

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 August 31, 2019

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

For the transition period from _____ to _____

Commission file number 333-234372

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.)

888 Prospect Street, Suite 210, La Jolla CA

(Address of principal executive offices)

92037

(Zip Code)

Registrant's telephone number, including area code: **(760) 943-1689**

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	Nasdaq
Warrants	ARTLW	Nasdaq

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 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging Growth Company

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

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

The aggregate market value of Common Stock held by non-affiliates of the Registrant on February 28, 2019, was \$12,168,442 based on a \$9.12 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.

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

3,426,276 shares of common stock issued and outstanding as of November 21, 2019.

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FORWARD-LOOKING STATEMENTS

These statements contain 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 section 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:

- the timing of the initiation and completion of our clinical studies;
- our plans to obtain funding for our operations, including funding necessary to develop, manufacture and commercialize our product candidates;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our expectation that our capital resources will not be sufficient to fund our operations for our operations for at least the next 12 months;
- regulatory developments in the U.S. and in non-U.S. countries;
- the development, regulatory approval, efficacy and commercialization of competing product candidates;
- our ability to retain key scientific or management personnel;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products and technology;
- the terms and conditions of licenses granted to us and our ability to license additional intellectual property related to our product candidates, as appropriate;
- potential claims related to our intellectual property;
- the cost, timing and outcomes of any potential litigation involving our product candidates;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our ability to develop innovative new product candidates; and
- the size and growth of the markets for our product candidates;

In addition, you should refer to the "Risk Factors" section, including a risk regarding the volatility of our stock price, for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all, and failure to do so may cause our stock price to decline. 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 "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this filing, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Our audited financial statements are stated in United States Dollars (US\$) and are prepared in accordance accounting principles generally accepted in the United States of America (“GAAP”). The following discussion should be read in conjunction with our financial statements and the related notes that appear elsewhere in this 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 quarterly report.

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

As used in this 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, and Trinity Research & Development Limited, in England and Wales unless otherwise indicated.

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PART I

ITEM 1. BUSINESS

Corporate Overview

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

Our product candidate pipeline broadly leverages leading scientific methodologies to ECS modulation, balances risk across mechanism of action and stages of development, and represents a comprehensive approach in utilizing the power of the ECS to develop pharmaceuticals for patients with unmet healthcare needs. In addition to our cocrystal program, we are currently evaluating ART27.13, which we currently anticipate will enter a Phase 1b/2a trial for cancer related anorexia in the second quarter of 2020, and ART26.12, which is being studied as an endocannabinoid modulator and cancer therapeutic and is in the late pre-clinical stage.

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

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U.S. and international patent applications including broad claims to our novel cocrystal composition of CBD were filed in late 2018 and a continuation filing with the United States Patent and Trademark Office (the “USPTO”) in April 2019. Composition claims are generally known in the pharmaceutical industry as the most desired type of intellectual property and, if issued, should provide for long lasting market exclusivity for our CBD cocrystal drug product candidate. In addition, due to the reasons outlined above, we believe that our CBD cocrystal will have superior pharmaceutical properties compared to non-cocrystal CBD products under development at other competing companies.

In addition to our own internal discovery research, we are currently developing two patent protected product candidates that we obtained through our in-licensing activities. Our first program is a synthetic small molecule program, ART27.13, being developed for cancer-related anorexia. ART27.13 is a peripherally-restricted high-potency dual CB₁ and CB₂ receptor agonist which was originally developed at AstraZeneca plc (“AstraZeneca”). We have exercised our option to exclusively license this product candidate through the NEOMED Institute, a Canadian not-for-profit corporation, renamed adMare in June 2019 (“NEOMED”). In Phase 1 single dose studies in healthy volunteers and a multiple ascending dose study in otherwise healthy patients with

back pain conducted by AstraZeneca, ART27.13 exhibited an attractive pharmacokinetic and absorption, distribution, metabolism, and excretion 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 U.K. 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 are planning to initiate a Phase 1b/2a clinical study of cancer-related anorexia with ART27.13 upon successful completion of manufacturing new study material and when the regulatory authorities in the U.K. which we currently anticipate will be in the second quarter of 2020, with initial data expected by year end.

Our second in-licensed program is a platform of small-molecule inhibitors for fatty acid binding protein 5 (“FABP5”), based upon scientific developments achieved at Stony Brook University (“SBU”) which we have designated ART26.12. To date, SBU has received nearly \$4 million in funding from the National Institutes of Health to begin developing these candidates. Fatty acid binding proteins (“FABPs”) are attractive therapeutic targets, however, their high degree of similarity among the various types has proven challenging to the creation of drugs targeting specific FABPs. FABP5 is believed to specifically target and regulate one of the body’s endogenous cannabinoids, anandamide (“AEA”). While searching for a FABP5 inhibitor to regulate AEA, we believe researchers at SBU discovered the chemistry for creating a highly specific and potent small molecule inhibitor for FABP5. In addition to its potential as an endocannabinoid modulator, FABP5 is also an attractive target for cancer drug development. Large amounts of human clinical epidemiological and animal model data support FABP5 as a well validated oncology therapeutic target, especially for triple negative breast cancer and castration-resistant prostate cancer. We licensed exclusive world-wide rights to these inhibitors from SBU. The program is in the final stages of lead optimization, and we plan to initiate regulatory enabling studies thereafter. We anticipate clinical studies in cancer can begin in 2021.

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

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Product Candidate Pipeline:

Product Candidate	Target Indications	Development Phase	Market Size
ART27.13 - Cannabinoid Agonist	Anorexia associated with cancer	Phase 1	Cancer anorexia cachexia syndrome: \$2 billion
ART12.11 – CBD Cocrystal	Inflammatory Bowel Disease (IBD) and Post-Traumatic Stress Disorder (PTSD)	Pre-clinical	IBD: \$9 billion PTSD: \$7 billion
ART26.12 – FABP5 inhibitor	Prostate cancer and Breast cancer	Pre-clinical	Prostate cancer: \$8 billion Breast cancer: \$13 billion

Therapeutics market size based upon total global annual prescription drug sales in 2016, 2017 or 2018

Sources: <http://wiseawareness.com/cancer-cachexia-market/>; <http://www.openpr.com/wiki/global-breast-cancer-therapeutics-market>;
<http://www.globenewswire.com/news-release/2018/09/24/1575060/0/en/Global-Prostate-Cancer-Therapeutics-Market-Will-Reach-USD-17-200-Million-By-2024-Zion-Market-Research.html>; <http://www.prnewswire.com/news-releases/the-global-inflammatory-bowel-diseases-ibd-drug-market-is-estimated-at-6-7bn-in-2017-and-7-6bn-in-2023--300688523.html>; <http://www.credenceresearch.com/report/post-traumatic-stress-disorder-therapeutics-market>

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Background

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

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

The actions of endogenous ligands can be enhanced or attenuated by targeting mechanisms that are associated with their transport within the cellular and extra cellular matrix as well as their synthesis and breakdown. Small molecule chemical modulators of the ECS can be derived from the cannabis plant (“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: pain, inflammation, anorexia, cardiovascular, and cancer.

Business Strategy

Our objective is to develop and commercialize ethical pharmaceutical products that provide physicians access to the therapeutic potential of cannabinoid therapeutics and other modulators of the ECS for their patients. We intend to pursue technologies and compounds that offer promising therapeutic approaches to cannabinoid-based therapies, including mimetics of naturally-occurring cannabinoids and fully synthetic cannabinoids, as well as compounds that promote the effectiveness of the ECS.

Corporate History

We were initially incorporated as Knight Knox Development Corp. in the State of Nevada on May 2, 2011 with a plan to develop an online business using our domain www.offeritnow.com to generate revenues by (i) selling ad space to third party websites, (ii) charging a fee for listing items for sale on the Company’s website or (iii) selling items on the auction section of our website. On November 18, 2016, James Manley, who had served as President, Chief Executive Officer, Chief Financial Officer, Secretary and director resigned from the Company. On that date, Peter O’Brien acquired all 1,000,000 shares of common stock that had previously been owned by James Manley and assumed the positions of President, Chief Executive Officer, Chief Financial Officer, Secretary and director of the Company.

On November 11, 2016, we registered a fully owned subsidiary in Ireland, Trinity Reliant Ventures Limited and on June 2, 2017 we registered a fully owned subsidiary in the UK, Trinity Research and Development Limited, to oversee our European operations. To date, activities within the subsidiary have consisted of raising equity capital and performing research and development activities in the United Kingdom.

On January 19, 2017, a majority of stockholders and the Board approved a change of our name to Reactive Medical, Inc. to pursue the licensing, development and commercialization of cannabinoid-based therapeutics.

On April 3, 2017, Mr. O’Brien resigned from the positions of President, Chief Executive Officer, Chief Financial Officer, Secretary and Treasurer of our Company and the Board appointed Gregory D. Gorgas to assume those positions. At that time, Mr. Gorgas also became a member of our Board. Mr. O’Brien retained his seat on the Board and was appointed Senior Vice President – European Operations. Mr. Gorgas purchased a total of 293,333 shares of our common stock at a price of \$0.001 per share, which shares are subject to a repurchase option by us should Mr. Gorgas’ employment end prior to the fourth anniversary of his employment. Mr. O’Brien has since resigned from the Board on March 1, 2019.

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On April 14, 2017, with the approval of our Board and stockholders owning a majority of our outstanding shares, we filed a Certificate of Change with the Secretary of State of Nevada to change our name to Artelo Biosciences, Inc. The new name more accurately informs our stockholders about our focus and business strategy. The name “Artelo” was selected to portray our focus on improving and/or administering products distributed via arterial blood flow, and “Biosciences” to more accurately reflect our focus on drug development, including those derived from or synthetic mimetics of botanically sourced chemicals.

On May 2, 2017, Mr. O’Brien entered into an agreement to sell fifty percent (50%) of his shares to an investor for \$3,000. In addition, we increased the size of our Board from two members to four members and appointed Connie Matsui and Steven Kelly as members of our Board.

On June 2, 2017, we registered a wholly owned subsidiary in England and Wales, Trinity Research & Development Limited.

On July 31, 2017, we closed a private placement offering of 244,038 Series A Units (the “Series A Units”) of our equity securities at a price of \$3.20 per Unit for aggregate proceeds of \$780,921 (the “Series A Offering”). Each Series A Unit consists of: (i) one (1) share of common stock, and (ii) one (1) Series A Common Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$8.00 per share for a period of five (5) years from the issue date (the “Series A Common Stock Warrants”). The Series A Common Stock Warrants cannot be exercised on a cashless basis by non-affiliates. The consummation of the transactions contemplated by the Subscription Agreement (the “Series A Subscription Agreement”) occurred on July 31, 2017. As part of the Series A Offering, the Company and the investors entered into a Series A Registration Rights Agreement, which requires the Company to register for resale all of the shares of common stock sold as part of the Series A Offering, including those issuable upon exercise of the Series A Common Stock Warrants, within one hundred eighty (180) days from the closing of Series A the Offering.

On July 31, 2017, Douglas Blayney, M.D. was appointed to the Board. On September 20, 2017, Georgia Erbez and R. Martin Emanuele, Ph.D. were appointed to the Board.

On March 23, 2018, we closed a private placement offering of 163,606 Series B Units (the “Series B Units”) of our equity securities at a price of \$5.20 per Series B Unit for aggregate proceeds of \$850,751 (the “Series B Offering”). Each Series B Unit consists of: (i) one (1) share of common stock, and (ii) one (1) Series B Common Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$9.90 per share for a period of five (5) years from the issue date (the “Series B Common Stock Warrants”). The Series B Common Stock Warrants cannot be exercised on a cashless basis by non-affiliates. The consummation of the transactions contemplated by the Subscription Agreement (the “Series B Subscription Agreement”) occurred on March 23, 2018. As part of the Series B Offering, the Company and the investors entered into a Series B Registration Rights Agreement, which requires the Company to register for resale all of the shares of common stock sold as part of the Series B Offering, including those issuable upon exercise of the Series B Common Stock Warrants, within one hundred eighty (180) days from the closing of the Series B Offering.

