

January 12, 2022



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

*Complete Enrollment of Phase 1 CARES Trial Anticipated by End of First Quarter of Calendar Year 2022*

*\$26.4 Million in Cash and Marketable Securities as of November 30, 2021*

SOLANA BEACH, Calif., Jan. 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 first quarter of its fiscal year ended November 30, 2021 and provided a business update.

Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences, said, "We continue our Cancer Appetite Recovery Study (CAREs), evaluating ART27.13 as a potential treatment for cancer-related anorexia. The results of Phase 1 will determine the safe and effective dose recommended for the Phase 2 portion of CAREs. We expect to complete patient enrollment in Phase 1 by the end of first quarter of calendar year 2022 and will announce results immediately after all data is verified."

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 holds the exclusive license to develop ART27.13 on a worldwide basis.

"With \$26.4 million in cash and marketable securities as of November 30, 2021," Mr. Gorgas added, "We believe we have the capital to achieve significant clinical and non-clinical milestones into the second half of 2023. We maintain our disciplined focus on significant value drivers as we move into the new year and look forward to providing meaningful updates as they occur."

## **First Quarter Fiscal 2022 Financial Results:**

- Operating expenses for the three months ended November 30, 2021 were \$2.55 million compared to \$1.44 million for the same period in 2020. The increase in operating expenses for the three months ended November 30, 2021 were primarily related to increases in stock-based compensation expense and an increase in subcontractor expenditures relating to the Company's ART27.13 clinical trials.

- Net loss was approximately \$2.55 million, \$0.08 per basic and diluted share, for the three months ended November 30, 2021 compared to a net loss of \$1.44 million, \$0.14 per basic and diluted share, for the same period in 2020.
- As of November 30, 2021, the Company had approximately \$26.4 million in cash and marketable securities, compared to \$10.07 million as of August 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>/CB<sub>2</sub>, which has the potential to increase appetite and food intake. Over 200 healthy subjects participated in five Phase 1 studies with ART27.13, and the product candidate is now being investigated in cancer patients over a longer 12 week duration. 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 that will be used 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 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.*

**Investor Relations Contact:**

Crescendo Communications, LLC

Tel: 212-671-1020

Email: [ARTL@crescendo-ir.com](mailto:ARTL@crescendo-ir.com)



Source: Artelo Biosciences