

March 21, 2022



# Artelo Biosciences Reports Four-Month 2021 Financial Results in Connection with its Amended Fiscal Year End and Provides Business Update

## Reports \$25.6 Million in Cash and Marketable Securities as of December 31, 2021, Expected to Support Operations Into Second Half of 2023

SOLANA BEACH, Calif., March 21, 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 four month transitional period from September 1, 2021 to December 31, 2021 and provided a business update. The reporting of this four-month period and the concurrent filing of its Form 10-KT reflects the Company's previously disclosed change in its fiscal year end from August 31 to December 31.

"We achieved a number of important milestones in 2021 and look forward to multiple data readouts in 2022," stated Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. "We currently expect to report initial Phase 1 data from our Cancer Appetite Recovery (CAREs) study evaluating ART27.13 as a potential treatment for cancer-related anorexia in the first half of 2022 and to report randomized Phase 2 data in the second half of 2022. Importantly, the United Kingdom's Home Office recently classified ART27.13, as a "non-controlled" substance. This new ruling not only streamlines the addition of clinical sites in the U.K. and accelerates patient enrollment, it also enhances the overall commercial potential of ART27.13."

"At the same time," Mr. Gorgas added, "we continue to advance both our ART26.12 cancer program and ART12.11, our patented cocrystal of cannabidiol (CBD). 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 preclinical research supporting the initiation of human trials for both ART26.12 and ART12.11."

### December 31, 2021 Year End Financial Results:

Operating expenses for the four months ended December 31, 2021, were \$4.0 million compared to \$2.1 million for the same period in 2020. The increase in operating expenses for the four months ended December 31, 2021, was primarily related to increases in payroll and stock-based compensation and an increase in subcontractor expenditures relating to the Company's ART27.13 clinical trials.

Net loss was approximately \$4.0 million, or \$0.12 per basic and diluted share, for the four months ended December 31, 2021, compared to a net loss of \$2.1 million, or \$0.18 per basic and diluted share, for the four months ended December 31, 2020.

As of December 31, 2021, the Company had approximately \$25.6 million in cash and investments, compared to \$10.1 million as of December 31, 2020.

### **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>/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 1/2 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 1 portion of the CAREs study is designed to determine the most effective and safest dose of ART27.13 for dosage in the Phase 2 stage. The Phase 2 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 1 and 25 participants in the Phase 2. (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 developing 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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