any negative outlook on cannabinoid-derived products and treatments could adversely affect our business prospects.

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

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

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

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

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

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

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

Cannabinoid-based research activities in the pharmaceutical industry may make it difficult to obtain insurance coverage.

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

We face a potentially highly competitive market.

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

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

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

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

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

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

Our ability to compete in our highly competitive industry depends upon our ability to attract and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our Chief Executive Officer, Chief Financial Officer, President, Treasurer and Secretary, Gregory D. Gorgas. The loss of the services of Mr. Gorgas, and our inability to find a suitable replacement could result in delays in research and development and product development and harm our business. Additionally, although we have entered into an employment agreement with Mr. Gorgas, this employment agreement provides for at-will employment, which means that Mr. Gorgas could leave our employment at any time, with or without notice. We maintain a “key person” insurance policy on the life of Mr. Gorgas.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable service providers to remain at our company, in addition to salary and cash incentives, we have issued stock options and restricted stock awards that vest over time. The value to service providers of stock options and restricted stock awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our success depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers and scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations.

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

To execute our business plan, we will need to rapidly add other management, accounting, regulatory, and scientific staff. We currently have four employees and approximately twenty consultants and contractors. We will need to attract, retain and motivate a significant number of new additional managerial, operational, sales, marketing, financial, and other personnel, as well as highly skilled scientific and medical personnel, and to expand our capabilities to successfully pursue our research, development, manufacturing and commercialization efforts and secure collaborations to market and distribute our products. This growth may strain our existing managerial, operational, financial and other resources. We also intend to add personnel in our research and development and regulatory departments as we expand our clinical trial and research capabilities. Moreover, we will need to hire additional accounting and other personnel and augment our infrastructure as we continue to grow the company. Any inability to attract and retain qualified employees to enable our planned growth and establish additional capabilities or our failure to manage our growth effectively could delay or curtail our product development and commercialization efforts and harm our business.

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

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

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

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

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

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

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

We may not successfully manage our growth.

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

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

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our product candidates or utilize similar science or technology but that are not covered by the claims of the patents that we may own or license from our licensors or that incorporate certain research in our product candidates that is in the public domain;
- we, or our licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we or our licensors own now or in the future;
- we, or our licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our or our licensors' current or future pending patent applications will not lead to issued patents;
- issued patents that we or our licensors hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we or our licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary product candidates that are patentable;
- the patents of others may harm our business if, for example, we or our licensors are found to have infringed those patents or if those patents serve as prior art to our or our licensors' patents which could potentially invalidate our or our licensors' patents; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property, which could ultimately result in public disclosure of the intellectual property if the third party's patent application is published or issues to a patent.

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

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

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

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

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

RISKS RELATED TO OUR SECURITIES

Our Common Stock may be delisted from the Nasdaq Capital Market if we cannot maintain compliance with Nasdaq's continued listing requirements.

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

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were afforded an initial period of 180 calendar days, or until March 14, 2022, to regain compliance with the Minimum Bid Price Rule. We were then afforded a second grace period of an additional 180 calendar days, or until September 12, 2022, to regain compliance with the Minimum Bid Price Rule. On August 24, 2022, we received a formal notification via letter from Nasdaq confirming that we had regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2), which requires that our Common Stock maintain a minimum bid price of at least \$1.00 per share, and that the matter is now closed.

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

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

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

The price of our securities may be volatile, and you could lose all or part of your investment. Further, we do not know whether an active, liquid and orderly trading market will continue for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of our securities.

Although our securities are listed on the Nasdaq Capital Market, an active, liquid, and orderly trading market for our securities may not continue, and you may not be able to sell your shares quickly or at the market price if trading in shares of our securities is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our securities and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our securities as consideration, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, the trading price of our securities is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume.

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

Our stock may experience limited trading volume. Many of our securities will be subject to restrictions on transfer under the Securities Act and may not be transferred in the absence of registration or the availability of a resale exemption. In particular, in the absence of registration, such securities cannot be resold to the public until certain requirements under Rule 144 promulgated under the Securities Act have been satisfied, including certain holding period requirements and other requirements applicable to companies that have previously been a shell company. An investor may be unable to sell such securities at the time or at the price or upon such other terms and conditions as the investor desires, and the terms of such sale may be less favorable than might be obtainable because of a limited market, which may never develop.

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

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

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

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

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

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

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

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

As a public company, we will continue to incur significant legal, accounting, and other expenses. We are subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities, and our stock price may be more volatile.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

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. We do not currently own any properties, laboratories, or manufacturing facilities.

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

Our common stock and warrants began trading on the Nasdaq Capital Market on June 21, 2019, under the trading symbols "ARTL" and "ARTLW," respectively.

Our shares are issued in registered form. American Stock Transfer & Trust Company, LLC, 6201 15th Ave, Brooklyn, NY 11219, Telephone: 800-937-5449 is the registrar and transfer agent for our common shares.

On March 27, 2023, the shareholders' list showed 165 registered shareholders with 2,855,688 shares of common stock outstanding.

Description of Securities

The Company's authorized capital stock consists of 50,416,667 shares of capital stock, par value \$0.001 per share, of which 50,000,000 shares are common stock, par value \$0.001 per share and 416,667 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; (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 pre-emptive, 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 on which stockholders may vote. Reference is made to the Company's Articles of Incorporation, By-laws and the applicable statutes of the State of Nevada for a more complete description of the rights and liabilities of holders of the Company's securities.

Preferred Stock

The Company has authorized 416,667 shares of preferred stock. There is no preferred stock outstanding. Our Board may designate the rights, preferences, privileges, and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock or delaying, deterring or preventing a change in control. Such issuance could have the effect of decreasing the market price of the common stock. We currently have no plans to issue any shares of preferred stock.

Non-cumulative Voting

Holders of shares of our common stock do not have cumulative voting rights; meaning that the holders of 50.1% of the outstanding shares, voting for the election of directors, can elect all of the directors to be elected, and, in such event, the holders of the remaining shares will not be able to elect any of our directors.

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, 2022, 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, 2022.

Issuer Purchases of Equity Securities

We did not purchase any of our shares of common stock or other securities during our fourth quarter ended December 31, 2022.

ITEM 6. [RESERVED]**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

Overview

We are a clinical stage biotech company currently focused on the development of therapeutics that target lipid-signaling pathways, including the endocannabinoid system. Our first in-licensed program, ART27.13, is being developed for cancer-related anorexia, with enrollment and dosing of the first patient of the Company's Phase 1b/2a CARES clinical study occurring in April 2021. 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 regulatory authority, such as the FDA.

Results of Operations

The following summary of our results of operations, for the year ended December 31, 2022, four months ended December 31, 2021 and the year ended August 31, 2021 should be read in conjunction with our audited financial statements, as included in this Form 10-K.

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

Year ended December 31, 2022, compared to the year ended December 31, 2021

The Company changed its fiscal year end from August 31 to December 31 effective December 31, 2021. Accordingly, the following presentation and discussion of the audited results of operations for the year ended December 31, 2022 has been compared to the unaudited results of operations for the year ended December 31, 2021 to provide a comparable year-over-year analysis and discussion of results of operations.

(In thousands)	Years ended December 31,		Change
	2022	2021 (unaudited)	
Operating Expenses			
General and administrative	\$ 5,963	\$ 5,633	\$ 330
Research and development	4,324	3,784	540
Total Operating Expenses	<u>10,287</u>	<u>9,417</u>	<u>870</u>
Loss from Operations	(10,287)	(9,417)	870
Other income	204	10	194
Net Loss	<u>\$ (10,083)</u>	<u>\$ (9,407)</u>	<u>\$ 676</u>

[Table of Contents](#)

Our operating expenses, for the year ended December 31, 2022, were \$10.3 million compared to \$9.4 million for the same period in 2021. The increase in operating expenses was primarily due to an increase in research and development, including the ongoing expenses related to the CARES trial, and general and administrative expense related to payroll and director compensation including stock-based compensation.

We have not generated any revenues since inception through December 31, 2022.

Four months ended December 31, 2021, compared to the four months ended December 31, 2020

(In thousands)	Four months ended December 31,		Change
	2021	2020 (unaudited)	
Operating Expenses			
General and administrative	\$ 2,098	\$ 1,067	\$ 1,031
Research and development	1,944	999	945
Total Operating Expenses	4,042	2,066	1,976
Loss from Operations	(4,042)	(2,066)	(1,976)
Other income	7	1	6
Net Loss	\$ (4,035)	\$ (2,065)	\$ (1,970)

Our operating expenses, for the four months ended December 31, 2021, were \$4.0 million compared to \$2.1 million for the same period in 2020. Our operating expenses were comprised of research and development, and general and administrative expenses, including professional fees for ongoing regulatory requirements. The increase in general and administrative expenses and research and development expenses were primarily due to increases in payroll and stock-based compensation and an increase in subcontractor expenditures relating to the Company's CARES trials.

Year ended August 31, 2021, compared to the year ended August 31, 2020

(In thousands)	Years ended August 31,		Change
	2021	2020	
Operating Expenses			
General and administrative	\$ 4,602	\$ 2,767	\$ 1,835
Research and development	2,839	1,919	920
Total Operating Expenses	7,441	4,686	2,755
Loss from Operations	(7,441)	(4,686)	(2,755)
Other income	4	31	(27)
Net Loss	\$ (7,437)	\$ (4,655)	\$ (2,782)

Our operating expenses, for the year ended August 31, 2021, were \$7.4 million compared to \$4.7 million for the same period in 2020. The increase in operating expenses was primarily due to an increase in research and development, including the initiation and ongoing expenses related to the ART27.13 trial, and general and administrative expense related to payroll and director compensation including stock-based compensation.

