

November 8, 2022



Artelo Biosciences Reports Third Quarter 2022 Financial Results and Provides Business Update

Enrollment of Phase 2a CAReS Study Expected to Commence Near Year-End

\$19.5 Million in Cash and Investments as of September 30, 2022

SOLANA BEACH, Calif., Nov. 08, 2022 (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 three months ended September 30, 2022 and provided a business update.

“Based on ART27.13’s favorable safety profile to date, the Phase 1b Cancer Appetite Recovery Study (CAReS) evaluating ART27.13 for the treatment of cancer-related anorexia and weight loss was expanded to include a fourth, higher dose cohort earlier this year. This final cohort is nearly fully enrolled. Once clinical results are evaluated, we expect to commence enrollment of our Phase 2a clinical trial near year-end,” stated Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences.

“With over \$19.5 million in cash and investments as of September 30, 2022, we expect to fund operations through the first half of 2024 and, thus, support the achievement of key clinical and preclinical milestones,” added Mr. Gorgas.

Other Business Highlights

Promising Non-clinical Data for Multiple Potential Uses from Artelo’s Fatty Acid Binding Protein 5 (FABP5) Platform

At the International Cannabinoid Research Society’s annual meeting in Galway, Ireland, June 26-30, 2022, Artelo shared data from multiple non-clinical animal research studies with ART26.12, its lead FABP5 inhibitor, indicating that chronic, oral administration was effective at preventing and treating both oxalplatin- and paclitaxel-induced pain sensitivity without any sedating effects. These findings support further development of ART26.12 in neuropathies, including neuropathy associated with chemotherapy, which represents a significant unmet need for which there are no approved treatments in the US, UK, or Europe. With regulatory enabling research well underway, Artelo anticipates filing an Investigational New Drug application with the FDA late next year.

In addition to the research with ART26.12, Artelo reported positive non-clinical results from one of its other novel FABP5 inhibitors, which suggests that the inhibition of FABP5 can be a

promising neurobiological approach for the development of anxiety-inhibiting pharmacotherapies. Data from this research are expected to be shared at the Society for Neuroscience annual meeting in San Diego November 12-16, 2022 by Steven Laviolette, PhD whose research was conducted at the University of Western Ontario, Canada.

Financial Results Ended September 30, 2022

Operating expenses for the three months ended September 30, 2022, were \$2.4 million compared to \$2.2 million for the same period in 2021. The increase in operating expenses for the three months ended September 30, 2022, was primarily related to increases in payroll and in subcontractor expenditures relating to the CAREs trial.

Net loss was approximately \$2.3 million, or \$0.82 per basic and diluted common share, for the three months ended September 30, 2022, compared to a net loss of \$2.2 million, or \$1.37 per basic and diluted common share, for the three months ended September 30, 2021.

As of September 30, 2022, the Company had approximately \$19.5 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 G-Protein Coupled Receptor agonist believed to target the cannabinoid receptors CB₁ and CB₂, 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>)

About ART26.12

Fatty Acid Binding Proteins (FABPs) are a family of intracellular proteins that chaperone lipids including endocannabinoids and fatty acids. Various inhibitors of FABPs may be particularly useful for the treatment of specific cancers, neuropathic and nociceptive pain,

and anxiety disorders. ART26.12, Artelo's lead FABP inhibitor compound, is a selective inhibitor of FABP5. While developing our lead molecule for Chemotherapy-Induced Peripheral Neuropathy, additional compounds from our extensive library of potent and selective inhibitors of FABPs. have been identified for advancement towards regulatory-enabling studies in anxiety, cancer and other areas of high-unmet need where inhibition of FABPs show significant promise.

About Artelo Biosciences

Artelo Biosciences, Inc. is a clinical-stage pharmaceutical company focused on modulating lipid-signaling pathways to develop treatments for people living with cancer, pain, and neurological conditions. 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 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 the Company'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 the Company'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. The Company 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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