

March 31, 2023



# Artelo Biosciences Reports Fiscal 2022 Year-End Financial Results and Provides Business Update

**\$17.5 Million in Cash and Marketable Securities as of December 31, 2022; Expected to Support Operations Into Second Half of 2024**

SOLANA BEACH, Calif., March 31, 2023 (GLOBE NEWSWIRE) -- [Artelo Biosciences, Inc. \(Nasdaq:ARTL\)](#), a clinical-stage pharmaceutical company focused on modulating lipid-signaling pathways to develop treatments for people living with cancer, pain, and neurological conditions, today reported financial and operating results for the fiscal year ended December 31, 2022 and provided a business update.

"We achieved meaningful clinical progress throughout 2022," stated Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. "Importantly, we completed enrollment of the first three cohorts in our Cancer Appetite Recovery Study (CAREs), evaluating ART27.13 for the treatment of cancer-related anorexia and weight loss. Given ART27.13's better-than-expected safety profile and absence of drug-related grade three or four toxicity, we elected to advance to a fourth cohort at a 650-microgram dose. Since enrollment of the fourth cohort is now complete, we are awaiting the final patient's results to be fully evaluable before initiation of the Phase 2a stage of CAREs, which is anticipated in April 2023."

"We are well funded into the second half of 2024 and intend to aggressively advance our product pipeline to develop new treatment options for people suffering from cancer and other debilitating diseases."

## **Additional 2022 Business Highlights:**

- Selected for an oral presentation at the 32<sup>nd</sup> International Cannabinoid Research Society (ICRS) Symposium. Artelo's Vice President of Translational Sciences, Saoirse O'Sullivan, presented pre-clinical data related to ART26.12, the Company's lead fatty acid binding protein 5 (FABP5) inhibitor. The pre-clinical research showed that chronic, oral treatment with ART26.12 was effective at both preventing and treating both oxaliplatin and paclitaxel-induced pain sensitivity without any sedating effects. Additionally, ART26.12 minimized the acute weight loss caused by oxaliplatin, supporting further development in neuropathy associated with chemotherapy and other neuropathies.
- Published pre-clinical results with one of the Company's novel FABP5 inhibitors which selectively reduced activity in an area of the brain associated with anxiety indicating

that modulation of the FABP5 system may serve as a promising target for the development of novel anxiolytics. This research was led by Taygun C. Uzuneser, Ph.D., and Steven R. Laviolette, Ph.D., both of the University of Western Ontario, London, Ontario, and was published in the journal [Cerebral Cortex](#).

- Reported positive pre-clinical results of ART27.13 showing protection of human muscle cells from cancer-induced muscle degeneration (cachexia) via a CB<sub>2</sub> mediated mechanism of action.
- Entered into a second collaboration with Richard K. Porter, Ph.D., of the School of Biochemistry & Immunology at Trinity College Dublin, Ireland to investigate the molecular basis of FABP inhibition in cancer and the potential of the ART26.12 platform for the treatment of various tumors.
- Announced United Kingdom's Home Office had classified the Company's lead clinical cannabinoid, ART27.13, as "non-controlled" and, therefore, is no longer considered a Schedule 1 controlled substance. This is expected to streamline onboarding of additional clinical sites in the U.K. for expansion of the Phase 2a stage of CARES, accelerate acceptance by patients, and enhance the commercial potential of ART27.13.
- Received Notice of Allowance for Method-of-Use Patent in the United States for ART12.11, a proprietary cocrystal of cannabidiol (CBD).

### **Fiscal 2022 Year-End Financial Results:**

- Operating expenses for the year ended December 31, 2022 were \$10.3 million compared to \$4.0 million for the four months ended December 31, 2021, and \$7.4 million for the year ended August 31, 2021. The increase in operating expenses for the year ended December 31, 2022 were primarily related to the increase in general and administrative fees and research and development expenses.
- Net loss was approximately \$10.1 million, or \$3.56 per basic and diluted share for the year ended December 31, 2022 compared to a net loss of \$4.0 million, or \$1.81 per basic and diluted share for the four months ended December 31, 2021, and \$7.4 million or \$5.97 per basic and diluted share for the year ended August 31, 2021.
- As of December 31, 2022, the Company had approximately \$17.5 million in cash and marketable securities, compared to \$25.6 million as of December 31, 2021 and \$10.0 million as of August 31, 2021.

### **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, anxiety, pain, neuropathy, and inflammation. Led by proven biopharmaceutical executives collaborating with highly

respected researchers and technology experts, the company 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).

### **About ART27.13**

ART27.13 is a highly potent, peripherally restricted synthetic, dual G-Protein Couple Receptor 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 dosing in the Phase 2a stage. The Phase 2a portion of the CAREs study is designed to determine estimates of activity of ART27.13 in terms of lean body mass, weight gain, and improvement of anorexia. (ISRCTN registry: <https://www.isrctn.com/ISRCTN15607817>)

### **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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