On September 12, 2018, we closed a private placement offering of 87,629 Series C Units (the “Series C Units”) of our equity securities at a price of \$6.00 per Series C Unit for aggregate proceeds of \$525,823 (the “Series C Offering”). Each Series C Unit consists of: (i) one (1) share of common stock, and (ii) one (1) Series C Common Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$10.50 per share for a period of five (5) years from the issue date (the “Series C Common Stock Warrants”). The Series C Common Stock Warrants cannot be exercised on a cashless basis by non-affiliates. The consummation of the transactions contemplated by the Subscription Agreement (the “Series C Subscription Agreement”) occurred on September 12, 2018. As part of the Series C Offering, the Company and the investors entered into a Series C Registration Rights Agreement, which requires the Company to register for resale all of the shares of common stock sold as part of the Series C Offering, including those issuable upon exercise of the Series C Common Stock Warrants, within one hundred eighty (180) days from the closing of Series C the Offering.

On January 30, 2019, we closed a private placement offering of 209,635 Series D Units (the “Series D Units”) of our equity securities at a price of \$6.00 per Series D Unit for aggregate proceeds of \$1,257,905 (the “Series D Offering”). Each Series D Unit consists of: (i) one (1) share of common stock, and (ii) one (1) Series D Common Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$14.00 per share for a period of five (5) years from the issue date (the “Series D Common Stock Warrants”). The Series D Common Stock Warrants cannot be exercised on a cashless basis by non-affiliates. The consummation of the transactions contemplated by the Subscription Agreement (the “Series D Subscription Agreement”) occurred on January 30, 2019. As part of the Series D Offering, the Company and the investors entered into a Series D Registration Rights Agreement, which requires the Company to register for resale all of the shares of common stock sold as part of the Series D Offering, including those issuable upon exercise of the Series D Common Stock Warrants, within one hundred eighty (180) days from the closing of Series D the Offering.

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On April 25, 2019, we held an initial closing of a private placement offering of our Series E Units (the “Series E Units”). On May 24, 2019, we held a final closing of our Series E Units. We sold an aggregate total of 54,940 Series E Units at a price of \$7.60 per Series E Unit for aggregate proceeds of \$417,732.10 (the “Series E Offering”). Each Series E Unit consists of: (i) one (1) share of common stock; and (ii) a Series E Common Stock Purchase Warrant to purchase one-half (1/2) share of common stock at a price of \$16.00 per share for a period of three (3) years from the issue date. The Series E Common Stock Warrants cannot be exercised on a cashless basis by non-affiliates. The consummation of the transactions contemplated by the Subscription Agreement (the “Series E Subscription Agreement”) occurred on May 24, 2019. As part of the Series E Offering, the Company and the investors entered into a Series E Registration Rights Agreement, which requires the Company to register for resale all of the shares of common stock sold as part of the Series E Offering, including those issuable upon exercise of the Series E Common Stock Warrants, within one hundred eighty (180) days from the closing of Series E the Offering.

On June 25, 2019, the Company sold an aggregate of 1,300,813 units with each unit consisting of one (1) share of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), and a warrant to purchase one (1) share of Common Stock at an exercise price equal to \$6.4575 per share (the “Warrants”) pursuant to that certain Underwriting Agreement dated as of June 21, 2019 (the “Underwriting Agreement”) with Maxim Group LLC (“Maxim”), as representative for the several underwriters named in Schedule I thereto (the “Underwriters”). In addition, the Company granted the Underwriters a 45-day option to purchase up to 195,121 additional shares of Common Stock, or Warrants, or any combination thereof, to cover over-allotments, if any. The Common Stock and the Warrants were offered and sold to the public (the “Offering”) pursuant to the Company’s registration statement on Form S-1 (File No. 333-230658), filed by the Company with the Securities and Exchange Commission (the “Commission”) pursuant to the Securities Act of 1933, as amended (the “Securities Act”), on April 1, 2019, as amended, and which became effective on June 20, 2019. The offering price to the public was \$6.15 per unit. In addition, simultaneously with the closing of the Offering the Company sold 191,102 Warrants upon the partial exercise of the Underwriters’ over-allotment option. The Company received gross proceeds of approximately \$8,000,000, before deducting underwriting discounts and commissions of eight percent (8%) of the gross proceeds and estimated Offering expenses.

The Underwriting Agreement contains customary representations, warranties, and covenants by the Company. It also provides for customary indemnification by each of the Company and the Underwriters, severally and not jointly, for losses or damages arising out of or in connection with the Offering, including for liabilities under the Securities Act, other obligations of the parties and termination provisions. In addition, pursuant to the terms of the Underwriting Agreement, certain existing stockholders and each of the Company’s directors and executive officers have entered into “lock-up” agreements with the Underwriters that generally prohibit the sale, transfer, or other disposition of securities of the Company for a period of at least 180 days following June 20, 2019 without the prior written consent of Underwriters.

Pursuant to the Underwriting Agreement, the Company also agreed to issue to the Underwriters warrants (the “Underwriter’s Warrants”) to purchase up to a total of 104,065 shares of Common Stock (8% of the shares of Common Stock sold in the Offering). The Underwriter’s Warrants are exercisable at \$6.765 per share of Common Stock and have a term of three years. Pursuant to the customary FINRA rules, the Underwriter’s Warrants are subject to a 180-day lock-up pursuant to which the representative will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the date of the prospectus relating to the Offering.

In addition, pursuant the Underwriting Agreement, the Company granted Maxim, a right of first refusal, for a period of twelve months from the commencement of sales of this Offering, to act as sole and exclusive investment banker, book-runner, financial advisor, underwriter and/or placement agent, at Maxim’s sole and exclusive discretion, for each and every all future public or private equity, equity-linked, or debt (excluding commercial bank debt) financings.

The total expenses of the Offering were approximately \$636,000 which included Maxim’s expenses relating to the Offering.

In connection with the Offering described above, the Common Stock and the Warrants began trading on the Nasdaq Capital Market on June 21, 2019 under the trading symbols “ARTL” and “ARTLW,” respectively.

On June 21, 2019, the Company also entered into a Warrant Agency Agreement with Globex Transfer, LLC (“Warrant Agency Agreement”) pursuant to which Globex Transfer, LLC agrees to act as transfer agent with respect to the Warrants.

The Company filed a Certificate of Change with the Secretary of State of Nevada, pursuant to which, effective at 4:18 p.m. Pacific Standard Time on June 20, 2019 (the “Effective Time”), the Company effected a one-for-eight reverse split of its authorized and issued and outstanding Common Stock (the “Reverse Stock Split”). The number of authorized shares of Common Stock was reduced from 150,000,000 to 18,750,000.

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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 - Cannabinoid Agonist	Two (2) issued patents (US & Intl) including composition of matter, term 11/3/25	Worldwide exclusive license
ART12.11 – CBD Cocrystal	Pending composition of matter applications (US & Intl), filed 12/10/18, priority 12/11/17	N/A (wholly owned by Artelo)
ART26.12 – FABP5 inhibitor	Two (2) patents issued (US), term 7/19/30 and 7/19/33, and three (3) pending (Intl) covers the target, composition of matter, and utility claims, filed 7/19/10, 7/19/13, and 3/10/17	Worldwide exclusive license

The NEOMED Relationship

On December 20, 2017, the Company entered into 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 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 to NEOMED in connection with the Company's exercise of the NEOMED Option. The Company also issued 11,363 shares of common stock 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 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.

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In clinical development studies with NEOMED’s prior sponsor, NEO1940 was dosed in over 200 subjects. From 2007 to 2008, NEO1940 was evaluated in five phase I clinical trials under its original sponsor, AstraZeneca. NEO1940 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 Caucasian population. 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 of the third molar extraction model in the other case. The last phase I study was a Multiple Ascending Dose (“MAD”) study, where patients with chronic lower back pain received NEO1940 for a scheduled period of 12 days. Further details of the studies are found in Table 1.

Table 1 – Clinical studies performed with NEO1940

Year	Full Title	Schedule	Primary Endpoint	Secondary Endpoints
2007	Phase I, 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 I, 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 I, 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 I, 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

(1) Kalliomäki J, et al. Clin Exp Pharmacol Physiol. 2013 Mar;40(3):212-8.

(2) <http://clinicaltrials.gov/ct2/show/NCT00659490?term=AZD1940&rank=2>

(3) <http://clinicaltrials.gov/ct2/show/NCT00689780?term=AZD1940&rank=1>

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NEO1940 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 I studies, analgesia in acute pain models was also measured as an end-point; no convincing analgesic efficacy has been 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 (the “Patent Rights”) to develop, make, manufacture, have made, use, sell, have sold, import, export, and offer for sale Patent Product(s) (as defined in the Stony Brook Agreement) and Other Product(s) (as defined in the Stony Brook Agreement) worldwide in all fields, including without limitation the field of human therapeutics. The Stony Brook Agreement has an effective date of January 18, 2018 (the “SBU Effective Date”).

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

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

Milestone	Milestone Payment (\$US)
Lead candidate selection (milestone one of the Commercialization business plan) or second anniversary of SBU Effective Date, whichever comes first	\$ 25,000.00
Initiation of a Phase II 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 III 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.

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Research & Development

In view of the urgent need for new and more effective drugs, we intend to combine innovative science and accelerated clinical development to create and develop novel therapies using cannabinoid-based medications and similar compounds which modulate the ECS. Our current research and development efforts have been limited to investigative work surrounding cannabinoids, including creating and developing novel 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 University of Nottingham, U.K. and various CRO's in the U.S. and U.K.

Scientific Approach

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

- *Synthetics and Mimetics.* We plan to acquire rights to intellectual property for research and clinical stage assets developed within the pharmaceutical industry and leading research institutions which utilize synthetically developed mimetics or alternatives to plant-based cannabinoids. Our efforts to secure rights to synthetics and novel compounds led us to the NEOMED Agreement with NEOMED for the Compound.
- *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 modulate the ECS or related signaling pathways. 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 for modulating the ECS. Our initiatives for this strategy led us to the license novel technology from Stony Brook University, which we expect to be a core program for the Company.

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 collaborations 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.

- *ART12.11* – Our novel solid-state CBD composition 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.
- *ART26.12* – Our FABP5 inhibitor program is intended for treatment of breast cancer, prostate cancer, and neuropathic and nociceptive pain. Our near-term goal is to identify a lead development compound and assess its activity in models of cancer and pain. Once one or more lead compound(s) are selected, we intend to initiate regulatory-enabling studies.
- *ART27.13* – ART27.13 is our name for the compound formerly known as NEO1940 and AZD1940. We intend to develop a formulation suitable for treatment of anorexia/weight loss associated with cancer. ART27.13 has been in 205 subjects in prior clinical studies and is clinic-ready for a Phase 1b/2a study in anorexia associated with cancer.

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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., Cannabics Pharmaceuticals Inc., and GW Pharmaceuticals OLC, 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.

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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 IND application, which must take effect before human clinical trials may begin;
- approval by an independent 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 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 for one or more proposed indications;
- 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 Practices, 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 clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and 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.

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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. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

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.

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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. Among the ACA’s provisions of importance to our business are the following:

- implementation of a 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, which, due to subsequent legislation will not go into effect until January 1, 2020;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

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.” Additionally, on January 22, 2018, Executive Office of the President of the United States signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, and the annual fee imposed on certain health insurance providers based on market share.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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. 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.

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Employees

We currently have one (1) full-time employee, Mr. Gregory D. Gorgas, serving as President and CEO, and three (3) contractors, Mr. Peter O'Brien, serving as our Senior Vice President - European Operations, Mr. Jason Baybutt, serving as our Senior Vice President – Finance, and Dr. Steven Reich, M.D., serving as our Chief Medical Officer. We also engage multiple consultants and advisors who provide services on a part-time basis. Our employee, 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 employee, consultants, and contractors to be satisfactory.