Liquidity and Capital Resources

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

[Table of Contents](#)

The Company has incurred losses since inception and incurred a net loss of \$10.1 million during the year ended December 31, 2022. However, in November 2021, the Company completed an equity offering which generated net proceeds of \$18.3 million. Additionally, in May 2022, the Company entered into a purchase agreement and a registration rights agreement (the "Equity Line") with an institutional investor, providing for the sale of up to \$20.0 million worth of the Company's common stock, over the thirty-six (36) month term of the purchase agreement. Under the terms and subject to the conditions of the purchase agreement, the Company has the right, but not the obligation, to sell to the institutional investor, and the institutional investor is obligated to purchase, up to \$20.0 million worth of shares of the Company's Common Stock. As of December 31, 2022, there have been no sales under the Equity Line. Consequently, there is substantial doubt about the Company's ability to continue as a going concern, however, the Company's working capital is expected to sustain operations into the second half of 2024.

Working Capital

(In thousands)	December 31, 2022	December 31, 2021	Change
Current Assets	\$ 18,322	\$ 24,609	\$ (6,287)
Current Liabilities	998	1,027	(29)
Working Capital	<u>\$ 17,324</u>	<u>\$ 23,582</u>	<u>\$ (6,258)</u>

(In thousands)	December 31, 2021	August 31, 2021	Change
Current Assets	\$ 24,609	\$ 10,317	\$ 14,292
Current Liabilities	1,027	526	501
Working Capital	<u>\$ 23,582</u>	<u>\$ 9,791</u>	<u>\$ 13,791</u>

Our total current assets as of December 31, 2022, were \$18.3 million as compared to total current assets of \$24.6 million as of December 31, 2021. The decrease in current assets was primarily due to a decrease in cash and cash equivalents as well as short-term investments funded the Company's operating activities during the year.

Our total current liabilities as of December 31, 2022, were \$1.0 million as compared to total current liabilities of \$1.0 million as of December 31, 2021.

Our total current assets as of December 31, 2021, were \$24.6 million as compared to total current assets of \$10.3 million as of August 31, 2021. The increase in current assets is primarily due to an increase in cash and short-term investments from issuance of common stock in connection with the Company's at-the-market equity program.

Our total current liabilities as of December 31, 2021, were \$1.0 million as compared to total current liabilities of \$0.5 million as of August 31, 2021.

On May 13, 2022, we entered into a purchase agreement and a registration rights agreement (together, the "Lincoln Park Agreements") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), providing for the purchase of up to \$20.0 million worth of our Common Stock over the thirty-six-month term of the Lincoln Park Agreements.

Under the terms and subject to the conditions of the Lincoln Park Agreements, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$20.0 million worth of shares of our Common Stock. Such future sales of Common Stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our option, over the thirty-six-month term of the Lincoln Park Agreements. In addition to regular purchases, we may also under certain circumstances direct Lincoln Park to purchase other amounts as accelerated purchases. Actual sales of shares of Common Stock to Lincoln Park under the Lincoln Park Agreements will depend on a variety of factors to be determined by us from time to time. The net proceeds under the Lincoln Park Agreements to us will depend on the frequency and prices at which we sell shares of our stock to Lincoln Park. We expect that any proceeds received from such sales to Lincoln Park will be used for working capital and general corporate purposes.

Cash Flows

(In thousands)	Years ended December 31,		
	2022	2021	Change
	(unaudited)		
Cash Flows used in operating activities	\$ (8,008)	\$ (6,938)	\$ (1,070)
Cash Flows provided by (used in) investing activities	2,958	(12,417)	15,375
Cash Flows provided by financing activities	-	25,795	(25,795)
Effect of exchange rate changes on cash	(224)	(61)	(163)
Net change in cash and cash equivalents during period	<u>\$ (5,274)</u>	<u>\$ 6,379</u>	<u>\$ (11,653)</u>

(In thousands)	Four months ended December 31,		
	2021	2020	Change
	(unaudited)		
Cash Flows used in operating activities	\$ (2,667)	\$ (1,874)	\$ (793)
Cash Flows used in investing activities	(10,033)	(1,055)	(8,978)
Cash Flows provided by financing activities	18,261	6,578	11,683
Effect of exchange rate changes on cash	(28)	(8)	(20)
Net change in cash during period	<u>\$ 5,533</u>	<u>\$ 3,641</u>	<u>\$ 1,892</u>

(in thousands)	Years ended August 31,		
	2021	2020	Change
	(unaudited)		
Cash Flows used in operating activities	\$ (6,141)	\$ (4,347)	\$ (1,794)
Cash Flows used in investing activities	(3,439)	-	(3,439)
Cash Flows provided by financing activities	14,112	1,981	12,131
Effect of exchange rate changes on cash	(45)	84	(129)
Net change in cash during period	<u>\$ 4,487</u>	<u>\$ (2,282)</u>	<u>\$ 6,769</u>

Cash Flows from Operating Activities

During the year ended December 31, 2022, cash used in operating activities was \$8.0 million compared to cash used in operating activities of \$6.9 million during the year ended December 31, 2021. Cash used in operating activities during the year ended December 31, 2022, of \$8.0 million was primarily attributed to a net loss of \$10.1 million, increases in operating assets and liabilities of \$0.3 million and offset by stock-based compensation of \$2.5 million. Cash used in operating activities during the year ended December 31, 2021, was \$6.9 million which was primarily attributed to a net loss of \$9.4 million offset by stock-based compensation of \$2.4 million.

During the four months ended December 31, 2021, cash used in operating activities was \$2.7 million compared to cash used in operating activities of \$1.9 million during the four months period ended December 31, 2020. During the four months ended December 31, 2021, cash used in operating activities of \$2.7 million was primarily attributed to net loss of \$4.0 million offset by stock-based compensation of \$0.9 million. During the four months ended December 31, 2020, cash used in operating activities of \$1.9 million was primarily attributed to net loss of \$2.1 million.

During the year ended August 31, 2021, cash used in operating activities was \$6.1 million compared to cash used in operating activities of \$4.3 million during the year ended August 31, 2020. Cash used in operating activities during the year ended August 31, 2021, of \$6.1 million was primarily attributed to a net loss of \$7.4 million, increases in operating assets and liabilities of \$0.2 million and offset by stock-based compensation of \$1.5 million. Cash used in operating activities during the year ended August 31, 2020, of \$4.3 million was primarily attributed to a net loss of \$4.7 million offset by stock-based compensation of \$0.4 million.

Cash Flows from Investing Activities

During the year ended December 31, 2022, cash flows provided by investing activities of \$3.0 million was the result of \$15.7 million received from dispositions of trading marketable securities and \$0.5 million received from dispositions of available-for-sale securities and offset by \$12.7 million from purchases of trading marketable securities and \$0.5 million of available-for-sale securities. During the year ended December 31, 2021, the Company's cash flows used in investing activities of \$12.4 million was the result of purchases of securities of \$17.1 million offset by \$4.7 million from dispositions.

During the four months ended December 31, 2021, cash flows used in investing activities of \$10.0 million was the result of a \$11.2 million investment in trading marketable securities and a \$1.5 million investment in available-for-sale securities, offset by proceeds of \$2.7 million from dispositions. During the four months ended December 31, 2020, cash flows used in investing activities of \$1.1 million was the result of a \$1.8 million investment in trading marketable securities and proceeds of \$0.7 million from dispositions.

During the year ended August 31, 2021, cash flows used in investing activities of \$3.4 million was the result of a \$6.1 million investment in trading marketable securities and offset by proceeds of \$2.7 million from dispositions. The Company did not have any cash flows from or used in investing activities during the year ended August 31, 2020.

Cash Flows from Financing Activities

During the year ended December 31, 2022, cash provided by financing activities was \$0.0 million. During the year ended December 31, 2021, cash provided by financing activities of \$25.8 million was primarily the result of net proceeds from the issuance of common stock of \$19.8 million and exercise of warrants of \$6.6 million.

During the four months ended December 31, 2021 and 2020, cash flows from financing activities of \$18.3 million and \$6.6 million, respectively were primarily the result of net proceeds of \$18.3 million and \$6.6 million, respectively, from the issuance of common stock.

During the year ended August 31, 2021, cash provided by financing activities of \$14.1 million was primarily the result of net proceeds from the issuance of common stock of \$8.1 million and proceeds from the exercise of warrants of \$6.0 million. During the year ended August 31, 2020, cash provided by financing activities of \$2.0 million was primarily the result of net proceeds from the issuance of common stock of \$2.0 million.

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. These estimates and assumptions are affected by management's application of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved with the following aspects of our financial statements is critical to an understanding of our financial statements.

Use of Estimates

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

Recent Accounting Pronouncements

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic "Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions". These amendments clarify that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The amendments in this update are effective for public business entities for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2023. Early adoption is permitted. We are currently assessing the impact of the adoption of this standard on our consolidated financial statements.

