

November 29, 2021



# Artelo Biosciences Reports Fiscal 2021 Year-End Financial Results and Provides Business Update

## **\$26.8 Million in Cash and Marketable Securities as of November 15, 2021, Expected to Support Operations Well Into 2023**

SOLANA BEACH, Calif., Nov. 29, 2021 (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 fiscal year ended August 31, 2021 and provided a business update.

"We achieved significant progress throughout the past year, both clinically and operationally," stated Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. "Importantly, we initiated and continue to enroll patients into our Cancer Appetite Recovery (CAREs) Study, evaluating ART27.13 as a potential treatment for cancer-related anorexia. We expect to report Phase 1 data from our CAREs study first quarter of 2022 with randomized Phase 2 data anticipated in the second half of next year."

"In addition, we strengthened our balance sheet with additional capital raised through our at-the-market equity offering, resulting in more than \$26.8 million in cash and marketable securities on a pro-forma basis as of November 15, 2021," added Mr. Gorgas. "With funding well into 2023, we expect to reach meaningful clinical and developmental milestones, including complete data readout from our CAREs study as well as initiation of preclinical research to enable the start of human trials for both our ART26.12 cancer program and ART12.11, our proprietary cocrystal of cannabidiol."

### **Additional 2021 Corporate Highlights Include:**

- [Filed](#) patent application for new solid formulation of ART27.13 with the UK Patent Office
- Entered [research collaboration](#) with Trinity College Dublin to investigate ART27.13 for the treatment of cancer cachexia
- [Presented](#) two posters featuring ART27.13 and ART12.11 at the 31<sup>st</sup> Annual International Cannabinoid Research Society Symposium
- Announced [publication](#) of [study results](#) comparing the pharmacological effects of plant-derived versus synthetic cannabidiol in human cell lines
- Filed new patent application covering new generation three inhibitors of Fatty Acid Binding Protein 5 chemistries

- [Awarded](#) a Mitacs Accelerate Canadian government grant with University of Western Ontario; grant expected to fund 50% of research costs evaluating ART26.12 as a potential treatment for anxiety disorders
- Announced [positive pre-clinical data](#) associated with Artelo's proprietary CBD cocrystal, ART12.11, showing potential pharmacodynamic interactions of co-administration of cannabidiol (CBD) and tetramethylpyrazine (TMP) in cell-based models of cancer

### **Fiscal 2021 Year End Financial Results:**

- Operating expenses for the year ended August 31, 2021 were \$7,441,155 compared to \$4,685,775 for the same period in 2020. The increase in operating expenses for the year ended August 31, 2021 were primarily related to the increase in general and administrative fees and research and development expenses.
- Net loss was approximately \$7,436,760, or \$0.40 per basic and diluted share for the year ended August 31, 2021 compared to a net loss of \$4,654,862, or \$1.26 per basic and diluted share for the year ended August 31, 2020.
- As of August 31, 2021, the Company had approximately \$10,065,408 in cash and marketable securities, compared to \$2,142,072 as of August 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 predicted 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 target 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)



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