Implications of being an Emerging Growth Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, enacted in April 2012. An “emerging growth company” may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of “Selected Financial Data” and related “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year ending August 2020. However, if certain events occur prior to the end of such period, including if we become a “large accelerated filer,” our annual gross revenue exceeds \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR BUSINESS AND PRODUCT CANDIDATES

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

We are a party to license agreements with NEOMED Institute, a Canadian not-for-profit corporation, renamed adMare in June 2019 (“NEOMED”) 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”). If we are found in the future 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 these 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 licenses in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

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

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

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

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 for reexamination, 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

We have very limited operating history and capabilities.

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

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

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

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to transition from a company with a research and development focus to a company capable of undertaking

commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

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

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

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

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

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

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

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

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

- identify, recruit and enroll suitable patients to participate in a clinical trial;
- have a sufficient number of patients complete a clinical trial or return for post-treatment follow-up;
- 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.

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

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

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

Due to our limited resources and capabilities, we will have to decide to focus on developing a limited number of product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our

resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

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

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

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

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

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

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

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

We currently do not have any manufacturing facilities. We also do not own any properties, laboratories, or manufacturing facilities. However, we have offices in La Jolla, California, and Dublin, Ireland. Our facilities could be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, fires, power shortages, telecommunications failures, water shortages, famines, pestilence, floods, hurricanes, typhoons, tornadoes, extreme

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

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

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensor's patent rights are highly uncertain. Our and our licensor's pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the

scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensor were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. We may become involved in opposition or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our product candidates without infringing third-party patent rights.

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.

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

In the United States, the DEA regulates the cultivation, possession and supply of cannabis for medical research and/or commercial development, including the requirement of annual registrations to manufacture or distribute 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 a Schedule 1 controlled substance. We plan to obtain the required licenses regulating the possession and supply of cannabinoids and to utilize third party contractors to conduct research who have the required registrations, however there is no assurance that we will be successful in obtaining the required licenses or that we will be successful identifying or engaging third party contractors who have the required registrations.

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

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

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

Some of our product candidates may contain controlled substances as defined in the federal Controlled Substances Act of 1970 (the “CSA”). Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA

classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, no currently “accepted medical use” in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the United States which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

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

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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, manufacturing or repackaging/relabeling in the U.S.

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

If one of our product candidates is approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If a product is listed as a Schedule II substance, we will not be allowed to import that drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. It is always possible the DEA could find that the active substance in a product, even if it is a plant derived substance, could be manufactured in the US. Moreover, Schedule I controlled substances, 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.

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Manufacture in the United States. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of any future product candidates, 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 of these products. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

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

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

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

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

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

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

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

- lack of effectiveness of any formulation or delivery system during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- delays in obtaining regulatory authorization to commence a trial, including IRB approvals, licenses required for obtaining and using 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. We believe that as cannabinoid-derived products become more widely accepted by the medical and scientific communities and the public at large, the stigma associated with cannabinoid-derived products and treatments will moderate and, as a result, consumer demand will likely continue to grow. However, we cannot predict the future growth rate and size of the market, assuming that the regulatory framework is favorable of which there can be no assurance. Any negative outlook on cannabinoid-derived products and treatments could adversely affect our business prospects.

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

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

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

Since our product candidates may contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our product candidates. These pressures could also limit or restrict

the introduction and marketing of our product candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid-derived products may adversely affect the commercial success or market penetration achievable by our product candidates. The nature of our business will likely attract a high-level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed.

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

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

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

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

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

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

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

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

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

In certain foreign markets, including countries in the European Union, pricing of prescription pharmaceuticals is subject to governmental control. Price negotiations with governmental authorities may range from 6 to 12 months or longer after the receipt of regulatory marketing approval for a product. Our business could be detrimentally impacted if 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 only employee, our Chief Executive Officer, Chief Financial Officer, President, Treasurer and Secretary,

Gregory D. Gorgas. The loss of the services of Mr. Gorgas, and our inability to find a suitable replacement could result in delays in research and development and product development and harm our business. Additionally, although we have an employment agreement with our sole employee, this employment agreement provides for at-will employment, which means that Mr. Gorgas could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the life of Mr. Gorgas.

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 as well as junior, mid-level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

We have incurred losses since inception. We expect to continue to incur significant expenses and increasing operating and net losses for the foreseeable future. To date, we have financed our operations primarily through the sale of equity securities. Although we have closed five (5) equity offerings between July 2017 and May 2019 we continue to have very limited resources. To date our primary activities have been limited to, and our limited resources have been dedicated to, raising capital, non-clinical research on our programs, recruiting service providers, negotiating with business partners and licensors of intellectual property, filing patent applications, and complying with public reporting requirements.

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

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

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

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We may not successfully manage our growth.

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

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

Patents also have a limited lifespan. In the United States, subject to certain extensions that may be obtained in some cases, the natural expiration of a utility patent is generally 20 years from its earliest effective filing date, and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our products

and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced.

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

requirements.

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

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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

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 develop for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of our securities.

Although our securities are listed on the Nasdaq Capital Market, an active trading market for our shares may never develop or be sustained. 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.

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

As of August 31, 2019, our current executive officers and certain large stockholders of the Company hold approximately 23% of the voting power of our outstanding shares. These officers and investors have a controlling influence in determining the outcome of any corporate transaction or other matters submitted to our stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets, election of directors, and other significant corporate actions. As such, our executive officers and these investors have the power to prevent or cause a change in control; therefore, without their consent we could be prevented from entering into transactions that could be beneficial to us. The interests of our executive officers may give rise to a conflict of interest with the Company and the Company's stockholders.

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

Our common stock was previously listed for trading on the OTC Market’s OTCQB service under the symbol “ARTL.” Our stock has 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 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.

Our public warrants are speculative in nature.

Our public warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to purchase shares of our common stock for a limited period of time. Specifically, commencing on the date of issuance, holders of public warrants may exercise their rights to acquire shares of our common stock until the fifth (5th) anniversary of the issuance date after which dates any unexercised warrants will expire and have no further value. There can be no assurance that the fair market value of our common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

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

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

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Holders of our public warrants will have no rights as common stockholders until such holders exercise the public warrants and acquire our common stock.

Until holders of public warrants acquire shares of our common stock upon exercise of the warrants, holders of the public warrants will have no rights with respect to the shares of our common stock. Upon exercise of the public warrants, the holders thereof will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

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

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.

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

Additionally, as we are now listed on the Nasdaq Capital Market, we expect the rules and regulations applicable to Nasdaq-listed companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements 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, 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.

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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.

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

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

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

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

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 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.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

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

ITEM 2. PROPERTIES

Our principal executive office is currently located at 888 Prospect Street, Suite 210, La Jolla, CA, 92037, U.S. Additionally, we have an office located at 29 Fitzwilliam Street Upper, Dublin 2 Ireland which serves as administrative space for managing our European subsidiaries: Trinity Reliant Ventures, Ltd (Ireland) and Trinity Research & Development, Ltd. (U.K.). We do not currently own any properties, laboratories, or manufacturing facilities. The leases for our office space are month-to-month.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation relating to claims arising out of our operations in the normal course of business. We are not involved in any pending legal proceeding or litigation and, to the best of our knowledge, no governmental authority is contemplating any proceeding to which we are a party and which would reasonably be likely to have a material adverse effect on our company. To date, our company has never been involved in litigation, as either a party or a witness, nor has our company been involved in any legal proceedings commenced by any regulatory agency against our company.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

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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. Globex Transfer, LLC at 780 Deltona Blvd, Suite 202, Deltona, FL 32725 (Telephone: (813) 344-4490; Facsimile: (386) 267-3124) is the registrar and transfer agent for our common shares.

On November 21, 2019, the shareholders' list showed 180 registered shareholders with 3,426,276 shares of common stock outstanding.

Description of Securities

The Company's authorized capital stock consists of 25,000,000 shares of capital stock, par value \$0.001 per share, of which 18,750,000 shares are common stock, par value \$0.001 per share and 6,250,000 of preferred stock, par value \$0.001 per share. As of November 21, 2019, the Company has 3,426,726 shares of common stock outstanding held by approximately one hundred eighty (180) stockholders of record, and no shares of preferred stock outstanding.

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 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, 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 6,250,000 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.

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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 August 31, 2019 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 July 31, 2019

Issuer Purchases of Equity Securities

We did not purchase any of our shares of common stock or other securities during our fourth quarter of our fiscal year ended August 31, 2019.

ITEM 6. SELECTED FINANCIAL DATA

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

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

Results of Operations

The following summary of our results of operations, for the year ended August 31, 2019 and 2018, should be read in conjunction with our audited financial statements, as included in this Form 10-K.

Our Company does not have any revenue. We classify our operating expenses into research and development, professional fees, and selling, 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.

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

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

Balance Sheet Data

	<u>August 31,</u> <u>2019</u>	<u>August 31,</u> <u>2018</u>	<u>Change</u>
Cash	\$ 4,423,965	\$ 337,424	\$ 4,086,541
Total Assets	\$ 6,482,726	\$ 396,998	\$ 6,085,728
Total Liabilities	\$ 1,021,513	\$ 531,972	\$ 489,541
Stockholders’ Equity (Deficit)	\$ 5,461,213	\$ (134,974)	\$ 5,596,187

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We have not generated any revenues since inception through August 31, 2019. The increase cash was primarily due to equity raising activities.

For the Year ended August 31, 2019 Compared to the Year ended August 31, 2018

	Year ended August 31,		Change
	2019	2018	
Operating Expenses			
General and administrative expense	\$ 952,334	\$ 508,278	\$ 444,056
Professional fees	1,164,695	585,069	579,626
Research and development	1,091,992	1,249,854	(157,862)
Depreciation	510	290	220
Total Operating Expenses	3,209,531	2,343,491	866,040
Loss from Operations	(3,209,531)	(2,343,491)	(866,040)
Interest Expense	31,256	-	31,256
Change in fair value of derivative liabilities	1,006,099	-	1,006,099
Net Loss	\$ (2,172,176)	\$ (2,343,491)	\$ 171,315

Our operating expenses, for the year ended August 31, 2019 were \$3,209,531 compared to \$2,343,491 for the same period in 2018. The higher operating expenses during the year ended August 31, 2019 were primarily related to professional fees for ongoing regulatory requirements, and general and administrative expenses for application fee, stock based compensation and payroll.

Liquidity and Capital Resources

Working Capital

	August 31,	August 31,	Change
	2019	2018	
Current Assets	\$ 4,442,588	\$ 396,435	\$ 4,046,153
Current Liabilities	1,021,513	531,972	489,541
Working Capital	<u>\$ 3,421,075</u>	<u>\$ (135,537)</u>	<u>\$ 3,556,612</u>

Cash Flows

	Year ended August 31,		Change
	2018	2017	
Cash Flows used in operating activities	\$ (2,792,676)	\$ (1,610,020)	\$ (1,182,656)
Cash Flows used in investing activities	(1,500,688)	(845)	(1,499,843)
Cash Flows provided by financing activities	8,377,427	1,388,451	6,988,976
Effects on changes in foreign exchange rate	2,478	(12,937)	15,415
Net change in cash during period	<u>\$ 4,086,541</u>	<u>\$ (235,351)</u>	<u>\$ 4,321,892</u>

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Our total current assets as of August 31, 2019 were \$4,442,588 as compared to total current assets of \$396,435 as of August 31, 2018. The increase in current assets is primarily due to an increase in cash from share issuance and intangible assets.

Our total current liabilities as of August 31, 2019 were \$1,021,513 as compared to total current liabilities of \$531,972 as of August 31, 2018. The increase in current liabilities was primarily due to an increase in accounts payable and accrued liabilities and increase in stock payable.

The report of our auditors on our audited consolidated financial statements for the fiscal year ended August 31, 2019, contains a going concern qualification as we have suffered losses since our inception. We have minimal assets and have achieved no operating revenues since our inception. We have been dependent on sales of equity securities to conduct operations. Unless and until we commence material operations and achieve material revenues, we will remain dependent on financings to continue our operations.