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

	<u>Page</u>
Report of Independent Registered Public Accounting Firm (PCAOB ID 206)	F-2
Consolidated Balance Sheets at December 31, 2022, December 31, 2021 and August 31, 2021	F-3
Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2022, four months ended December 31, 2021 and year ended August 31, 2021	F-4
Consolidated Statements of Stockholders' Equity for the year ended December 31, 2022, four months ended December 31, 2021 and year ended August 31, 2021	F-5
Consolidated Statements of Cash Flows for the year ended December 31, 2022, four months ended December 31, 2021, and year ended August 31, 2021	F-6
Notes to the Consolidated Financial Statements	F-7

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, 2022, December 31, 2021 and August 31, 2021, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years ended December 31, 2022 and August 31, 2021, and for the four-month transition period ended December 31, 2021, 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, 2022, December 31, 2021 and August 31, 2021, and the results of their operations and their cash flows for the years ended December 31, 2022 and August 31, 2021, and for the four-month transition period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

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 audit 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

March 31, 2023

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

	<u>December 31, 2022</u>	<u>December 31, 2021</u>	<u>August 31, 2021</u>
ASSETS			
Current Assets			
Cash and cash equivalents	\$ 6,888	\$ 12,162	\$ 6,629
Trading marketable securities	9,150	11,951	3,436
Available-for-sale securities (amortized cost of \$1,502, \$0 and \$0, respectively)	1,495	-	-
Prepaid expenses and other current assets	789	496	252
Total Current Assets	<u>18,322</u>	<u>24,609</u>	<u>10,317</u>
Available-for-sale securities (amortized cost of \$0, \$1,521 and \$0, respectively)	-	1,519	-
Operating lease right-of-use assets	60	81	90
Intangible asset	2,039	2,039	2,039
Other assets	3	3	189
TOTAL ASSETS	<u>\$ 20,424</u>	<u>\$ 28,251</u>	<u>\$ 12,635</u>
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current Liabilities			
Accounts payable and accrued liabilities	\$ 905	\$ 975	\$ 471
Due to related parties	53	21	27
Operating lease liabilities - current portion	40	31	28
Total Current Liabilities	<u>998</u>	<u>1,027</u>	<u>526</u>
Operating lease liabilities	23	57	67
TOTAL LIABILITIES	<u>1,021</u>	<u>1,084</u>	<u>593</u>
STOCKHOLDERS' EQUITY			
Preferred Stock, par value \$0.001, 416,667 shares authorized, 0 shares issued and outstanding	-	-	-
Common Stock, par value \$0.001, 50,000,000 shares authorized, 2,855,688, 2,820,068 and 1,635,109 shares issued and outstanding, respectively	3	3	2
Additional paid-in capital	50,675	48,120	28,925
Accumulated deficit	(31,021)	(20,938)	(16,903)
Accumulated other comprehensive income (loss)	(254)	(18)	18
Total Stockholders' Equity	<u>19,403</u>	<u>27,167</u>	<u>12,042</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 20,424</u>	<u>\$ 28,251</u>	<u>\$ 12,635</u>

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

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

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31, 2021
OPERATING EXPENSES			
General and administrative	\$ 5,963	\$ 2,098	\$ 4,602
Research and development	4,324	1,944	2,839
Total Operating Expenses	<u>10,287</u>	<u>4,042</u>	<u>7,441</u>
Loss from Operations	(10,287)	(4,042)	(7,441)
OTHER INCOME (EXPENSE)			
Interest income	2	1	2
Interest expense	(5)	-	-
Net change in fair value of trading marketable securities	207	6	2
Total other income	<u>204</u>	<u>7</u>	<u>4</u>
Provision for income taxes	-	-	-
NET LOSS	<u>\$ (10,083)</u>	<u>\$ (4,035)</u>	<u>\$ (7,437)</u>
OTHER COMPREHENSIVE INCOME (LOSS)			
Net unrealized loss on available-for-sale securities	(24)	(5)	-
Foreign currency translation adjustments	(212)	(31)	(46)
Total Other Comprehensive Loss	<u>(236)</u>	<u>(36)</u>	<u>(46)</u>
TOTAL COMPREHENSIVE LOSS	<u>\$ (10,319)</u>	<u>\$ (4,071)</u>	<u>\$ (7,483)</u>
Basic and Diluted Loss per Common Share	<u>\$ (3.56)</u>	<u>\$ (1.81)</u>	<u>\$ (5.97)</u>
Basic and Diluted Weighted Average Common Shares Outstanding	<u>2,833</u>	<u>2,230</u>	<u>1,245</u>

The accompanying notes are an integral part of these 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, August 31, 2020	333	\$ -	\$ 13,277	\$ (9,466)	\$ 64	3,875
Common shares issued for cash, net of issuance costs	767	1	8,102	-	-	8,103
Common shares issued for exercise of warrants	535	1	6,015	-	-	6,016
Common shares issued for services - officers	-	-	34	-	-	34
Stock based compensation	-	-	1,497	-	-	1,531
Net loss for the period	-	-	-	(7,437)	-	(7,437)
Other comprehensive loss	-	-	-	-	(46)	(46)
Balance, August 31, 2021	<u>1,635</u>	<u>\$ 2</u>	<u>\$ 28,925</u>	<u>\$ (16,903)</u>	<u>\$ 18</u>	<u>\$ 12,042</u>
Common shares issued for cash, net of issuance costs	1,185	1	18,261	-	-	18,262
Stock based compensation	-	-	934	-	-	934
Net loss for the period	-	-	-	(4,035)	-	(4,035)
Other comprehensive loss	-	-	-	-	(36)	(36)
Balance, December 31, 2021	<u>2,820</u>	<u>\$ 3</u>	<u>\$ 48,120</u>	<u>\$ (20,938)</u>	<u>\$ (18)</u>	<u>\$ 27,167</u>
Common shares issued as commitment fee	20	-	97	-	-	97
Stock based compensation	-	-	2,458	-	-	2,458
Reverse stock split adjustment	16	-	-	-	-	-
Net loss for the period	-	-	-	(10,083)	-	(10,083)
Other comprehensive loss	-	-	-	-	(236)	(236)
Balance, December 31, 2022	<u>2,856</u>	<u>\$ 3</u>	<u>\$ 50,675</u>	<u>\$ (31,021)</u>	<u>\$ (254)</u>	<u>\$ 19,403</u>

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

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

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31, 2021
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (10,083)	\$ (4,035)	\$ (7,437)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	2,458	934	1,531
Net change in fair value of trading marketable securities	(207)	(6)	2
Non-cash lease expense	39	10	7
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(195)	(63)	(239)
Accounts payable and accrued liabilities	(10)	507	(3)
Accounts payable - related parties	33	(7)	-
Fixed cash payments related to operating leases	(43)	(7)	(2)
Net cash used in operating activities	<u>(8,008)</u>	<u>(2,667)</u>	<u>(6,141)</u>
CASH FLOWS FROM INVESTING ACTIVITIES			
Investment in trading marketable securities	(12,725)	(11,243)	(6,098)
Investment in available-for-sale securities	(499)	(1,524)	-
Proceeds from disposition of trading marketable securities	15,657	2,734	2,659
Proceeds from disposition of available-for-sale securities	525	-	-
Net cash provided by (used in) investing activities	<u>2,958</u>	<u>(10,033)</u>	<u>(3,439)</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of common shares for cash, net	-	18,262	8,103
Proceeds from exercise of warrants	-	-	6,016
Advances from related parties	-	-	1
Repayments to related parties	-	(1)	(8)
Net cash provided by financing activities	<u>-</u>	<u>18,261</u>	<u>14,112</u>
Effect of exchange rate changes on cash	(224)	(28)	(45)
Net change in cash and cash equivalents	(5,274)	5,533	4,487
Cash and cash equivalents – beginning of period	12,162	6,629	2,142
Cash and cash equivalents – end of period	<u>\$ 6,888</u>	<u>\$ 12,162</u>	<u>\$ 6,629</u>
Supplemental Cash Flow Information			
Cash paid for interest	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
Cash paid for income taxes	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
NON-CASH FINANCING AND INVESTING ACTIVITIES:			
Initial recognition of the right-of-use asset and lease liability	<u>\$ 20</u>	<u>\$ -</u>	<u>\$ 97</u>
Common shares issued as commitment fee	<u>\$ 97</u>	<u>\$ -</u>	<u>\$ -</u>
Unrealized loss from available-for-sale securities	<u>\$ 24</u>	<u>\$ 5</u>	<u>\$ -</u>

The accompanying notes are an integral part of these 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 San Diego County, California. The accounting and reporting policies of the Company conform to accounting principles generally accepted in the United States of America, and the Company’s fiscal year end is December 31.

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

The Company is a clinical stage biopharmaceutical company focused on developing and commercializing treatments intended to modulate the endocannabinoid system.

Liquidity

The Company has incurred losses since inception and incurred a net loss of \$10,083 during the year ended December 31, 2022. However, in November 2021, the Company completed an equity offering which generated net proceeds of \$18,262. Additionally, in May 2022, the Company entered into a purchase agreement and a registration rights agreement (the “Equity Line”) with an institutional investor, providing for the sale of up to \$20,000 worth of the Company’s common stock, over the thirty-six (36) month term of the purchase agreement. Under the terms and subject to the conditions of the purchase agreement, the Company has the right, but not the obligation, to sell to the institutional investor, and the institutional investor is obligated to purchase, up to \$20,000 worth of shares of the Company’s Common Stock. As of December 31, 2022, there have been no sales under the Equity Line. The Company’s existing cash resources and the cash received from the November 2021 equity offering are expected to provide sufficient funds to carry out the Company’s planned operations into the second half of 2024. To continue operations beyond such time frame, 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.

