

May 12, 2022



# Artelo Biosciences Reports First Quarter 2022 Financial Results and Provides Business Update

**\$23.5 Million in Cash and Investments as of March 31, 2022, Expected to Support Completion of the CARES Trial and Operations Into Second Half of 2023**

## **Results of Phase 1b CARES Trial Anticipated in Q3 2022**

SOLANA BEACH, Calif., May 12, 2022 (GLOBE NEWSWIRE) -- [Artelo Biosciences, Inc. \(Nasdaq: ARTL\)](#), a clinical stage pharmaceutical company developing therapeutics that modulate lipid-signaling pathways, including the endocannabinoid system, today reported financial and operating results for the three months ending March 31, 2022.

"We remain highly encouraged by the clinical data to date and we have yet to reach a maximum tolerated dose in our Phase 1b portion of the Cancer Appetite Recovery Study (CAREs) evaluating ART27.13 for the treatment of cancer-related anorexia," stated Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. Mr. Gorgas continued, "We are also excited by new pre-clinical evidence of ART27.13 protecting from muscle wasting (cachexia), which is often associated with anorexia in cancer patients. Cachexia has multiple causes and affects more than 60% of late-stage cancer patients."

"With cash on hand expected to support operations into the second half of 2023, we expect to reach meaningful clinical and developmental milestones, namely, the complete data readout from our CAREs study, as well as the progress of pre-clinical research supporting the initiation of human trials for both ART26.12 and ART12.11," concluded Mr. Gorgas.

## Other Business Highlights

- Research conducted at Trinity College Dublin, Ireland with ART27.13 showed positive pre-clinical evidence that the Company's dual CB<sub>1</sub> and CB<sub>2</sub> cannabinoid agonist can protect human muscle cells from cancer-induced muscle degeneration via a CB<sub>2</sub>-mediated mechanism of action and may offer advantages over single mechanism approaches in the treatment of Cancer Anorexia Cachexia syndrome.
- New collaboration with Richard K. Porter, Ph.D., of the School of Biochemistry & Immunology at Trinity College Dublin, to investigate the molecular basis of fatty acid binding protein inhibition in cancer and the potential of the ART26.12 platform for the treatment of various tumors.
- Notice of Allowance received from the U.S. Patent and Trademark Office for patent

application 16/835,383 entitled “Solid Forms of Cannabidiol and Uses Thereof” related to the Company’s [ART12.11](#) program, a proprietary cocrystal composition of cannabidiol (CBD).

## **Financial Results Ended March 31, 2022**

Operating expenses for the three months ended March 31, 2022, were \$1.9 million compared to \$1.7 million for the same period in 2021. The increase in operating expenses for the three months ended March 31, 2022, was primarily related to increases in payroll and in subcontractor expenditures relating to the Company’s ART27.13 clinical trial.

Net loss was approximately \$2.0 million, or \$0.05 per basic and diluted share, for the three months ended March 31, 2022, compared to a net loss of 1.7 million, or \$0.09 per basic and diluted share, for the three months ended March 31, 2021.

As of March 31, 2022, the Company had approximately \$23.5 million in cash and investments, compared to \$25.6 million as of December 31, 2021.

## **About ART27.13**

ART27.13 is a highly potent, peripherally restricted synthetic, dual GPCR agonist believed to target the cannabinoid receptors CB<sub>1</sub> and CB<sub>2</sub>, which has the potential to increase appetite and food intake. Originally developed by AstraZeneca plc, ART27.13 has been in five Phase 1 clinical studies including over 200 subjects where it demonstrated a statistically significant and dose-dependent increase in body weight in healthy subjects. Importantly, the changes in body weight were not associated with fluid retention and the distribution of the drug enables systemic metabolic effects while minimizing central nervous system-mediated toxicity. Artelo is advancing ART27.13 as a supportive care therapy for cancer patients suffering from anorexia and weight loss, where the current annual global market is estimated to be valued in excess of \$2 billion.

## **About CAREs**

The Cancer Appetite Recovery Study (CAREs) is a Phase 1b/2a randomized, placebo-controlled trial of the Company’s lead clinical program, ART27.13, in patients with cancer anorexia and weight loss. Anorexia, or the lack or loss of appetite in cancer patients, may result from the cancer and/or its treatment with radiation or chemotherapy. It is common for patients with cancer to lose weight. Anorexia and the resulting weight loss can affect a patient’s health, often weakening their immune system and causing discomfort and dehydration. A weight loss of more than 5% can predict a poor outcome for cancer patients and a lower response to chemotherapy. The Phase 1b portion of the CAREs study is designed to determine the most effective and safest dose of ART27.13 for dosage in the Phase 2a stage. The Phase 2a portion of the CAREs study is designed to determine point estimates of activity of ART27.13 in terms of lean body mass, weight gain, and improvement of anorexia. The study is planned to enroll up to 24 patients in the Phase 1b and 25 participants in the Phase 2a. (ISRCTN registry: <https://www.isrctn.com/ISRCTN15607817>)

## **About Artelo Biosciences**

Artelo Biosciences, Inc. is a clinical stage pharmaceutical company dedicated to the development and commercialization of proprietary therapeutics that modulate lipid-signaling pathways, including the endocannabinoid system. Artelo is advancing a portfolio of broadly

applicable product candidates designed to address significant unmet needs in multiple diseases and conditions, including anorexia, cancer, PTSD, pain, and inflammation. Led by proven pharmaceutical executives collaborating with highly respected researchers and technology experts, Artelo applies leading edge scientific, regulatory, and commercial discipline to develop high-impact therapies. More information is available at [www.artelobio.com](http://www.artelobio.com) and Twitter: [@ArteloBio](https://twitter.com/ArteloBio).

## **Forward Looking Statements**

*This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to Artelo's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in Artelo's filings with the Securities and Exchange Commission, including our ability to raise additional capital in the future. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. Artelo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by applicable securities laws.*

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