Cash Flow from Operating Activities

During the year ended August 31, 2019, cash used in operating activities was \$2,792,676 compared to cash used in operating activities of \$1,610,020 during the year ended August 31, 2018. The cash used from operating activities was primarily attributed to net loss of \$2,712,176 and change in fair value gain of derivative of \$1,006,099, offset by stock-based compensation of \$425,110, increase in stock payable of \$100,000 decrease in prepaid expenses of \$27,048, and decrease in accounts payable and accrued liabilities of \$180,409 for the year ended August 31, 2019. The cash used from operating activities was primarily attributed to net loss of \$2,343,491, offset by stock-based compensation of \$290,004, and an increase in accounts payable and accrued liabilities of \$500,696 for the year ended August 31, 2018.

Cash Flow from Investing Activities

The Company used \$688 and \$845 to purchase equipment and \$1,500,000 and \$0 as partial payment for a license for the year ended August 31, 2019 and 2018, respectively.

Cash Flow from Financing Activities

During the year ended August 31, 2019 and 2018, the Company received \$8,376,379 and \$1,386,613 from issuance of common stock and \$18,758 and \$19,894 from advance from related parties and repaid \$17,228 and \$18,056 to related parties, respectively.

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

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.

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Recent Accounting Pronouncements

In July 2017, the Financial Accounting Standards Board (“FASB”) issued a two-part Accounting Standards Update (“ASU”) No. 2017-11, I. Accounting for Certain Financial Instruments With Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception (“ASU 2017-11”). ASU 2017-11 amends guidance in FASB ASC 260, Earnings Per Share, FASB ASC 480, Distinguishing Liabilities from Equity, and FASB ASC 815, Derivatives and Hedging. The amendments in Part I of ASU 2017-11 change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments in Part II of ASU 2017-11 re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. ASU 2017-11 is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018 with early adoption permitted. We have early adopted this standard. Certain cash subscription agreements entered into by the Company contain embedded derivative features, which in accordance with the new guidance, do not give rise to an associated derivative liability.

The Company has considered all recent accounting pronouncements issued and determined that the adoption of these pronouncements would not have a material effect on the financial position, results of operations or cash flows of the Company.

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

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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 August 31, 2019 and 2018, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of August 31, 2019 and 2018, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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.

/s/ *MaloneBailey, LLP*

www.malonebailey.com

We have served as the Company's auditor since 2015.

Houston, Texas

November 25, 2019

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ARTELO BIOSCIENCES, INC.
Consolidated Balance Sheets

	<u>August 31,</u> <u>2019</u>	<u>August 31,</u> <u>2018</u>
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 4,423,965	\$ 337,424
Prepaid expenses	8,336	35,384
Deposits	1,500	1,500
Other receivable	8,787	22,127
Total Current Assets	<u>4,442,588</u>	<u>396,435</u>
Equipment, net of accumulated depreciation of \$792 and \$282, respectively	721	563
Intangible asset	<u>2,039,417</u>	<u>-</u>
TOTAL ASSETS	<u>6,482,726</u>	<u>396,998</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 348,863	\$ 529,272
Due to related party	3,732	2,700
Derivative liability	29,501	-
Stock payable	<u>639,417</u>	<u>-</u>
Total Current Liabilities	<u>1,021,513</u>	<u>531,972</u>
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred Stock, par value \$0.001, 6,250,000 shares authorized, 0 and 0 shares issued and outstanding as of August 31, 2019 and 2018, respectively	-	-
Common Stock, par value \$0.001, 18,750,000 shares authorized, 3,353,616 and 1,750,268 shares issued and outstanding as of August 31, 2019 and 2018, respectively	3,354	1,750
Additional paid-in capital	10,278,421	2,514,136
Accumulated deficit	(4,810,756)	(2,638,580)
Accumulated other comprehensive loss	<u>(9,806)</u>	<u>(12,280)</u>
Total Stockholders' Equity (Deficit)	<u>5,461,213</u>	<u>(134,974)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$ 6,482,726</u>	<u>\$ 396,998</u>

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

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ARTELO BIOSCIENCES, INC.
Consolidated Statements of Operations

	Year ended	
	August 31,	
	<u>2019</u>	<u>2018</u>
OPERATING EXPENSES		
General and administrative	\$ 952,334	\$ 508,278
Professional fees	1,164,695	585,069
Research and development	1,091,992	1,249,854
Depreciation	510	290
Total Operating Expenses	<u>3,209,531</u>	<u>2,343,491</u>
Loss from Operations	(3,209,531)	(2,343,491)
OTHER INCOME (EXPENSE)		
Other income	31,256	-
Change in fair value of derivative liabilities	1,006,099	-
Total other income	<u>1,037,355</u>	<u>-</u>
Provision for income taxes	-	-
NET LOSS	<u>(2,172,176)</u>	<u>\$ (2,343,491)</u>
OTHER COMPREHENSIVE LOSS		
Foreign currency translation adjustments	2,474	(12,937)
Total Other Comprehensive Income Loss	<u>2,474</u>	<u>(12,937)</u>
TOTAL COMPREHENSIVE LOSS	<u>\$ (2,169,702)</u>	<u>\$ (2,356,428)</u>
Basic Loss per Common Share	<u>\$ (1.00)</u>	<u>\$ (1.84)</u>
Diluted Loss per Common Share	<u>\$ (1.46)</u>	<u>\$ (1.84)</u>
Basic Weighted Average Common Shares Outstanding	2,172,465	1,277,527
Diluted Weighted Average Common Shares Outstanding	2,172,465	1,277,527

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

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

	Common stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	paid-in capital (deficiency)			
Balance, August 31, 2017	1,415,908	\$ 1,416	\$ 837,853	\$ (295,089)	\$ 657	\$ 544,837
Common shares issued for cash	254,360	254	1,386,359	-	-	1,386,613
Stock option granted for services	-	-	107,169	-	-	107,169
Common shares issued for services - officers	65,000	65	56,770	-	-	56,835
Common shares issued for services	15,000	15	125,985	-	-	126,000
Net loss for the period	-	-	-	(2,343,491)	-	(2,343,491)
Other comprehensive gain	-	-	-	-	(12,937)	(12,937)
Balance, August 31, 2018	<u>1,750,268</u>	<u>1,750</u>	<u>2,514,136</u>	<u>(2,638,580)</u>	<u>(12,280)</u>	<u>(134,974)</u>
Common shares issued for cash	1,565,388	1,566	8,374,813	-	-	8,376,379
Common shares issued for price protection	12,950	13	(13)	-	-	-
Common shares issued for services - officers	-	-	52,000	-	-	52,000
Common shares issued for services - related party	25,000	25	239,975	-	-	240,000
Reclass of warrant derivative liability from equity	-	-	(1,035,600)	-	-	(1,035,600)
Stock option granted for services	-	-	133,110	-	-	133,110
Reverse stock split adjustment	10	-	-	-	-	-
Net loss for the period	-	-	-	(2,172,176)	-	(2,172,176)
Other comprehensive loss	-	-	-	-	2,474	2,474
Balance, August 31, 2019	<u>3,353,616</u>	<u>\$ 3,354</u>	<u>\$ 10,278,421</u>	<u>\$ (4,810,756)</u>	<u>\$ (9,806)</u>	<u>\$ 5,461,213</u>

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

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ARTELO BIOSCIENCES, INC.
Consolidated Statements of Cash Flows

	Year ended	
	August 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (2,172,176)	\$ (2,343,491)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	425,110	290,004
Depreciation	510	282
Change in fair value of derivative	(1,006,099)	-
Stock payable	100,000	-
Changes in operating assets and liabilities:		
Prepaid expenses	27,048	(35,384)
Other receivable	13,340	(22,127)
Accounts payable and accrued liabilities	(180,409)	500,696
Net cash used in operating activities	(2,792,676)	(1,610,020)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of equipment	(688)	(845)
Purchase of license	(1,500,000)	-
Net cash used in investing activities	(1,500,688)	(845)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common shares for cash	8,376,379	1,386,613
Advance from related party	18,276	19,894
Repayment to related party	(17,228)	(18,056)
Net cash provided by financing activities	8,377,427	1,388,451
Effects on changes in foreign exchange rate	2,478	(12,937)
Net decrease in cash and cash equivalents	4,086,541	(235,351)
Cash and cash equivalents - beginning of period	337,424	572,775
Cash and cash equivalents - end of period	<u>\$ 4,423,965</u>	<u>\$ 337,424</u>
Supplemental Cash Flow		
Cash paid for interest	\$ -	\$ -
Cash paid for income taxes	\$ -	\$ -
Non-cash financing and investing activities:		
Reclass of warrant derivative liability from equity	\$ 1,035,600	\$ -
Stock payable for acquisition of license	\$ 539,417	-
Share issuance for price protection	\$ 13	\$ -

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

Consolidated Notes to the Financial Statements
For the years ended August 31, 2019 and 2018

NOTE 1 - ORGANIZATION AND DESCRIPTION OF BUSINESS

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

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

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

The Company intends to license, develop and commercialize novel cannabinoid therapeutic treatments. To date, the Company’s activities have been limited to its formation and the raising of equity capital.

Reverse stock split

The Company filed a Certificate of Change with the Secretary of State of Nevada, pursuant to which, effective on June 20, 2019, the Company effected a one-for-eight reverse split of its authorized and issued and outstanding common stock (the “Reverse Stock Split”). The number of authorized shares of common stock was reduced from 150,000,000 to 18,750,000. The Company’s authorized Preferred Stock was reduced from 50,000,000 to 6,250,000. 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.

Basis of Consolidation

The financial statements have been prepared on a consolidated basis, with the Company’s wholly-owned subsidiaries, Trinity Reliant Ventures Limited, and Trinity Research & Development Limited.

Property, plant and equipment

Property and equipment are stated at cost. Depreciation is computed on the straight-line method. The depreciation and amortization methods are designed to amortize the cost of the assets over their estimated useful lives, in years, of the respective assets as follows:

Furniture and Fixtures	3 Years
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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.

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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. During the year ended August 31, 2019, no impairment losses have been identified.

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, 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 \$4,423,965 and \$337,424 in cash and cash equivalents at August 31, 2019 and 2018, respectively.

Intangible Assets

The Company capitalizes certain costs to acquire 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.

Deferred Offering Costs

Deferred offering costs were capitalized and consisted of fees and expenses incurred directly in connection with the Company's offering that was completed during the year ended August 31, 2019. At the time of the completion of the offering the amounts were transferred to additional paid in capital. Deferred offering costs included legal and accounting costs.

Foreign Currency Transactions

Some of the Company's planned operations are outside of the United States, which results in exposure to market risks from changes in foreign currency rates. The financial risk arise 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.

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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.

Derivative Financial Instruments

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

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 plans to assess the financial strength and credit worthiness 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).

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The Company has recently adopted the guidance included under ASU 2018-07, stock-based compensation issued to non-employees and consultants. Equity-Based Payments to non-employees are measured at grant-date fair value of the equity instruments that the Company is obligated to issue when the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity-classified nonemployee share based payment awards are measured at the grant date

There were \$425,110 and \$290,004 share-based expenses for the year ending August 31, 2019 and 2018, 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. No deferred tax assets or liabilities were recognized as at August 31, 2019 and 2018.

Net Loss per Share of Common Stock

The Company has adopted ASC Topic 260, "Earnings per Share," ("EPS") which requires presentation of basic EPS on the face of the income statement for all entities with complex capital structures and requires a reconciliation of the numerator and denominator of the basic EPS computation. In the accompanying financial statements, basic earnings (loss) per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period.

For the years ended August 31, 2019 and 2018, potentially dilutive instruments are as follows:

	August 31, 2019	August 31, 2018
Warrants	2,334,937	495,306
Options	234,000	50,000
Total	<u>2,568,937</u>	<u>545,306</u>

Related Parties

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

Prepaid Expenses and Deposits

Prepaid expenses and deposits consist of security deposits paid.

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.