Reverse stock split

On August 8, 2022, 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-fifteen (1-for-15) reverse stock split (the “Reverse Stock Split”) of the Company’s issued and outstanding Common Stock, par value \$0.001 per share. The Reverse Stock Split was effective as of August 10, 2022.

As a result of the Reverse Stock Split, the number of authorized shares of Common Stock has been reduced from 750,000,000 to 50,000,000, while the number of authorized shares of the Company’s preferred stock has been reduced from 6,250,000 to 416,667.

COVID-19

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

All share and per share information in these financial statements retroactively reflect this Reverse Stock Split.

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 Generally Accepted Accounting Principles (“GAAP”) of the United States.

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, with the Company’s wholly owned subsidiaries, Trinity Reliant Ventures Limited, Artelo Biosciences Limited and Artelo Biosciences Corporation. All intercompany transactions and balances have been eliminated.

Property and equipment

Property and equipment are stated at cost. Depreciation is computed on the straight-line method.

Maintenance and repairs are charged to expense as incurred. Improvements of a major nature are capitalized. At the time of retirement or other disposition of property and equipment, the cost and accumulated depreciation are removed from the accounts and any gains or losses are reflected in income.

The long-lived assets of the Company are reviewed for impairment in accordance with ASC No. 360, “Property, Plant and Equipment” (“ASC No. 360”), whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. No impairment losses were recorded during the year ended December 31, 2022, the four months ended December 31, 2021, and the year ended August 31, 2021.

Research and Development (“R&D”)

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

The Company recognizes R&D tax credits receivable from the United Kingdom government for spending on R&D as an offset of R&D expenses.

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 expenses during the reporting period. Actual results could differ from these good faith estimates and judgments.

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 \$6,888, \$12,162 and \$6,629 in cash and cash equivalents at December 31, 2022, December 31, 2021 and August 31, 2021, respectively.

[Table of Contents](#)

Periodically, the Company may carry cash balances at financial institutions more than the federally insured limit of \$250 per institution. The amount in excess of the FDIC insurance as of December 31, 2022, was approximately \$6,388. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

Marketable Securities

Our investments in debt securities are carried at fair value. Investments in debt securities that are not classified as held-to-maturity are carried at fair value and classified as either trading or available-for-sale. Realized and unrealized gains and losses on trading debt securities are charged to income and unrealized gains and losses on available-for-sale debt securities are included in other comprehensive income or loss. The marketable securities held by the Company, classified as trading marketable securities, had an outstanding balance of \$9,150, \$11,951 and \$3,436 as of December 31, 2022, December 31, 2021 and August 31, 2021, respectively. The Company's holdings in US Treasury instruments, classified as available-for-sale securities had an outstanding balance of \$1,495, \$1,519 and \$0 as of December 31, 2022, December 31, 2021 and August 31, 2021, respectively.

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, 2022, December 31, 2021 and August 31, 2021.

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

Level 1

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

Level 2

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

Level 3

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

The carrying amounts 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.

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

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Marketable securities – trading securities				
Commercial paper	\$ -	\$ 9,150	\$ -	\$ 9,150
	-	9,150	-	9,150
Available-for sale securities				
US Treasury	-	1,495	-	1,495
	-	1,495	-	1,495
	<u>\$ -</u>	<u>\$ 10,645</u>	<u>\$ -</u>	<u>\$ 10,645</u>
	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Marketable securities				
Commercial paper	\$ -	\$ 10,486	\$ -	\$ 10,486
Asset-backed securities	-	1,165	-	1,165
Corporate debt securities	-	300	-	300
	-	11,951	-	11,951
Available-for sale securities				
US Treasury	-	1,519	-	1,519
	-	1,519	-	1,519
	<u>-</u>	<u>13,470</u>	<u>-</u>	<u>13,470</u>

	August 31, 2021			
	Level 1	Level 2	Level 3	Total
Marketable securities				
Commercial paper	\$ -	\$ 2,724	\$ -	\$ 2,724
Asset-backed securities	-	409	-	409
Corporate debt securities	-	303	-	303
	-	3,436	-	3,436

Concentrations of Credit Risk

The Company's financial instruments that are exposed to concentrations of credit risk primarily consist of its cash and cash equivalents. The Company places its cash and cash equivalents with financial institutions of high credit worthiness. At times, its cash and cash equivalents with a particular financial institution may exceed any applicable government insurance limits. The Company's management has assessed the financial strength and credit worthiness, and will continue to do so on an ongoing basis, of any parties to which it extends funds, and as such, it believes that any associated credit risk exposures are limited.

Share-based Expenses

ASC 718 "Compensation – Stock Compensation" prescribes accounting and reporting standards for all share-based payment transactions in which employee services are acquired. Transactions include incurring liabilities, or issuing or offering to issue shares, options, and other equity instruments such as employee stock ownership plans and stock appreciation rights. Share-based payments to employees, including grants of employee stock options, are recognized as compensation expense in the financial statements based on their fair values. That expense is recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period).

Share-based expenses were \$2,458, \$934 and \$1,531 for the year ended December 31, 2022, the four months ended December 31, 2021, and the year ended August 31, 2021, respectively.

Deferred Income Taxes and Valuation Allowance

The Company accounts for income taxes under ASC 740 "Income Taxes." Under the asset and liability method of ASC 740, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period the enactment occurs. A valuation allowance is provided for certain deferred tax assets if it is more likely than not that the Company will not realize tax assets through future operations.

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 year ended December 31, 2022, four months ended December 31, 2021, and year ended August 31, 2021, the following common stock equivalents were excluded from the computation of diluted net loss per share as the result was anti-dilutive.

	December 31, 2022	December 31, 2021	August 31, 2021
Stock options	313,109	333,945	190,623
Warrants	270,053	295,601	295,561
	583,162	629,546	486,184

Related Parties

The Company follows ASC 850, *Related Party Disclosures*, for the identification of related parties and disclosure of related party transactions.

Commitments and Contingencies

The Company follows ASC 450-20, "*Loss Contingencies*," to report accounting for contingencies. Liabilities for loss contingencies arising from claims, assessments, litigation, fines and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated.

Recent Accounting Pronouncements

In June 2022, the FASB issued ASU 2022-03, ASC Subtopic "Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions". These amendments clarify that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The amendments in this update are effective for public business entities for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2023. Early adoption is permitted. The Company is currently assessing the impact of the adoption of this standard on its consolidated financial statements.

NOTE 3 - RELATED PARTY TRANSACTIONS

During the year ended December 31, 2022, four months ended December 31, 2021, and the year ended August 31, 2021, a company owned by the Senior Vice President, European Operations, provided consulting services totaling \$35, \$20, and \$60, respectively. As of December 31, 2022, December 31, 2021, and August 31, 2021, there was \$1, \$5, and \$5 outstanding, respectively.

During the year ended December 31, 2022, and four months ended December 31, 2021, a company significantly influenced by a director of a subsidiary of the Company provided professional services totaling \$111 and \$46, respectively. As of December 31, 2022, and December 31, 2021, there was \$0 and \$11 outstanding, respectively.

During the year ended December 31, 2022, a company controlled by a director of a subsidiary of the Company provided professional services totaling \$9. As of December 31, 2022, and December 31, 2021, there was \$23 and \$5 outstanding, respectively.

NOTE 4 - EQUITY

Preferred shares

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

During the year ended December 31, 2022, the four months ended December 31, 2021, and the year ended August 31, 2021, there were no shares of preferred stock issued or outstanding.

Common Shares

Amendment to Articles of Incorporation or Bylaws

The Company has authorized 50,000,000 shares of Common Stock with a par value of \$0.001 per share. Each share of Common Stock entitles the holder to one vote, in person or proxy, on any matter on which an action of the stockholders of the Company is sought.

[Table of Contents](#)

On May 13, 2022, the Company entered into a purchase agreement and a registration rights agreement (together, the “Lincoln Park Agreements”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”) providing for the purchase by Lincoln Park of up to \$20,000 worth of the Company’s Common Stock, over the thirty-six (36) month term of the Lincoln Park Agreements. The Company issued to Lincoln Park 19,532 shares of its Common Stock as commitment shares in consideration for entering into the Lincoln Park Agreements and received no funds in exchange for such commitment shares, valued at \$97. Upon initiation of the Lincoln Park Agreements, the Company recorded \$381 as an expense within general and administrative expenses as the Company has not yet determined whether any portion of the equity line will be utilized.

During the four months ended December 31, 2021, the Company issued 1,184,959 shares of common stock at an average price of \$15.90 per share in connection with the Company’s at-the-market equity program for proceeds, net of commission and fees, of \$18,262. The agent of the program was entitled to compensation at a commission rate of 3.0% of the gross sales price per sold share of common stock.

During the year ended August 31, 2021, the Company issued 1,302,363 shares of common stock as follows:

- On October 14, 2020, the Company issued and sold, through a public offering (i) 674,667 shares of common stock (which includes 88,000 shares of common stock sold pursuant to the exercise by the underwriter to the public offering of their overallotment option) and (ii) warrants to purchase 674,667 shares of common stock (which includes warrants to purchase 88,000 shares of common stock sold pursuant to the exercise by the underwriter of their overallotment option). The net proceeds to the Company, after deducting the underwriting discount and commissions and offering expenses were \$6,579.
- 92,917 shares of common stock were issued for net proceeds of \$1,524, at an average price of \$18.00 per share in connection with the Company’s at-the-market (“ATM”) equity program net of commission and fees, of \$51. The agent of the program was entitled to commissions at a rate of 3.0% of the gross sales price per share of common stock sold. The Company also incurred offering costs of \$96.
- 534,779 shares of common stock were issued for the exercise of warrants for proceeds of \$,016.

Warrants

A summary of activity of the warrants during the year ended December 31, 2022, four months ended December 31, 2021, and year ended August 31, 2021 follows:

	Number of shares	Weighted Average Exercise Price	Weighted Average Life (years)
Outstanding, August 31, 2020	155,703	\$ 121.80	3.30
Granted	674,667	11.25	5.00
Expired	-	-	-
Exercised	(534,769)	(11.25)	(4.68)
Outstanding, August 31, 2021	295,601	\$ 69.45	3.16
Granted	-	-	-
Expired	-	-	-
Exercised	-	-	-
Outstanding, December 31, 2021	295,601	\$ 69.45	2.83
Granted	-	-	-
Expired	(25,548)	(125.92)	-
Exercised	-	-	-
Outstanding, December 31, 2022	270,053	\$ 64.16	2.05

Table of Contents

The intrinsic value of the warrants as of December 31, 2022 and 2021 is \$0, and \$0, respectively. All of the outstanding warrants are exercisable as of December 31, 2022.

2018 Equity Incentive Plan

On August 17, 2018, the Board of Directors of the Company approved the 2018 Equity Incentive Plan (the “2018 Plan”). The 2018 Plan initially permitted the Company to issue up to 25,000 shares of common stock upon exercise of options granted to selected employees, officers, directors, consultants, and advisers. The options may be either “incentive stock options” (as such term is defined in the Internal Revenue Code of 1986) or non-statutory stock options that are not intended to qualify as “incentive stock options”. Incentive stock options may be granted only to employees. The 2018 Plan is administered by the Board or, at the discretion of the Board, a Board committee. The administrator determines who will receive options and the terms of the options, including the exercise price, expiration date, vesting and the number of shares. The exercise price of each stock option may not be less than the fair market value of the Common Stock on the date of grant, although the exercise price of any incentive stock option granted to a 10% stockholder may not be less than 110% of the fair market value on the grant date. Options may be exercisable (“vest”) immediately or in increments based on time and/or performance criteria as determined by the administrator. The term of any option may not exceed 10 years (five years for any incentive stock option granted to a 10% stockholder), and unless otherwise determined by the administrator, each option must terminate no later than three months after the termination of the optionee’s employment (one year in the event of death or disability). Subject to a few minor exceptions, options may not be transferred other than by will or by the laws of descent and distribution. The 2018 Plan will expire on August 17, 2028.

On December 3, 2020, the Company held a special meeting of stockholders and approved an amendment to increase the number of shares of Common Stock reserved for issuance by 133,334 shares and to extend the term of the 2018 Plan.

On September 1, 2021, the 2018 Plan was increased to permit the issuance of an additional 244,940 shares of common stock.

As of December 31, 2022, the 2018 Plan permits the Company to issue up to an aggregate of 622,526 shares of common stock for grant of which 309,417 shares are available to be issued.

On January 6, 2023, the 2018 Plan was increased to permit the issuance of an additional 428,353 shares of common stock, which increased the number of shares available for issuance pursuant to the 2018 Plan to a new total of 737,770 shares.

Options granted during the year ended December 31, 2022

On February 15, 2022, 17,177 shares of Common Stock were returned to the 2018 Plan and on February 18, 2022, the number of shares of Common Stock reserved for issuance under the 2018 Plan increased by 141,003 shares. Such additional shares were registered on a Registration Statement on Form S-8 filed with the Securities and Exchange Commission on April 7, 2022. On May 15, 2022, and July 20, 2022, an additional 6,077 and 1,584 shares, respectively, were returned to the 2018 Plan.

In June 2022, the Company granted options to certain directors of the Company to purchase an aggregate of 4,002 shares of the Company’s Common Stock with an exercise price of \$4.89 and vesting on the earlier of the one-year anniversary of the vesting commencement date or the date prior to the date of the Company’s annual meeting following the vesting commencement date. The vesting commencement date is June 24, 2022.

Options granted during the four months ended December 31, 2021

On December 1, 2021, the Company granted 52,988 options with an exercise price of \$9.45, with a term of ten (10) years to exercise from the grant date, to employees, directors, and consultants of the Company, of which 17,187 were issued to related parties. Options issued to non-employees vest as to 33% of shares subject to the option on the one-year anniversary of the vesting commencement date, and the balance of the unvested shares shall vest ratably each month thereafter for a 24-month period, on the first day of each such month. Commencing on the grant date, options issued to employees vest as to 25% of shares subject to the option on December 1, 2022, and the balance of the unvested shares shall vest ratably each month thereafter for a 36-month period, on the first day of each such month.

Table of Contents

On December 3, 2021, the Company granted an option to the Company's principal executive officer to purchase 90,334 shares of the Company's common stock, with an exercise price of \$9.45, with a term of ten (10) years to exercise from the grant date, under the 2018 Plan. Commencing on the grant date, options issued vest as follows: 25% of the shares subject to the option shall vest on December 3, 2022, and the balance of the unvested shares shall vest ratably each month thereafter for a 36-month period, on the third day of each such month.

Options granted during the year ended August 31, 2021

On November 30, 2020, the Company appointed a new director and granted 8,000 options of the Company's common stock vesting monthly over a four-year period for his service on the Board at exercise price of \$9.05, expiring ten years after the grant date. The director will be eligible for equity award grants on the same terms as other non-employee members of the Board.

On February 12, 2021, the Company granted an option to the Company's president to purchase 55,634 shares of the Company's common stock with an exercise price of \$39.90 and vesting as follows: 50% shall vest on the one-year anniversary of the grant date and 50% shall vest on the two-year anniversary of the grant date, subject to our president's continued service to the Company.

On February 12, 2021, the Company granted an option to the Company's directors to purchase a total of 47,036 shares of the Company's common stock with an exercise price of \$39.90 and vesting as follows: 50% shall vest on the one-year anniversary of the grant date and 50% shall vest on the two-year anniversary of the grant date, subject to our directors' continued service to the Company.

On February 12, 2021, the Company granted an option to the Company's employees to purchase a total of 28,001 shares of the Company's common stock with an exercise price of \$39.90 and vesting as follows: 25% shall vest on the one-year anniversary of the vesting commencement date, and 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.

On March 5, 2021, the Company granted an option to the Company's president to purchase a total of 38,340 shares of the Company's common stock with an exercise price of \$22.80 and vesting as follows: 25% shall vest on the one-year anniversary of the vesting commencement date, and 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.

On March 5, 2021, the Company granted an option to a director of the Company to purchase 2,000 shares of the Company's common stock with an exercise price of \$22.80 and vesting as follows: one third shall vest on the one-year anniversary of the vesting commencement date, one third shall vest on the two-year anniversary of the vesting commencement date and one third shall vest on the three-year anniversary of the vesting commencement date, subject to this director's continued service to the Company.

On July 16, 2021, the Company granted options to certain directors of the Company to purchase a total of 4,669 shares of the Company's common stock with an exercise price of \$15.00 and vesting on the earlier of the one-year anniversary of the vesting commencement date or the date prior to the date of the Company's annual meeting following the vesting commencement date. The vesting commencement date is July 16, 2021.

Valuation

The Company utilizes the Black-Scholes model to value its stock options. The Company utilized the following assumptions:

	Year Ended December 31, 2022	Four Month Ended December 31, 2021	Year Ended August 31, 2021
Expected term	5.50 years	6 - 6.25 years	5 years
Expected average volatility	153%	144 - 158%	151 - 157%
Expected dividend yield	-	-	-
Risk-free interest rate	3.18%	1.13 - 1.15%	0.36 - 0.79%

During the year ended December 31, 2022, the Company granted 4,002 options valued at \$18. During the year ended December 31, 2022, the Company recognized stock-based compensation expense of \$2,458, of which \$2,216 was for related parties, and as of December 31, 2022, \$1,748 remains unamortized, of which \$1,219 is for related parties. The intrinsic value of the 313,109 options outstanding as of December 31, 2022, is \$0.

During the four months ended December 31, 2021, the Company granted 143,322 options valued at \$1,170. During the four months ended December 31, 2021, the Company recognized stock option expense of \$934, of which \$811 was to related parties, and as of December 31, 2021, \$4,489 remains unamortized, of which \$3,717 is for related parties. The intrinsic value of the 333,945 options outstanding as of December 31, 2021, is \$0.

During the year ended August 31, 2021, the Company granted 183,680 options valued at \$5,760. During the year ended August 31, 2021, the Company recognized stock option expense of \$1,497, of which \$1,340 was to related parties, and as of August 31, 2021, \$4,263 remains unamortized, of which \$3,664 is with related parties. The intrinsic value of the 190,623 options outstanding as of August 31, 2021, is \$37.