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Recent Accounting Pronouncements

In July 2017, the Financial Accounting Standards Board (“FASB”) issued a two-part Accounting Standards Update (“ASU”) No. 2017-11, I. Accounting for Certain Financial Instruments With Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception (“ASU 2017-11”). ASU 2017-11 amends guidance in FASB ASC 260, Earnings Per Share, FASB ASC 480, Distinguishing Liabilities from Equity, and FASB ASC 815, Derivatives and Hedging. The amendments in Part I of ASU 2017-11 change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments in Part II of ASU 2017-11 re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. ASU 2017-11 is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018 with early adoption permitted. We have early adopted this standard. Certain cash subscription agreements entered into by the Company contain embedded derivative features, which in accordance with the new guidance, do not give rise to an associated derivative liability.

The Company has considered all recent accounting pronouncements issued and determined that the adoption of these pronouncements would not have a material effect on the financial position, results of operations or cash flows of the Company.

NOTE 3 - GOING CONCERN

The Company’s financial statements are prepared using accounting principles generally accepted in the United States of America applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has not established any revenue to cover its operating cost, and requires additional capital to continue its operating plan. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. These factors raise substantial doubt about its ability to continue as a going concern.

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

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

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the liquidation of liabilities in the normal course of business. During the year ended August 31, 2019, the Company had a net loss of \$2,172,176. As of August 31, 2019, the Company had an accumulated deficit of \$4,810,756 and has earned no revenues. The Company intends to fund operations through equity financing arrangements, which may be insufficient to fund its capital expenditures, working capital and other cash requirements for future periods.

NOTE 4 - RELATED PARTY TRANSACTIONS

During the year ended August 31, 2019 and 2018, the president of the Company incurred \$1,530 and \$1,340 of expenses on behalf of the Company. The amounts owed to the related party as of August 31, 2019 and 2018 are \$3,732 and \$2,202, respectively. The amounts are non-interest bearing and have no terms of repayment.

During the year ended August 31, 2019 and 2018, the former President, and current Senior Vice President, European Operations, who is a major stockholder of the Company, paid for expenses on behalf of the Company for a total of \$16,746 and \$18,554, respectively. The amount of \$17,228 and \$18,056 was repaid during the year ended August 31, 2019 and 2018, respectively. The amounts owed to the related party as of August 31, 2019 and 2018 are \$0 and \$498, respectively. The amounts are non-interest bearing and have no terms of repayment.

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During the year ended August 31, 2019, Blackrock Ventures, Ltd., an entity owned by the Senior Vice President, European Operations, who is a major stockholder of the Company, provided \$38,000 worth of consulting services to the Company. On March 15, 2019, the Board approved the issuance of 25,000 shares of our common stock valued at \$240,000 in exchange for its prior services to the Company.

On November 18, 2016, the former President of the Company transferred all of the 750,000 shares that he held to the Company's current Senior Vice President, European Operations.

The Company has an employment contract with a key employee, Mr. Gregory Gorgas, who is an officer of the Company. As of August 31, 2019, and 2018 no salary is owed. During the year ended August 31, 2019 and 2018, \$209,369 and \$74,840 were paid as salary to Mr. Gorgas, respectively.

The amounts and terms of the above transactions may not necessarily be indicative of the amounts and terms that would have been incurred had comparable transactions been entered into with independent third parties.

Stock based compensation

On January 26, 2018, the Company received \$65,000 from two related parties from shares issuance under subscription agreement. The amounts have been recorded as stock common stock issued and was be settled with shares of the Company subsequent to quarter end. The amounts of \$65,000 with related parties is for the issuance of 99,999 common shares, purchase price of \$0.65 and 12,500 warrants with an exercise price of \$12 per share, and five years expiry date. (See note 5).

During the year ended August 31, 2019 and 2018, the company recorded \$52,000 and \$56,835 of stock compensation expense for all five members of the Company's Board of Directors, respectively. The stock based compensation related to restricted stock awards issued in 2017.

NOTE 5 - EQUITY

Preferred shares

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

During the year ended August 31, 2019 and 2018, there were no issuance of preferred stock.

Common Shares

The Company has authorized 18,750,000 common stock with a par value of \$0.001 per share. Each common stock entitles the holder to one vote, in person or proxy, on any matter on which action of the stockholders of the corporation is sought.

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During the year ended August 31, 2019, the Company issued 1,603,348 shares of common stock as follows,

- The Company received cash of \$1,257,905 for 209,635 units at a price of \$6.00 per unit (a “Series D Unit”) pursuant to the Company’s Series D offering. Each Series D Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series D Common Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$14.00 per share, for a period of 5 years from the issue date.
- The Company received cash of \$417,732 for 54,940 units at a price of \$7.60 per unit (a “Series E Unit”) pursuant to the Company’s Series E Offering. Each Series E Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series E Common Stock Purchase Warrant to purchase one-half (1/2) share of common stock at a price of \$16.00 per share for a period of 3 years from the issue date.
- On March 15, 2019, the Board approved the issuance of 25,000 shares of our common stock valued at \$240,000 to Blackrock Ventures, Ltd., a Company owned by a former director, in exchange for its prior services to the Company.
- On June 25, 2019, the Company sold an aggregate of 1,300,813 units with each unit consisting of one (1) share of the Company’s common stock, par value \$0.001 per share and a warrant to purchase one (1) share of common stock at an exercise price equal to \$6.4575 per share. The offering price to the public was \$6.15 per unit. In addition, the Company granted the Underwriters a 45-day option to purchase up to 195,121 additional shares of common stock, or warrants, or any combination thereof, to cover over-allotments, if any. Simultaneously with the closing of the offering the Company sold 191,102 warrants at \$0.01 per warrant for cash proceeds of \$1,911 upon the partial exercise of the underwriters’ over-allotment option. The Company received gross proceeds of approximately \$8,001,911, before deducting underwriting discounts and commissions of eight percent (8%) of the gross proceeds and estimated offering expenses.
- The Company issued 12,950 shares and 6,490 warrants for price protection provision related to the Series E units. The company recorded the issuance at par value of \$0.001, adjusting to additional paid in capital of \$13.
- 10 shares were issued in related to a reconciliation of the reverse stock split.

During the year ended August 31, 2018, the Company issued 334,360 shares of common stock as follows,

- On January 2, 2018, the Company issued 15,000 shares of its common stock valued at \$126,000 to NEOMED for services.
- The Company received \$10,000 that has been recorded as stock issued in relation to a subscription agreement on June 30, 2017, for the issuance of 3,125 shares of common stock.
- The Company received cash of \$850,785 that has been recorded for the issuance of 163,606 shares of common stock at a price of \$5.20 per Unit pursuant to a private placement offering conducted by the Company in relation to subscription agreements accepted on January 26, 2018 and March 15, 2018. Each Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series B Common Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$12.00 per share for a period of 5 years from the issue date.
- The Company received cash of \$525,828 that has been recorded for the issuance of 87,629 shares of common stock at a price of \$6.00 per Unit pursuant to a private placement offering conducted by the Company in relation to subscription agreements accepted up to August 31, 2018. Each Unit consists of: (i) one (1) share of common stock; and (ii) one (1) Series C Common Stock Purchase Warrant to purchase one (1) share of common stock at a price of \$14.00 per share for a period of 5 years from the issue date.

Per the terms of the subscription agreement, following the closing date until the earlier of (i) the date that the registration is declared effective by the SEC, or (ii) the date the shares become freely tradable, if the Company issues any common stock or common stock equivalent entitling the holder to acquire common stock at a price below \$3.20, the Company will be required to issue the subscribers that number of additional units equal to the difference between the units issued at closing, and the number units the Company would have issued to the subscriber had the offering been completed at this discounted price. In accordance with ASU 2017-11, these cash subscription agreements entered into by the Company contain embedded derivative features, which in accordance with the new guidance, do not give rise to an associated derivative liability.

- The Company has issued 65,000 Restricted Shares Award (the “RSAs”) to five of the Company’s Directors, vesting annually over a four-year period, in each case subject to the director’s continued service to the Company. Refer to Note 4 for further discussion related to the RSAs.

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Stock Payable

During the year ended August 31, 2019, the Company recorded stock payable of 72,660 shares of common stock to NEOMED as follows:

- 61,297 shares, valued at \$539,417, for the exercise of an option for an exclusive worldwide license to develop and commercialize products comprising or containing the compound NEO1940. The worldwide license has been capitalized as an intangible asset
- 11,363 shares for settlement of accrued liability of \$100,000

Warrants

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

For each unit purchased in the Company's Series A offering, Series B offering, Series C offering and Series D offering, each investor will receive one Series A, Series B, Series C and Series D Common Stock Purchase Warrant, respectively, to purchase one share of the Company's common stock for a period of five years from the date of the subscription agreement at a price per share from \$8.00 to \$14.00, depending on the subscription round. For each unit purchased in the Company's Series E offering, each investor will receive one Series E Common Stock Purchase Warrant to purchase one-half (1/2) share of the Company's common stock for a period of three years from the date of the subscription agreement at a price per share of \$16.00.

Under the terms of the subscription agreements for the Company's private placement offerings, following the closing date of such private offering until the earlier of (i) the date that the registration statement of the shares issued in such offering is declared effective by the SEC, or (ii) the date the shares otherwise become freely tradable, if the Company issues any common stock or common stock equivalent entitling the new investor to acquire common stock at a price below the purchase price for that particular prior subscription agreement, the Company will be required to issue the prior investor additional units, each consisting of one share of common stock and a warrant to purchase one share of common stock, equal to the difference between the units actually issued at such closing to the new investor, and the number of units we would have issued to the prior investor had the offering been completed at this new, lower price per share. Management reviewed the terms of the agreements and determined that in accordance with ASC 815, these cash subscription agreements entered into by the Company contain derivative features. As of August 31, 2019, a derivative liability of \$29,501 has been recorded.

During the year ended August 31, 2018, the Company issued warrants with the purchase of the Series A and Series B units. For each share purchased, the investor received one Series A or Series B or Series C Common Stock Purchase Warrant to purchase one share of the Company's common stock for a period of five years from the date of the share subscription with ranges of prices from \$8.00 per share to \$14.00 per share. A total of 254,389 warrants were issued during the year ended August 31, 2018.

On June 25, 2019, the Company sold an aggregate of 1,300,813 units with each unit consisting of one (1) share of the Company's common stock, par value \$0.001 per share and a warrant to purchase one (1) share of common stock at an exercise price equal to \$6.4575 per share.

In relation to the offering described above, the Company also agreed to issue to the underwriters warrants to purchase total of 104,065 shares of Common Stock (8% of the shares of Common Stock sold in the offering). The underwriter's warrants are exercisable at \$6.765 per share of common stock and have a term of three years. The warrants were issued for services provided by the underwriters.

A summary of activity of the warrants during the year ended August 31, 2019 and 2018 follows:

	Number of shares	Weighted Average Exercise Price	Weighted Average Life (years)
Outstanding, August 31, 2017	240,917	\$ 8.00	4.83
Granted	254,389	12.64	5.00
Forfeited	-	-	-
Exercised	-	-	-
Outstanding, August 31, 2018	495,306	\$ 10.40	4.23
Granted	1,839,575	7.46	3.23
Forfeited	-	-	-
Exercised	-	-	-
Outstanding, August 31, 2019	2,334,881	\$ 8.15	4.14

The intrinsic value of the warrants as of August 31, 2019 is \$0. All of the outstanding warrants are exercisable as of August 31, 2019.

The intrinsic value of the warrants as of August 31, 2018 was \$585,691.

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2018 Equity Incentive Plan

On August 17, 2018, the Board of Directors of the Company approved the Equity Incentive Plan (the “2018 Plan”). The 2018 Plan permits the Company to issue up to 375,000 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 nonstatutory 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 August 17, 2018, the Company granted options to directors and consultants to purchase an aggregate of 50,000 shares of our common stock at a price of \$10.8 per share with a various vesting schedule. The options expire August 17, 2028, unless such director and consultants ceases his or her service as a director or consultant prior the exercise or expiration of the option.