The following is a summary of stock option activity during the year ended December 31, 2022, the four months ended December 31, 2021, and the year ended August 31, 2021:

	Options Outstanding		Weighted Average Remaining life (years)
	Number of Options	Weighted Average Exercise Price	
Outstanding, August 31, 2020	18,795	\$ 53.55	8.90
Granted	183,680	34.20	10.00
Exercised	-	-	-
Forfeited/canceled	(11,852)	(38.55)	(8.33)
Outstanding, August 31, 2021	190,623	\$ 35.85	9.27
Granted	143,322	9.45	10.00
Exercised	-	-	-
Forfeited/canceled	-	-	-
Outstanding, December 31, 2021	333,945	\$ 24.45	9.36
Granted	4,002	4.89	10.00
Exercised	-	-	-
Forfeited/canceled	(24,838)	(25.69)	(8.74)
Outstanding, December 31, 2022	313,109	\$ 24.15	8.41
Exercisable options, December 31, 2022	131,859	\$ 29.35	8.19

NOTE 5 - INCOME TAXES

The Company has not made provision for income taxes for the year ended December 31, 2022, the four months ended December 31, 2021, and the year ended August 31, 2021, since the Company 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, 2022. The Company has incurred a net operating loss of \$20,559, 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 2014. 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, 2022	December 31, 2021	August 31, 2021
NOL Carryover	\$ 4,338	\$ 3,343	\$ 3,864
Valuation allowance	(4,338)	(3,343)	(3,864)
Net deferred tax asset	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

NOTE 6 – INTANGIBLE ASSET

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

The amount capitalized consisted of a \$1,500 payment and the fair value of 4,087 shares of common stock of \$539. During the year ended December 31, 2022, the four months ended December 31, 2021, and the year ended August 31, 2021, no additional costs met the criteria for capitalization as an intangible asset.

NOTE 7 - LEASE

On May 12, 2021, the Company entered into a lease arrangement for office space with Beckman/Lomas LLC, an entity controlled by a close family member of a director. Effective June 1, 2022, the related party had divested its interests in the property, and as such, no longer constitutes a related party transaction.

On April 19, 2022, the Company entered into a lease arrangement for office space with an annual rent of \$13 (£11) and the term of the arrangement is from April 2022 through September 2023.

[Table of Contents](#)

The following summarizes right-of use asset and lease information about the Company's operating lease as of December 31, 2022, December 31, 2021, and August 31, 2021:

	Year ended December 31, 2022	Four months ended December 31, 2021	Year ended August 31, 2021
Lease cost			
Operating lease cost	\$ 39	\$ 10	\$ 7
Other information			
Cash paid for operating cash flows from operating leases	\$ 43	\$ 7	\$ 2
Right-of-use assets obtained in exchange for new operating lease liability	\$ 20	\$ -	\$ 97
Weighted-average remaining lease term — operating leases (year)	1.57	2.67	3.00
Weighted-average discount rate — operating leases	2.98%	3.00%	3.00%

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

	Total
Year Ended December 31,	
2023	40
2024	24
Thereafter	-
	64
Less: Imputed interest	(1)
Operating lease liabilities	63
Operating lease liability - current	40
Operating lease liability - non-current	\$ 23

NOTE 8 – COMMITMENTS AND CONTINGENCIES

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

- The Company is invoiced monthly and quarterly in connection with several research and development contracts.
- The Company may be obligated to make additional payments related to research and development contracts entered into, dependent on the progress and milestones achieved through the programs.
- The Company's principal executive office is currently located at 505 Lomas Santa Fe Drive, Suite 160, Solana Beach, CA, US. Additionally, we have offices in Dublin, Ireland and outside Manchester, UK, which serve as administrative spaces for managing our subsidiaries, Trinity Reliant Ventures, Ltd (Ireland) and Artelo Biosciences Limited (UK). We do not currently own any properties, laboratories, or manufacturing facilities. All leases for our office space, other than for the principal executive office, are month-to-month.

NOTE 9 – COMPARATIVE FINANCIALS (UNAUDITED)

The Company changed its fiscal year end from August 31 to December 31 effective December 31, 2021. The unaudited consolidated results of operations for the year ended December 31, 2021 is as follows:

	Year ended December 31, 2021 (unaudited)
OPERATING EXPENSES	
General and administrative	\$ 5,633
Research and development	3,784
Total Operating Expenses	9,417
Loss from Operations	(9,417)
OTHER INCOME	
Interest income	2
Net change in market value	8
Change in fair value of derivative liabilities	-
Total other income	10
Provision for income taxes	-
NET LOSS	\$ (9,407)
OTHER COMPREHENSIVE INCOME (LOSS)	
Net unrealized loss on available-for-sale securities	(5)
Foreign currency translation adjustments	(54)
Total Other Comprehensive Income (Loss)	(59)
TOTAL COMPREHENSIVE LOSS	\$ (9,466)
Basic and Diluted Loss per Common Share	\$ (5.24)
Basic and Diluted Weighted Average Common Shares Outstanding	1,795

NOTE 10 – SUBSEQUENT EVENTS

On February 1, 2023, the Company granted an option to the Company's president to purchase a total of 85,000 shares of the Company's common stock with an exercise price of \$3.15 and vesting as follows: 25% of the shares subject to the option shall vest on the one-year anniversary of the vesting commencement date, and 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 February 1, 2023.

On February 2, 2023, the Company granted options to certain employees and consultants to purchase a total of 90,000 shares of the Company's common stock with an exercise price of \$3.15 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 February 1, 2023.

On February 2, 2023, the Company granted an option to certain employees and consultants to purchase a total of 19,750 shares of the Company's common stock with an exercise price of \$3.15 and vesting as follows: one hundred percent (100%) of the shares subject to the option shall vest on the one (1) year anniversary of the vesting commencement date on the same day of the month as the vesting commencement date. The vesting commencement date is February 1, 2023.

On February 2, 2023, the Company granted an option to an employee to purchase a total of 746 shares of the Company's common stock with an exercise price of \$3.15 and vesting as follows: 50% of the shares subject to the option shall vest on the one (1) year anniversary of the vesting commencement date, and one twenty-fourth (1/24th) 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 February 1, 2023.

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 and 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 Securities Exchange Act of 1934, as amended (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 and 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 Securities and Exchange Commission (“SEC”) reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

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 and Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022, 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, 2022, 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, 2022, 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

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

All directors of our company hold office until the next annual meeting of the security holders or until their successors have been elected and qualified. The officers of our company are appointed by our board of directors (“Board”) and hold office until their death, resignation or removal from office. Our directors and executive officers, their ages, positions held, and duration as such, are as follows:

<u>Name</u>	<u>Position Held with the Company</u>	<u>Date first appointed</u>	<u>Age</u>
Gregory D. Gorgas	President, Chief Executive Officer, Chief Financial Officer, Treasurer, Secretary and Director	April 3, 2017	60
Connie Matsui ⁽¹⁾⁽²⁾	Director, Chairperson of the Board	May 2, 2017	69
Steven Kelly ⁽¹⁾⁽³⁾	Director	May 2, 2017	57
Douglas Blayney, M.D. ⁽²⁾	Director	July 31, 2017	72
R. Martin Emanuele, Ph D. ⁽²⁾	Director	September 20, 2017	68
Greg Reyes, M.D., Ph D. ⁽³⁾	Director	November 30, 2020	69
Tamara A. (Seymour) Favorito ⁽¹⁾	Director	March 3, 2021	64

(1) Member of the audit committee

(2) Member of the corporate governance and nominating committee

(3) Member of the compensation committee

Business Experience

The following is a brief account of the education and business experience during at least the past five years of each director, executive officer and key employee of our company, indicating the person’s principal occupation during that period, and the name and principal business of the organization in which such occupation and employment were carried out.

Directors

Gregory D. Gorgas was appointed president, chief executive officer, chief financial officer, treasurer, secretary and director of our Company in April 2017. 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 applies 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 of directors because of his extensive experience and accomplishments in the biopharmaceutical industry and his past leadership positions at successful public companies.

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 and 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 of directors 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. Mr. Kelly is currently CEO at Carisma Therapeutics, a venture backed biotech pioneering the development of CAR macrophages, a disruptive approach to immunotherapy in cancer. From 2012 to 2018, Mr. Kelly was the principal of Kelly BioConsulting, 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 of directors 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 of directors 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 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 of directors because of his professional background experience in the biopharmaceutical industry.

Gregory Reyes, M.D., Ph.D., was elected to our Board on November 30, 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 also served as the Co-Founder of OROX Biosciences, Inc. from June 2017 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 currently serves as 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 of directors because of his extensive experience serving in leadership positions for biopharmaceutical companies.

Tamara A. (Seymour) Favorito was elected to our Board in March 2021. Ms. Favorito serves as a member of the board of directors, Chair of the audit committees and member of the compensation committees of Kintara Therapeutics, Inc. a publicly-traded drug development company. In addition she serves as a member of the board of directors and Chair of the audit and compensation committees of Zevra Therapeutics, Inc. (formerly KemPharm, Inc.), a rare disease therapeutics company. Ms. Favorito served as Interim Chief Financial Officer of Immunic, Inc., clinical-stage drug development company in 2019. She was Chief Financial Officer of Signal Genetics, Inc., a publicly traded molecular diagnostics company, from 2014 to 2017. She served as Chief Financial Officer of HemaQuest Pharmaceuticals, Inc., a venture-backed clinical-stage drug development company, from 2010 to 2014. From 2001 to 2009, she served as Chief Financial Officer of Favril, Inc., a publicly traded clinical-stage drug development company. Ms. Favorito has also served as consulting chief financial officer for a number of biotechnology companies, served as Director of Finance and Controller of Agouron Pharmaceuticals, Inc. (now Pfizer, Inc.) and 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). She received an MBA, emphasis in Finance, from Georgia State University, and a bachelor's degree in Business Administration, emphasis in Accounting, from Valdosta State University. Ms. Favorito also participated in an executive management program at Kellogg Graduate School of Management at Northwestern University.