On July 18, 2019, the Company granted options to a consultant to purchase 2,500 shares of our common stock at a price of \$3.12 per share. The options are immediately vested and expire July 18, 2029.

On August 29, 2019, the Company granted options to officers and directors to purchase an aggregate of 181,500 shares of our common stock at a price of \$1.99 per share with a various vesting schedule. The options expire August 29, 2029.

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

	Year Ended August 31, 2019	Year Ended August 31, 2018
Expected term	5 years	10 years
Expected average volatility	158%	170%
Expected dividend yield	-	-
Risk-free interest rate	1.40 %	2.87%

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Name	Number of Shares	Exercise Price	Vesting Commencement Date	Expiration Date	Vesting Schedule
Saoirse O’Sullivan	12,500	\$10.8	August 17, 2018	August 17, 2028	(1)
R. Martin Emanuele, Ph.D.	12,500	\$10.8	August 17, 2018	August 17, 2028	(1)
Andy Yates, Ph.D.	12,500	\$10.8	August 17, 2018	August 17, 2028	(1)
Steven D. Reich, M.D.	12,500	\$10.8	April 1, 2018	August 17, 2028	(2)
Rob Prince	2,500	\$3.12	July 18, 2019	July 18, 2029	100% vested
Gregory D. Gorgas	75,000	\$1.99	August 29, 2019	August 29, 2029	(3)
Connie Matsui	26,500	\$1.99	August 29, 2019	August 29, 2029	(4)
Douglas Blayney, MD	18,000	\$1.99	August 29, 2019	August 29, 2029	(4)
Georgia Erbez	22,250	\$1.99	August 29, 2019	August 29, 2029	(4)
R. Martin Emanuele, PhD	17,500	\$1.99	August 29, 2019	August 29, 2029	(4)
Steven Kelly	22,250	\$1.99	August 29, 2019	August 29, 2029	(4)
Total option grants:	234,000				

- (1) Twenty-five percent (25%) of the Shares subject to the Option shall vest on 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.
- (2) The number of Shares that will vest upon the first day following the end of such Vesting Period (a “Vesting Date”) will equal (i) the lesser of (a) the number of hours that the Company’s Chief Executive Officer certifies Participant provided the Services during such Vesting Period or (b) 60, multiplied by (ii) a number of Shares equal to 350 divided by the exercise price per Share of the option. “Vesting Period” means each three-month period during the term of the consulting agreement, beginning on the Vesting Commencement Date.
- (3) The shares subject to this option award will vest, subject to Mr. Gorgas’ continued service through the applicable vesting date, ratably over 48 months starting on August 29, 2019, such that the option will be fully vested on August 29, 2023.
- (4) One Hundred percent (100%) of the Shares subject to the Option shall vest on the earlier to occur of
 - (i) the date six (6) months from the Vesting Commencement Date or
 - (ii) the date immediately preceding the 2020 annual meeting of stockholders, subject to Participant continuing to be a Service Provider through each such date.

During the year ended August 31, 2019, \$133,110 was expensed, and as of August 31, 2019, \$637,865 remains unamortized. During the year ended August 31, 2018, \$107,169 was expensed, and as of August 31, 2018, \$429,519 remained unamortized.

The following is a summary of stock option activity during the year ended August 31, 2019 and 2018:

	Options Outstanding		Weighted Average
	Number of Options	Weighted Average Exercise Price	Remaining life (years)
Outstanding, August 31, 2017	-	\$ -	\$ -
Granted	50,000	10.80	10.0
Exercised	-	-	-

Forfeited/canceled	-		-		-
Outstanding, August 31, 2018	50,000	\$	10.80	\$	9.97
Granted	184,000		2.01		10.0
Exercised	-		-		-
Forfeited/canceled	-		-		-
Outstanding, August 31, 2019	234,000	\$	3.88	\$	9.78

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The following table summarizes information relating to exercisable stock options as of August 31, 2019:

	Options Outstanding		Options Exercisable	
Number of Options	Weighted Average Remaining	Weighted Average	Number of	Weighted Average

	Contractual life (in years)	Exercise Price	Shares	Exercise Price
50,000	8.97	\$ 10.80	21,700	\$ 10.80
2,500	9.89	\$ 3.12	2,500	\$ 3.12
181,500	10.00	\$ 1.99	-	\$ -

The intrinsic value of the 234,000 options as of August 31, 2019 is \$0. The intrinsic value of the 50,000 options outstanding as of August 31, 2018 was \$0.

NOTE 6 - PROVISION FOR INCOME TAXES

The Company has not made provision for income taxes for the year end August 31, 2019 and 2018, 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 asset as at August 31, 2019. The Company has incurred a net operating loss of \$5,041,541, the net operating losses carry forward will begin to expire in varying amounts from year 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. The Company's federal tax returns remain subject to examination by the IRS.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Act"), was signed into law. The Tax Act includes numerous changes to tax laws impacting business, the most significant being a permanent reduction in the federal corporate income tax rate from 34% to 21%. The rate reduction took effect on January 1, 2018. As the Company's 2018 fiscal year ended on August 31, 2018, the Company's federal blended corporate tax rate for fiscal year 2018 is 25.3%, based on the applicable tax rates before and after the Tax Act and the number of days in the fiscal year to which the two different rates applied.

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

	August 31, 2019	August 31, 2018
NOL Carryover	\$ (1,058,724)	\$ (578,959)
Valuation allowance	1,058,724	578,959
Net deferred tax asset	\$ -	\$ -

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NOTE 7 – INTANGIBLE ASSET

During the year ended August 31, 2019, the Company made a \$1,500,000 payment and recorded stock payable of 61,297 shares of common stock, valued at \$539,417 for the exercise of an option for an exclusive worldwide license to develop and commercialize products comprising or containing the compound NEO1940. The Company has capitalized the costs associated with acquiring the worldwide license as an intangible asset at a value of \$2,039,417 as of August 31, 2019.

NOTE 8 – COMMITMENTS AND CONTINGENCIES

The Company has certain financial commitments in relation to Research and Development contracts. As of August 31, 2019:

- The Company is invoiced monthly and quarterly in relation to several Research and Development contracts.
- The Company may be obligated to make additional payments related to Research and Development contracts entered into, dependent on the progress and milestones achieved through the programs.
- Our principal executive office is currently located at 888 Prospect Street, Suite 210, La Jolla, CA, 92037, U.S. Additionally, we have an office located at 29 Fitzwilliam Street Upper, Dublin 2 Ireland which serves as administrative space for managing our European subsidiaries: Trinity Reliant Ventures, Ltd (Ireland) and Trinity Research & Development, Ltd. (U.K.). We do not currently own any properties, laboratories, or manufacturing facilities. The leases for our office space are month-to-month.

NOTE 9 – DERIVATIVE LIABILITY AND FAIR VALUE MEASUREMENTS

The Company recognized a derivative liability related to the purchase price protection clause associated with the Series D and Series E private offerings (Note 5). Additional units would be issued to the unit holder if the Company should issue common stock or the equivalent at a share price less than \$6.00 per share (Series D) or a share price less than \$7.60 (Series E). In accordance with ASC 815-10- *Derivatives and Hedging* we measured the derivative liability using a Monte Carlo pricing model. Accordingly, at the end of each quarterly reporting date, the derivative fair market value is re-measured and adjusted to current market value.

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

Fair value – August 31, 2018	\$	-
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Reclass of warrant derivative liability from equity	1,035,600
Change in fair value for the period of warrant derivative liability	(1,006,099)
Fair value – August 31, 2019	29,501

As of August 31, 2019, there is no derivative liability associated with Series D shares as they are freely tradable.

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

	<u>Year Ended</u> <u>August 31,</u> <u>2019</u>	<u>Year Ended</u> <u>August 31,</u> <u>2018</u>
<u>Assumptions for Pricing Model:</u>		
Expected term in years	0.46	-
Volatility	127%	-
Risk-free interest rate	1.42%-2.10 %	-
Expected annual dividends	0%	-

NOTE 10 – SUBSEQUENT EVENTS

Management has evaluated subsequent events through the date these financial statements were issued. Based on our evaluation no events have occurred that require recognition or disclosure, other than those disclosed below.

Subsequent to August 31, 2019, the Company issued of 72,660 shares of common stock to NEOMED to settle \$639,417 of stock payable. A total of 61,297 shares of common stock were issued for the exercise of an option for an exclusive worldwide license to develop and commercialize products comprising or containing the compound NEO1940. A total of 11,363 shares of common stock were issued to settle \$100,000 of accrued liabilities with NEOMED.

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

There were no disagreements related to accounting principles or practices, financial statement disclosure, internal controls or auditing scope or procedure during the two fiscal years and interim periods.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our senior management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the 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 Officer and Chief Financial Officer concluded as of the Evaluation Date that our disclosure controls and procedures were not effective such that the information relating to us required to be disclosed in our Securities and Exchange Commission (“SEC”) reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

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 August 31, 2019 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 not maintain effective internal control over financial reporting as of August 31, 2019 based on the COSO framework criteria, as more fully described below. This was due to deficiencies that existed in the design or operation of our internal controls over financial reporting that adversely affected our internal controls and that may be considered to be material weaknesses.

The matters involving internal controls and procedures that our management considered to be material weaknesses under the standards of the Public Company Accounting Oversight Board were: (1) inadequate segregation of duties consistent with control objectives; and (2) management dominated by a single individual without adequate compensating controls. The aforementioned material weaknesses were identified by our Chief Executive Officer in connection with the review of our financial statements as of August 31, 2019. Management believes that the material weaknesses set forth above did not have an effect on our financial results.

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 have been no changes in our internal control over financial reporting that occurred during the period ended August 31, 2019 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Except as provided above, there is no information to be disclosed in a report on Form 8-K during the fourth quarter of the year covered by this Form 10-K that has not been previously filed with the Securities and Exchange Commission.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by Item 10 of Part III may be included in our proxy statement relating to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference. If we do not file a proxy statement with respect to a 2020 Annual Meeting prior to December 29, 2019, we will amend this Annual Report on Form 10-K to include the information required by this item.

ITEM 11. EXECUTIVE COMPENSATION

Information required by Item 11 of Part III may be included in our proxy statement relating to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference. If we do not file a proxy statement with respect to a 2020 Annual Meeting prior to December 29, 2019, we will amend this Annual Report on Form 10-K to include the information required by this item.

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

Information required by Item 12 of Part III may be included in our proxy statement relating to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference. If we do not file a proxy statement with respect to a 2020 Annual Meeting prior to December 29, 2019, we will amend this Annual Report on Form 10-K to include the information required by this item.

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

Information required by Item 13 of Part III may be included in our proxy statement relating to our 2020 Annual Meeting of Stockholders and is

incorporated herein by reference. If we do not file a proxy statement with respect to a 2020 Annual Meeting prior to December 29, 2019, we will amend this Annual Report on Form 10-K to include the information required by this item.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by Item 14 of Part III may be included in our proxy statement relating to our 2020 Annual Meeting of Stockholders and is incorporated herein by reference. If we do not file a proxy statement with respect to a 2020 Annual Meeting prior to December 29, 2019, we will amend this Annual Report on Form 10-K to include the information required by this item.

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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 and Amendments	S-1	333-199213	10/8/2014	
3.2	Certificate of Amendment filed with the Nevada Secretary of State on February 2, 2017 with an effective date of February 10, 2017.	8-K	333-199213	2/9/2017	
3.3	Certificate of Change.	8-K	333-199213	4/17/2017	
3.4	Bylaws	S-1	333-199213	10/8/2014	
3.5	Certificate of Amendment to Articles of Incorporation filed with the Nevada Secretary of State on June 19, 2019.	S-1/A	333-230658	06/20/2019	
3.6	Certificate of Change	8-K	001-38951	06/25/2019	
4.1	Form of the Underwriter's Warrant	S1/A	333-230658	06/20/2019	
10.1	Senior Promissory Note dated November 18, 2016	8-K	333-199213	11/18/2016	
10.2	Consultancy Agreement by and between the Company and Dr. Saoirse O'Sullivan, PhD dated March 22, 2017.	8-K	333-199213	4/7/2017	
10.3#	Amended and Restated Employment Agreement by and between the Company and Gregory D. Gorgas dated August 30, 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	Note Repayment Agreement by and between Artelo Biosciences, Inc. and Malibu Investments Limited	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#	Indemnification Agreement dated as of July 31, 2017	8-K	333-199213	8/4/2017	
10.8	Stock Purchase Agreement dated as of August 1, 2017	8-K	333-199213	8/4/2017	
10.9	Material and Data Transfer, Option and License Agreement dated as of December 20, 2017 by and between the Company and NEOMED Institute+	10-Q	33-199213	1/16/2018	
10.10+	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	
10.11#	2018 Equity Incentive Plan	S-1	333-227571	9/27/2018	
10.12+	License Agreement with Stony Brook University, by and between the Company and Stony Brook University, dated January 18, 2018	S-1/A	333-222756	4/17/2018	
10.13	Form of Warrant Agency Agreement	S-1/A	333-230658	06/20/2019	
31.1	Section 302 Certification				*
32.1**	Section 906 Certification				*
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

Management contracts or compensatory plans, contracts or arrangements.

+ Certain portions of this exhibit have been omitted.

** The certification attached as Exhibits 32.1 that accompany this 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.

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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 November 25, 2019

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: November 25, 2019

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

Dated: November 25, 2019

/s/ Connie Matsui
Connie Matsui

Director

Dated: November 25, 2019

/s/ Steven Kelly
Steven Kelly
Director

Dated: November 25, 2019

/s/ Douglas Blayney
Douglas Blayney
Director

Dated: November 25, 2019

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

Dated: November 25, 2019

/s/ Georgia Erbez

Georgia Erbez
Director

CERTIFICATION

I, Gregory D. Gorgas, President of Artelo Biosciences, Inc., certify that:

1. I have reviewed this Form 10-K of Artelo Biosciences, Inc. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure control and procedures to be designed under my supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: November 25, 2019

/s/ Gregory D. Gorgas

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

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

In connection with the Annual Report of Artelo Biosciences, Inc. (the "Company") on Form 10-K for the period ended August 31, 2019 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: November 25, 2019

/s/ Gregory D. Gorgas

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

ARTELO BIOSCIENCES, INC.

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (the “**Agreement**”) is entered into as of August 30, 2019, and is effective as of June 20, 2019 (the “**Effective Date**”) by and between Artelo Biosciences, Inc. (the “**Company**”), and Gregory D. Gorgas (“**Executive**”).

WHEREAS, Executive previously entered into an Employment Agreement with the Company dated April 3, 2017 (the “**Prior Agreement**”).

WHEREAS, the Company and Executive desire to amend and restate the Prior Agreement to provide the terms governing Executive’s employment to align with market practice.

WHEREAS, in consideration of the promises and mutual covenants contained herein, Executive and the Company agree as follows:

AGREEMENT

1. Duties and Scope of Employment.

(a) Positions and Duties. As of the Effective Date, Executive will continue to serve as the Company’s Chief Executive Officer reporting to the Company’s Board of Directors (the “**Board**”). Executive will render such business and professional services in the performance of his duties, consistent with Executive’s position within the Company and with those duties customarily performed by the chief executive officer at comparable companies, as will reasonably be assigned to him by Executive’s supervisor. The period of Executive’s employment under this Agreement is referred to herein as the “**Employment Term**.”

(b) Board Membership. During the Employment Term, Executive will serve as a member of the Board.

(c) Obligations. During the Employment Term, Executive will perform his duties faithfully and to the best of his ability and will devote his full business efforts and time to the Company. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration without the prior approval of the Board, except that Executive may engage in outside professional civic, charitable, and community activities that do not impair his ability to perform his obligations under this Agreement, including but not limited to fundraising for the UCSD Cancer Center and support of the Sickle Cell Disease Foundation of California.

2. At-Will Employment. The parties agree that Executive’s employment with the Company will be “at-will” employment and may be terminated at any time with or without cause or prior warning. Executive understands and agrees that neither his job performance nor promotions, commendations, bonuses or the like from the Company give rise to or in any way serve as the basis for modification, amendment, or extension, by implication or otherwise, of his employment with the Company. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive’s termination of employment with the Company.

3. Compensation.

(a) Base Salary. During the Employment Term, the Company will pay Executive an annual salary of not less than \$396,000 as compensation for his services (the "**Base Salary**"). The Base Salary will be paid periodically in accordance with the Company's normal payroll practices and be subject to the usual, required withholdings. Executive's salary will be subject to review and adjustments will be made based upon the Company's normal performance review practices.

(b) Target Bonus. During each calendar year of the Employment Term, Executive will be eligible to receive an annual bonus of up to 50% of Executive's Base Salary, less applicable withholdings, upon achievement of performance objectives to be determined by the compensation committee (the "**Compensation Committee**") of the Board in its sole discretion (the "**Target Bonus**") provided the Compensation Committee has met and conferred with Executive in good faith at or before the start of each calendar year and considered his input as the performance objectives for that year. The Target Bonus, or any portion thereof, will be paid as soon as practicable after the Compensation Committee determines that the Target Bonus has been earned, but in no event shall the Target Bonus be paid after the later of (i) the fifteenth (15th) day of the third (3rd) month following the close of the Company's fiscal year in which the Target Bonus is earned or (ii) March 15 following the calendar year in which the Target Bonus is earned. For the avoidance of doubt, Executive shall be eligible for a Target Bonus of \$198,000 for calendar year 2019.

(c) Stock Option. At the first meeting of the Compensation Committee following the Effective Date, it will be recommended that Executive be granted a stock option, which will be, to the extent possible under the \$100,000 rule of Section 422(d) of the Code, an "incentive stock option" (as defined in Section 422 of the Code), to purchase 75,000 shares at an exercise price equal to the fair market value on the date of grant (the "**Option**"). Subject to the accelerated vesting provisions set forth herein, the Option will vest as follows: 1/48th of the shares subject to the Option shall vest monthly on the same day of the month as the date of grant (and if there is no corresponding day, the last day of the month), so that the Option will be fully vested and exercisable four (4) years from the date of grant, subject to Executive continuing to provide services to the Company through the relevant vesting dates. The Option will be subject to the terms, definitions and provisions of the Company's 2018 Equity Incentive Plan (the "**Plan**") and the stock option agreement by and between Executive and the Company, both of which documents are incorporated herein by reference.

(d) Life Insurance. During the Employment Term, the Company shall pay the full premiums for a life insurance policy covering Executive for coverage of up to One Million dollars. Executive will be entitled to select personal beneficiaries for 100% of the proceeds of the life insurance policy. Executive may choose to pay any additional premiums to increase the coverage of this life insurance policy.

4. Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company, subject to the eligibility requirements of such plans. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time.

5. Paid-Time Off. During the Employment Term, Executive shall accrue and be entitled to take paid vacation in accordance with the Company's standard vacation and paid sick leave policies in effect from time to time, including the Company's policies regarding vacation accruals. Executive shall also be entitled to all other holiday and leave pay generally available to all other employees of the Company.

6. Business Expense Reimbursement. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furtherance of or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

7. Severance.

(a) Termination for other than Cause, Death or Disability Outside Change in Control Period If, outside the Change in Control Period (as defined below), the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause, death or Disability, then, subject to Section 1 of Appendix A, Executive will be entitled to receive:

(i) the Accrued Benefits (as defined below);

(ii) continuing payments of Executive's base salary, as then in effect, less applicable withholdings and in accordance with the Company's normal payroll procedures, for a period of twelve (12) months from the date Executive's employment with the Company terminates with the first payment to be made within 10 days following the effective date of the Release (and include any payments that otherwise would have been paid to Executive between Executive's termination date and the effective date of the Release under the Company's normal payroll cycle), with any remaining payments paid in accordance with the Company's normal payroll practices for the remainder of the twelve-month period following Executive's termination of employment (subject to any delay as may be required for compliance with Section 409A in accordance with Appendix A) (for the avoidance of doubt, in no case will Executive receive cash severance payments for greater than twelve (12) months following Executive's termination date, subject to compliance with Section 409A);

(iii) reimbursement for the cost of continuation of health coverage for Executive and Executive's eligible dependents pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") until the earlier of (i) twelve (12) months following Executive's termination of employment or (ii) the date Executive and Executive's eligible dependents are no longer eligible for COBRA; provided, however, if, at the time of Executive's termination of employment, the Company determines that providing the COBRA reimbursement in this paragraph would result in a violation of law or an excise tax to the Company, then the Company instead will pay a lump sum payment equal to twelve (12) months of Executive's estimated COBRA premiums, less applicable withholdings, within 10 days following the effective date of the Release (subject to any delay as may be required for compliance with Section 409A);

(iv) a lump-sum payment equal to a pro-rated portion of Executive's Target Bonus in the calendar year that Executive's employment is terminated based on the number of days worked in the year of Executive's termination up through Executive's termination date to be paid within 10 days following the effective date of the Release (subject to any delay as may be required for compliance with Section 409A); and

(v) accelerated vesting as of Executive's employment termination date in an amount equal to 100% of the then-unvested shares subject to Executive's then outstanding time-based equity awards (including the Option), provided that, with respect to any equity awards with performance-based vesting, such equity awards shall vest in accordance with the terms of the applicable award agreements if the applicable performance goals are satisfied at the time of termination or such performance goals are expected to be satisfied. The determination whether such performance goals are satisfied or are expected to be satisfied shall be in the sole discretion of the Compensation Committee or the Board, as the case may be. All equity awards with performance-based vesting that do not vest at termination by their terms or pursuant to this Section 7(v) shall be forfeited.

(b) Termination other than for Cause, death or Disability, or Resignation for Good Reason within the Change in Control Period If, within the period beginning within three (3) months prior to a Change in Control ending twelve (12) months following a Change in Control (the "**Change in Control Period**"), the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause, death or Disability or Executive terminates his employment for Good Reason, then, subject to Section 1 of Appendix A, Executive will be entitled to receive:

(i) the Accrued Benefits;

(ii) a lump-sum payment equal to twelve (12) months of Executive's base salary, as then in effect, to be paid within 10 days following the effective date of the Release (subject to any delay as may be required for compliance with Section 409A);

(iii) reimbursement for the cost of continuation of health coverage for Executive and Executive's eligible dependents pursuant to the COBRA until the earlier of (i) twelve (12) months following Executive's termination of employment or (ii) the date Executive and Executive's eligible dependents are no longer eligible for COBRA; provided, however, if, at the time of Executive's termination of employment, the Company (or its successor) determines that providing the COBRA reimbursement in this paragraph would result in a violation of law or an excise tax to the Company (or its successor), then the Company (or its successor) instead will pay a lump sum payment equal to twelve (12) months of Executive's estimated COBRA premiums, less applicable withholdings, within 10 days following the effective date of the Release (subject to any delay as may be required for compliance with Section 409A);

(iv) a lump-sum payment equal to a pro-rated portion of Executive's Target Bonus in the calendar year that Executive's employment is terminated based on the number of days worked in the year of Executive's termination up through Executive's termination date to be paid within 10 days following the effective date of the Release (subject to any delay as may be required for compliance with Section 409A); and

(v) accelerated vesting as of Executive's employment termination date in an amount equal to 100% of the then-unvested shares subject to Executive's then outstanding time-based and performance-based equity awards (including the Option).

(c) Termination for Cause, Death or Disability; Voluntary Resignation under Certain Circumstances. If Executive's employment with the Company is terminated voluntarily by Executive without Good Reason or for Good Reason outside the Change in Control Period, by the Company for Cause or due to Executive's death or Disability, then Executive shall be entitled to receive salary and accrued but unused vacation time through the effective date of termination plus any Bonus earned, but not yet paid, as of Executive's date of termination ("**Accrued Benefits**"). Moreover, on Executive's termination date: (i) all vesting will terminate immediately with respect to Executive's then outstanding equity awards; (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except Executive's Accrued Benefits); and (iii) Executive will only be eligible for severance benefits in accordance with the Company's established policies, if any, as then in effect.