We believe Ms. Favorito is qualified to serve as a member of our board of directors because of her experience leading public companies, her financial expertise and her familiarity with the biopharmaceutical industry.

Executive Officers

Gregory D. Gorgas. Please see biography in “Directors” section above.

Board Meetings

Since January 1, 2022, our Board has met six times. All of our directors 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.

Audit Committee

Our audit committee is currently comprised of Tamara A. (Seymour) 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 The Nasdaq Stock Market, LLC (“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 will 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 and certifications 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 www.artelobio.com.

Compensation Committee

Our compensation committee is currently comprised of Steven Kelly and Dr. Greg Reyes. 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 will 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 www.artelobio.com.

Corporate Governance and Nominating Committee

Our corporate governance and nominating committee is currently comprised of Douglas Blayney, M.D., and 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 will 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 www.artelobio.com.

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.

Family Relationships

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

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors and persons who own more than 10% of a registered class of our equity securities to file with the SEC initial statements of beneficial ownership, reports of changes in ownership and annual reports concerning their ownership of our shares of common stock and other equity securities, on Forms 3, 4 and 5, respectively. Executive officers, directors and greater than 10% shareholders are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely on our review of the copies of such forms received by our company, or written representations from certain reporting persons that no Form 5s were required for those persons, we believe that, during the fiscal year ended December 31, 2022, all filing requirements applicable to our officers, directors and greater than 10% beneficial owners as well as our officers, directors and greater than 10% beneficial owners of our subsidiaries were complied with.

ITEM 11. EXECUTIVE COMPENSATION

The particulars of the compensation paid to the following persons:

- (a) our principal executive officer (the Company has no other executive officers)

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Gregory D. Gorgas									
<i>President, CEO, CFO,</i>	2022/12	440,000	209,000	-	-	-	-	5,831	654,831
<i>Secretary, Treasurer and Director</i>	2021/12	141,667	217,281	-	730,093	-	-	1,944	1,090,985
	2021/08	415,333	210,375	-	2,840,064	-	-	5,831	3,471,603

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding equity awards granted to our named executive officer that remained outstanding as of December 31, 2022.

Name	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options: Exercisable (1)	Number of Securities Underlying Unexercised Options: Unexercisable (2)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (3)	Option Exercise Price (4)	Option Expiration Date (5)	Number of Shares or Units of Stock That Have Not Vested (6)	Market Value of Shares or Units of Stock That Have Not Vested (7)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Rights That Have Not Vested (8)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Rights That Have Not Vested (9)
Gregory D. Gorgas <i>President, CEO, CFO, Secretary, Treasurer and Director</i>	4,167	833 ⁽¹⁾	-	\$ 29.85	August 29, 2029	-	-	-	-
	27,817	27,817 ⁽²⁾	-	\$ 39.90	February 12, 2031	-	-	-	-
	16,774	21,566 ⁽³⁾	-	\$ 22.80	March 5, 2031	-	-	-	-
	24,466	65,868 ⁽⁴⁾	-	\$ 9.45	December 3, 2031	-	-	-	-

(1) 104 options vesting each month through July 2023 and 105 options vesting in August 2023.

(2) 27,817 options vesting in February 2023.

(3) 798 options vesting each month through July 2023. 799 Options vesting each month beginning August 2023 until March 2025.

(4) 1,881 options vesting each month through February 2023 and 1,882 options vesting each month beginning March 2023 until November 2025.

Executive Employment Agreements

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”).

[Table of Contents](#)

Mr. Gorgas' current annual base salary is \$475,000 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 Company's board of directors 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 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, 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.

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.

Director Compensation

The following table shows the compensation earned by persons who served on our Board of Directors during the year ended December 31, 2022, who are not one of our Named Executive Officers..

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Connie Matsui ⁽¹⁾	66,500	-	3,044	-	-	-	69,544
Douglas Blayney, M.D. ⁽²⁾	38,000	-	3,044	-	-	-	41,044
Gregory R. Reyes, M.D., Ph.D. ⁽³⁾	34,000	-	3,044	-	-	-	37,044
R. Martin Emanuele, Ph.D. ⁽⁴⁾	34,000	-	3,044	-	-	-	37,044
Steven Kelly ⁽⁵⁾	49,500	-	3,044	-	-	-	52,544
Tamara A. (Seymour) Favorito ⁽⁶⁾	45,000	-	3,044	-	-	-	48,044

- (1) 13,735 option awards outstanding as of December 31, 2022.
- (2) 11,834 option awards outstanding as of December 31, 2022.
- (3) 9,334 option awards outstanding as of December 31, 2022.
- (4) 11,369 option awards outstanding as of December 31, 2022.
- (5) 12,452 option awards outstanding as of December 31, 2022.
- (6) 3,334 option awards outstanding as of December 31, 2022.

Non-Employee Director Compensation Policy

Effective February 12, 2021, after reviewing data provided by F.W. Cook, an independent compensation consultant, the Company adopted an Outside Director Compensation Policy which provides that each outside director is entitled to receive the following cash compensation for their services:

- \$30,000 per year for service as a member of the board of directors;
- \$25,000 per year additionally for service as chairperson of the board;

[Table of Contents](#)

- \$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;
- \$4,000 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;
- \$4,000 per year additionally for service as a corporate governance and nominating committee member;

All cash payments to non-employee directors are paid quarterly in arrears on a prorated basis.

In addition, the Outside Director Compensation Policy provides that new non-employee directors receive, upon becoming a non-employee director, an initial award of stock options to purchase 2,000 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 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, provided that the board may make exceptions to this requirement, of stock options to purchase 667 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. 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 day 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 of directors and committees of our board of directors. 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.

Equity grants to our non-employee directors provide that in the event of a merger or change in control, each outstanding equity award granted 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.

On February 12, 2021, the Company granted options to certain directors of the Company to purchase a total of 47,036 shares of the Company's common stock with an exercise price of \$39.90 and vesting as follows: 50% shall vest on the one-year anniversary of the grant date and 50% shall vest on the two-year anniversary of the grant date, subject to our directors' continued service to the Company.

On March 5, 2021, the Company granted an option to a director of the Company to purchase 2,000 shares of the Company's common stock with an exercise price of \$22.80 and vesting as follows: one third shall vest on the one-year anniversary of the vesting commencement date, one third shall vest on the two-year anniversary of the vesting commencement date and one third shall vest on the three-year anniversary of the vesting commencement date, subject to this director's continued service to the Company.

On July 16, 2021, the Company granted options to certain directors of the Company to purchase a total of 4,669 shares of the Company's common stock with an exercise price of \$15.00 and vesting on the earlier of the one-year anniversary of the vesting commencement date or the date prior to the date of the annual meeting of the Company's stockholders next following the vesting commencement date. The vesting commencement date was July 16, 2021.

On June 24, 2022, the Company granted options to certain directors of the Company to purchase a total of 4,002 shares of the Company's common stock with an exercise price of \$4.89 and vesting on the earlier of the one-year anniversary of the vesting commencement date or the date prior to the date of the annual meeting of the Company's stockholders following the vesting commencement date. The vesting commencement date was June 24, 2023.

Employee Stock Plan

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 September 1, 2021, the 2018 Plan was increased to permit the issuance of an additional 244,940 shares of common stock awards. On February 18, 2022, the number of shares of Common Stock reserved for issuance under the 2018 Plan increased by 141,003 shares.

As of December 31, 2022, 622,526 shares of our common stock have been reserved for issuance pursuant to the 2018 Plan, of which options to purchase 313,109 shares of common stock are issued and outstanding. On January 6, 2023, the number of shares of Common Stock reserved for issuance under the 2018 Plan increased by 428,353 shares to a new total of 1,050,879 shares reserved for issuances pursuant to the 2018 Plan.

Plan Administration. Our board of directors or one or more committees appointed by our board of directors will administer the 2018 Plan. Our compensation committee of our board of directors 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 any clawback policy of ours, and the administrator also may specify in an award agreement that the participant's rights, payments, and/or benefits with respect to an award will be subject to reduction, cancellation, forfeiture, and/or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return, or reimburse us all or a portion of the award and/or shares issued under the award, any amounts paid under the award, and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

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, 2022, we granted stock options to purchase a total of 4,002 shares of common stock.

Option Exercises and Stock Vested

During the year ended December 31, 2022, there were no options exercised by our named 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. We have no material bonus or profit sharing plans pursuant to which cash or non-cash compensation is or may be paid to our directors or executive officers, except that stock options may be granted at the discretion of the board of directors or a committee thereof.

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 March 27, 2023, certain information with respect to the beneficial ownership of our common and preferred shares by each shareholder known by us to be the beneficial owner of more than 5% of our common and preferred shares, as well as by each of our current directors and executive officers as a group. Each person has sole voting and investment power with respect to the shares of common and preferred stock, except as otherwise indicated. Beneficial ownership consists of a direct interest in the shares of common and preferred stock, except as otherwise indicated.