(d) Exclusive Remedy. In the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company), the provisions of this Section 7 are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive or the Company may otherwise be entitled, whether at law, tort or contract, in equity, or under this Agreement. Executive will be entitled to no severance or other benefits upon termination of employment with respect to acceleration of award vesting or severance pay other than those benefits expressly set forth in this Section 7.

8. Confidential Information. Executive agrees to enter into the Company's standard At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement (the "**Confidential Information Agreement**") upon the Effective Date.

9. Non-Solicitation of Employees. In light of the amount of sensitive and confidential information involved in the discharge of Executive's duties, and the harm to the Company that would result if such knowledge or expertise were disclosed or made available to a competitor, and as a reasonable step to help protect the confidentiality of such information, Executive agrees that during the Employment Term and for a period of one (1) year thereafter, Executive will not directly or indirectly, individually or as a consultant to, or as an employee, officer, stockholder, director, or other owner of or participant in any business, solicit (or assist in soliciting) any person who is then, or at any time within six (6) months prior thereto was, an employee of the Company, who earned annually \$25,000 or more as an employee of the Company during the last six (6) months of his or her own employment to work for (as an employee, consultant or otherwise) any business, individual, partnership, firm, corporation, or other entity whether or not engaged in competitive business with the Company.

10. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive's death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "**successor**" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. The failure of the Company to secure a commitment from any successor to assume the obligations of this Agreement shall be considered a termination of Executive by the Company without Cause. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive's right to compensation or other benefits will be null and void.

11. Notices. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally, (ii) one (1) day after being sent by a well established commercial overnight service, or (iii) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

Artelo Biosciences, Inc.
888 Prospect Street, Suite 210
La Jolla, California 92037
Attn: Corporate Secretary

If to Executive:

at the last residential address known by the
Company.

12. Severability. In the event that any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision.

13. Arbitration. Executive agrees that any and all controversies, claims, or disputes with anyone (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from Executive's service to the Company, shall be subject to arbitration in accordance with the provisions of the Confidential Information Agreement.

14. Integration. This Agreement, together with the Confidential Information Agreement, represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral. With respect to stock options granted on or after the date of this Agreement, the acceleration of vesting provisions provided herein will apply to such stock options except to the extent otherwise explicitly provided in the applicable stock option agreement. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

15. Waiver of Breach. The waiver of a breach of any term or provision of this Agreement, which must be in writing, will not operate as or be construed to be a waiver of any other previous or subsequent breach of this Agreement.

16. Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

17. Tax Withholding. All payments made pursuant to this Agreement will be subject to withholding of applicable taxes.

18. Governing Law. This Agreement will be governed by the laws of the State of California (with the exception of its conflict of laws provisions).

19. Acknowledgment. Executive acknowledges that he has had the opportunity to discuss this matter with and obtain advice from his private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

20. Counterparts. This Agreement may be executed in counterparts, and may be signed electronically, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by their duly authorized officers, as of the day and year first above written.

COMPANY:

ARTELO BIOSCIENCES, INC.

By: /s/ Connie Matsui

Date: August 30, 2019

Name Connie Matsui

Title Chairperson of the Board of Directors

EXECUTIVE:

/s/ Gregory D. Gorgas
Gregory D. Gorgas

Date: August 30, 2019

ADDITIONAL TERMS TO EXECUTIVE EMPLOYMENT AGREEMENT

Unless otherwise defined below, capitalized terms used herein will have the meanings set forth in the Agreement.

1. Conditions to Receipt of Severance: No Duty to Mitigate

(a) Separation Agreement and Release of Claims. The receipt of any vesting acceleration, severance payments and benefits pursuant to Section 7(a) or (b) of the Agreement will be subject to Executive (1) signing and not revoking a customary separation agreement and release of claims related to Executive's service with the Company (which may include an agreement not to disparage the Company, non-solicit provisions and other standard terms and conditions) in a form reasonably satisfactory to the Company (the "**Release**") and provided that such Release becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the "**Release Deadline**"); and (2) resigning from the Board effective no later than the employment termination date, to the extent Executive is a member of the board. If the Release does not become effective and irrevocable by the Release Deadline or if Executive does not resign from the Board as specified above, Executive will forfeit any rights to severance or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Release becomes effective and irrevocable.

(b) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no Deferred Payments will be paid or otherwise provided until Executive has a "separation from service" (within the meaning of Section 409A) from the relevant position or positions. Similarly, no severance payable to Executive, if any, pursuant to this Agreement that otherwise would be exempt from Section 409A solely pursuant to Treasury Regulation Section 1.409A-1(b)(9) will be payable until Executive has a "separation from service" (within the meaning of Section 409A).

(ii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of Executive's termination of employment (other than due to death), then the Deferred Payments that are payable within the first six (6) months following Executive's separation from service, will, to the extent required to be delayed pursuant to Section 409A(a)(2)(B) of the Code, become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following Executive's separation from service, but prior to the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. In no event will the Company reimburse Executive for any taxes that may be imposed on Executive as a result of Section 409A. Each payment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b) (2) of the Treasury Regulations.

(iii) Any amount paid under this Agreement that satisfies the requirements of the “short-term deferral” rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of this Agreement.

(iv) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes of this Agreement.

(v) The provisions of this Agreement and the payments and benefits hereunder are intended to be exempt from or comply with the requirements of Section 409A so that none of the severance or other payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to be so exempt or so comply. The Company and Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A.

(c) Confidential Information Agreement. Executive’s receipt of any payments or benefits under Section 7 will be subject to Executive continuing to comply with the terms of Confidential Information Agreement (as defined in Section 8).

(d) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

2. Definitions.

(a) Cause. For purposes of this Agreement, “Cause” is defined as: (i) an act of dishonesty made by Executive in connection with Executive’s responsibilities as an employee that has caused the Company to suffer material harm; (ii) Executive’s conviction of, or plea of nolo contendere to, a felony or any crime involving fraud, embezzlement or any other act of moral turpitude; (iii) Executive’s gross misconduct that has caused the Company to suffer material harm; (iv) Executive’s unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom Executive owes an obligation of nondisclosure as a result of Executive’s relationship with the Company; (v) Executive’s willful breach of any obligations under any written agreement or covenant with the Company; (vi) Executive’s continued failure to perform Executive’s employment duties after Executive has received a written demand of performance from the Company which specifically sets forth the factual basis for the Company’s belief that Executive has not substantially performed Executive’s duties; provided, that Cause shall only exist after; (vii) the Board delivers written notice to Executive of the Board’s determination that Cause exists; (viii) such notice sets forth in reasonable detail such facts and circumstances; and (ix) Executive has failed to fully correct any of the events listed in clauses (iii), (v) and (vi) above, if such events are reasonably capable of being fully corrected, within 30 days after delivery to Executive of the Board’s written notice of its determination that Cause exists.

(b) Change in Control. For purposes of this Agreement, “**Change in Control**” has the meaning set forth in the Plan.

(c) Code. For purposes of this Agreement, “**Code**” means the Internal Revenue Code of 1986, as amended.

(d) Deferred Payment. For the purposes of this Agreement, “**Deferred Payment**” means any severance pay or benefits to be paid or provided to Executive (or Executive’s estate or beneficiaries) pursuant to this Agreement and any other severance payments or separation benefits to be paid or provided to Executive (or Executive’s estate or beneficiaries), that in each case, when considered together, are considered deferred compensation under Section 409A.

(e) Disability. For purposes of this Agreement, “**Disability**” means Executive’s (i) is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, or (ii) is, by reason of any medically determinable physical or mental impairment which can be expected to last for a continuous period of not less than 12 months, receiving income replacement benefits for a period of not less than 3 months under an accident and health plan covering Company employees.

(f) Good Reason. For purposes of this Agreement, “**Good Reason**” means Executive’s resignation within 30 days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Executive’s express written consent: (i) a material reduction of Executive’s duties, position or responsibilities, or the removal of Executive from such position and responsibilities, either of which results in a material diminution of Executive’s authority, duties or responsibilities, unless Executive is provided with a comparable position (i.e., a position of equal or greater organizational level, duties, authority, compensation and status); provided, however, that a reduction in duties, position or responsibilities solely by virtue of the Company being acquired and made part of a larger entity (as, for example, when the Chief Executive Officer of the Company remains as such following a Change in Control but is not made the Chief Executive Officer of the acquiring corporation) will not constitute “Good Reason”; (ii) a material reduction in Executive’s base salary (except where there is a reduction applicable to the management team generally); (iii) the failure of the Company to timely pay or provide to Executive any portion of Executive’s compensation or benefits then due to Executive; or (iv) a material change in the geographic location of Executive’s primary work facility or location; provided, that a relocation of less than 50 miles from Executive’s then present location will not be considered a material change in geographic location. Executive may not resign for Good Reason without first providing the Company with written notice of the acts or omissions constituting the grounds for “Good Reason” within 90 days of the initial existence of the grounds for “Good Reason” and a reasonable cure period of not less than 30 days following the date the Company receives such notice during which such condition must not have been cured.

(g) Section 409A. For purposes of this Agreement, “**Section 409A**” means Section 409A of the Code and the final regulations and any guidance thereunder and any applicable state law equivalent, as each may be amended or promulgated from time to time.

(h) Section 409A Limit. For purposes of this Agreement, “**Section 409A Limit**” will mean two (2) times the lesser of: (i) Executive’s annualized compensation based upon the annual rate of pay paid to Executive during Executive’s taxable year preceding Executive’s taxable year of his or her separation from service as determined under Treasury Regulation Section 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Code for the year in which Executive’s separation from service occurred.

3. Limitation on Payments. In the event that the severance and other payments and benefits provided for in this Agreement or otherwise payable to Executive (collectively, the “**Payments**”) (i) constitute “parachute payments” within the meaning of Section 280G of the Code and (ii) but for this Section 3 of Appendix A, would be subject to the excise tax imposed by Section 4999 of the Code, then such Payments will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such Payments being subject to the excise tax under Code Section 4999,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Code Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of Payments, notwithstanding that all or some portion of such Payments may be taxable under Code Section 4999. If a reduction in the Payments constituting “parachute payments” is necessary so that no portion of such Payments is subject to the excise tax under Code Section 4999, the reduction will occur in the following order: (1) reduction of the cash severance payments, which will occur in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced; (2) cancellation of accelerated vesting of equity awards which will occur in the reverse order of the date of grant for such stock awards (i.e., the vesting of the most recently granted stock awards will be reduced first); and (3) reduction of continued employee benefits, which will occur in reverse chronological order such that the benefit owed on the latest date following the occurrence of the event triggering such excise tax will be the first benefit to be reduced. If two or more equity awards are granted on the same date, each award will be reduced on a pro-rata basis. Notwithstanding the foregoing, to the extent the Company submits any Payment to the Company’s shareholders for approval in accordance with Treasury Reg. Section 1.280G-1 Q&A 7, the foregoing provisions will not apply following such submission and such payments and benefits will be treated in accordance with the results of such vote, except that any reduction in, or waiver of, such payments or benefits required by such vote will be applied without any application of discretion by Executive and in the order prescribed by this section. In no event will Executive have any discretion with respect to the ordering of payment reductions.

A nationally recognized certified professional services firm selected by the Company, the Company's legal counsel or such other person or entity to which the parties mutually agree (the "**Firm**") will perform the foregoing calculations related to the excise tax. The Company will bear all expenses with respect to the determinations by the Firm required to be made hereunder. For purposes of making the calculations required by this Section, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Code Sections 280G and 4999. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section. The Firm engaged to make the determinations hereunder will provide its calculations, together with detailed supporting documentation, to the Company and Executive within 15 calendar days after the date on which Executive's right to the severance benefits or other payments is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the Firm made hereunder will be final, binding, and conclusive upon the Company and Executive.