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. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

Name and Address of Beneficial Owner	Number of Shares Held	Number of Shares Subject to Options and Warrants Exercisable within 60 Days	Total Shares Beneficially Owned	
			Number	%
Directors and Named Executive Officers				
Gregory D. Gorgas ⁽¹⁾	20,446	113,086	133,532	4.68%
Connie Matsui ⁽²⁾	3,778	13,068	16,846	*
Steven Kelly ⁽³⁾	834	11,785	12,619	*
Douglas Blayney, M.D. ⁽⁴⁾	834	11,167	12,001	*
R. Martin Emanuele, Ph.D. ⁽⁵⁾	834	10,702	11,536	*
Gregory R. Reyes M.D., Ph.D. ⁽⁶⁾	-	5,500	5,500	*
Tamara A. (Seymour) Favorito ⁽⁷⁾	-	2,001	2,001	*
All Current Directors and Executive Officers as a Group	26,726	167,309	194,035	6.79%
5% Stockholders				
None				

[Table of Contents](#)

* Less than 1%

- (1) Consists of 20,446 shares held by Gregory D. Gorgas, option to purchase 112,980 shares of common stock and warrants to purchase 106 shares of common stock that are exercisable within 60 days of March 27, 2023.
- (2) Consists of 3,778 shares held by Connie Matsui and option to purchase 13,068 shares of common stock that are exercisable within 60 days of March 27, 2023.
- (3) Consists of 834 shares held by Steven Kelly and option to purchase 11,785 shares of common stock that are exercisable within 60 days of March 27, 2023.
- (4) Consists of 834 shares held by Douglas Blayney, M.D. and option to purchase 11,167 shares of common stock that are exercisable within 60 days of March 27, 2023.
- (5) Consists of 834 shares held by R. Marty Emanuele, Ph.D. and option to purchase 10,702 shares of common stock that are exercisable within 60 days of March 27, 2023.
- (6) Consists of option to purchase 5,500 shares held by Gregory R. Reyes. M.D., Ph.D. of common stock that are exercisable within 60 days of March 27, 2023.
- (7) Consists of option to purchase 2,001 shares held by Tamara A. (Seymour) Favorito of common stock that are exercisable within 60 days of March 27, 2023.

Equity Compensation Plan Information

The following table summarizes information about our equity compensation plans as of December 31, 2022. 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	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders:			
2018 Equity Incentive Plan	313,109	\$ 24.15	309,417
Equity compensation plans not approved by security holders	-	-	-
Total	313,109	\$ 24.15	309,417

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

None.

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 Capital Market. 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 year ended December 31, 2022, four months ended December 31, 2021 and year ended August 31, 2021:

<u>Fee Category</u>	<u>Year ended December 31, 2022</u>	<u>Four months ended December 31, 2021</u>	<u>Year ended August 31, 2021</u>
Audit Fees	\$ 113,500	\$ 48,000	75,000
Audit-Related Fees	-	-	54,000
Tax Fees	5,000	-	4,000
All Other Fees	-	-	-
Total Fees	<u>\$ 118,500</u>	<u>\$ 48,000</u>	<u>133,000</u>

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 Number	Description	Form	File No.	Filing Date	Filed Herewith
3.1	Articles of Incorporation, as amended	S-1	333-264967	5/16/2022	
3.2	Certificate of Change, effective August 9, 2022	8-K	001-38951	8/9/2022	
3.3	Amended and Restated Bylaws	10-Q	001-38951	11-08-2022	
4.1	Description of Securities				*
10.1	Purchase Agreement between the Company and Lincoln Park Capital Fund, LLC, dated May 13, 2022.	8-K	001-38951	05/16/2022	
10.2	Registration Rights Agreement between the Company and Lincoln Park Capital Fund, LLC, dated May 13, 2022.	8-K	001-38951	05/16/2022	
10.3#	Amended and Restated Employment Agreement by and between the Company and Gregory D. Gorgas dated August 30, 2019.	10-K	001-38951	11/25/2019	
10.4	Securities Purchase Agreement by and between the Company and Gregory D. Gorgas dated April 3, 2017.	8-K	333-199213	4/7/2017	
10.5#	Form of Indemnification Agreement	8-K	333-199213	5/8/2017	
10.6	Stock Purchase Agreement dated May 4, 2017	8-K	333-199213	5/8/2017	
10.7	Form of Private Placement Subscription Agreement	8-K	333-199213	8/4/2017	
10.8	Form of Registration Rights Agreement	8-K	333-199213	8/4/2017	
10.9	Stock Purchase Agreement dated as of August 1, 2017	8-K	333-199213	8/4/2017	
10.10	Material and Data Transfer, Option and License Agreement dated as of December 20, 2017 by and between the Company and NEOMED Institute+	10-Q	333-199213	1/16/2018	
10.11+	First Amendment to Material and Data Transfer, Option and License Agreement by and between the Company and NEOMED Institute, dated as of January 4, 2019	10-Q	333-199213	4/15/2019	
10.12#	2018 Equity Incentive Plan	S-8	333-264183	4/7/2022	
10.13#	Form of Stock Option Agreement—2018 Equity Incentive Plan	S-1	333-227571	9/27/2018	
10.14+	License Agreement with Stony Brook University, by and between the Company and Stony Brook University, dated January 18, 2018	S-1/A	333-222756	4/17/2018	
21.1	List of subsidiaries	10-Q	001-38951	11-08-2023	
23.1	Consent Of Independent Registered Public Accounting Firm				*
31.1	Section 302 Certification				*
32.1 **	Section 906 Certification				*
101 INS	Inline XBRL Instance Document				
101 SCH	Inline XBRL Taxonomy Extension Schema Document				
101 CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101 LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101 PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover page Interactive Data File (embedded with the Inline XBRL document)				

Management contracts or compensatory plans, contracts or arrangements.

+ Certain portions of this exhibit have been omitted.

** The certification attached as Exhibit 32.1 that accompanies this Annual Report, is deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Artelo Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this 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: March 31, 2023

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Gregory D. Gorgas, 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: March 31, 2023

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

Dated: March 31, 2023

/s/ Connie Matsui
Connie Matsui
Director

Dated: March 31, 2023

/s/ Steven Kelly
Steven Kelly
Director

Dated: March 31, 2023

/s/ Douglas Blayney
Douglas Blayney
Director

Dated: March 31, 2023

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

Dated: March 31, 2023

/s/ Greg Reyes
Greg Reyes
Director

Dated: March 31, 2023

/s/ Tamara A. (Seymour) Favorito
Tamara A. (Seymour) Favorito
Director

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

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

Description of Capital Stock

The following description of our common 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

The Company's authorized capital stock consists of 50,416,667 shares of capital stock, par value \$0.001 per share, of which 50,000,000 shares are common stock, par value \$0.001 per share and 416,667 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 on which stockholders may vote. Reference is made to the Company's Articles of Incorporation, Bylaws and the applicable statutes of the State of Nevada for a more complete description of the rights and liabilities of holders of the Company's securities.

Preferred Stock

The Company has authorized 416,667 shares of preferred stock. There is no preferred stock outstanding. Our Board may designate the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation of any series. The issuance of preferred stock could have the effect of restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock or delaying, deterring or preventing a change in control. Such issuance could have the effect of decreasing the market price of the common stock. We currently have no plans to issue any shares of preferred stock.

Non-cumulative Voting

Holders of shares of our common stock do not have cumulative voting rights; meaning that the holders of 50.1% of the outstanding shares, voting for the election of directors, can elect all of the directors to be elected, and, in such event, the holders of the remaining shares will not be able to elect any of our directors.

Dividends

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.

Warrants

As of the date hereof, the Series C Common Stock Warrants entitle their holders to purchase 5,836 shares of common stock, with a term of five (5) years from the date of issuance and an exercise price of \$210.00 per share. The Series C Common Stock Warrants contain “certain customary exceptions, as well as customary provisions for adjustment in the event of stock splits, subdivision or combination, mergers, etc.”

As of the date hereof, the Series D Common Stock Warrants entitle their holders to purchase 13,962 shares of common stock, with a term of five (5) years from the date of issuance and an exercise price of \$210.00 per share. The Series D Common Stock Warrants contain “certain customary exceptions, as well as customary provisions for adjustment in the event of stock splits, subdivision or combination, mergers, etc.”

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 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.

Undesignated Preferred Stock. The ability of our Board, without action by the stockholders, to issue up to 416,667 shares of preferred stock, which was previously authorized but remain undesignated, with voting or other rights or preferences as designated by our Board could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of us.

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 and warrants are listed on The Nasdaq Capital Market under the symbols “ARTL” and “ARTLW.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar’s address is 6201 15th Avenue, Brooklyn, New York 11219. The transfer agent’s telephone number is (800) 937-5449.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File no. 333-235917) and Forms S-8 (File Nos. 333-264183, 333-251387, 333-239434 and 333-235916) of our report dated March 31, 2023, with respect to the audited financial statements of Artelo Biosciences, Inc. (the "Company") appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2022.

/s/ MaloneBailey, LLP
www.malonebailey.com
Houston, Texas
March 31, 2023

CERTIFICATION

I, Gregory D. Gorgas, President of Artelo Biosciences, Inc., 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: March 31, 2023

/s/ Gregory D. Gorgas

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

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

In connection with the Annual Report of Artelo Biosciences, Inc. (the "Company") on Form 10-K for the period ended December 31, 2022 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: March 31, 2023

/s/ Gregory D. Gorgas

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