

May 13, 2024



Artelo Biosciences Reports First Quarter 2024 Financial Results and Provides Business Update

SOLANA BEACH, Calif., May 13, 2024 (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, dermatologic and neurological conditions, today reported financial and operating results for the three months ended March 31, 2024 and provided a business update.

“Our entire clinical and preclinical development portfolio is progressing as planned,” commented Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. “Significantly, our Investigational New Drug (IND) application to the U.S. Food and Drug Administration for ART26.12, our lead Fatty Acid Binding Protein 5 (FABP5) inhibitor for the treatment of neuropathic pain, is in the final stages of preparation.”

ART26.12 has shown great promise during preclinical studies in treating and preventing oxaliplatin-induced peripheral neuropathy as recently highlighted in the [Journal of Pain](#), a peer-reviewed journal. In addition, Artelo was one of three finalists in the Johnson & Johnson Innovation Challenge and presented positive preclinical psoriasis research on ART26.12 to the Johnson & Johnson dermatology leadership team. To initiate and support Phase 1 studies once ART26.12’s IND is approved, Artelo has selected a premier contract research organization (CRO), Worldwide Clinical Trials, with extensive experience in the neurology space.

“We are pleased with the progress made during the first quarter of 2024 and with over \$7.6 million of cash and cash equivalents and believe we are well positioned to achieve ART26.12’s IND submission by the middle of this year and to commence Phase 1 research soon thereafter. We also plan to fully enroll the Phase 2a portion of our Cancer Appetite Recovery Study (CAREs) placebo-controlled Phase 2a trial, evaluating ART27.13 for the treatment of cancer-related anorexia and weight loss by year-end and look forward to further announcing important preclinical data with ART12.11 over the next few months,” concluded Mr. Gorgas.

Financial Results Ended March 31, 2024

- **Cash and Investments:** Cash and investments totaled \$7.6 million as of March 31, 2024.
- **R&D Expenses:** Research and development expenses were \$1.5 million for the three months ended March 31, 2024, compared to \$1.2 million for the same period in 2023.
- **G&A Expenses:** General and administrative expenses were \$1.1 million for the three

months ended March 31, 2024, compared to \$1.1 million for the same period in 2023.

- **Net Loss:** For the three months ended March 31, 2024, net loss was \$2.5 million, or \$0.78 per basic and diluted common share, which included \$0.1 million of non-cash expenses, compared to a net loss of \$2.2 million, or \$0.76 per basic and diluted common share for the three months ended March 31, 2023, which included \$0.2 million of non-cash expenses.

About ART27.13

ART27.13 is a G-Protein Coupled Receptor (GPCR) agonist, a highly potent, peripherally restricted new chemical entity, targeting CB1 and CB2 receptors, with the potential to improve body weight, appetite, muscle degeneration, and quality of life in cancer patients. Originally developed by AstraZeneca plc, ART27.13 has been in clinical studies with over 250 subjects. A statistically significant and dose-dependent increase in body weight was observed in patients with back pain who were otherwise healthy. Importantly, the drug enables systemic metabolic effects while minimizing central nervous system-mediated toxicity. Having completed a phase 1 study in cancer patients where ART27.13 demonstrated an excellent safety profile, Artelo is now advancing it in the CAREs trial as a supportive care therapy for cancer patients suffering from anorexia and weight loss. Currently, there is no FDA approved treatment for cancer anorexia cachexia syndrome.

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. Cancer-related anorexia, or the lack or loss of appetite in the person with cancer, may result from the cancer and/or its treatment with radiation or chemotherapy. It is common for people 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. Now completed, the Phase 1b portion of the CAREs study was designed to determine the most effective and safest dose of ART27.13 for dosing in the Phase 2a stage. Currently enrolling, 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. FABP is overexpressed and associated with abnormal lipid signaling in a number of pathologies. ART26.12, Artelo's lead FABP inhibitor, is a potent and selective inhibitor of FABP5 being developed as a novel, peripherally acting, non-opioid, non-steroidal analgesic, with an initial clinical study planned for chemotherapy-induced peripheral neuropathy (CIPN). Beyond ART26.12, Artelo's extensive library of small molecule inhibitors of FABPs have shown therapeutic promise for the treatment of certain cancers, neuropathic and nociceptive pain, and anxiety disorders.

About ART12.11

ART12.11 is Artelo's wholly owned, proprietary cocrystal composition of cannabidiol (CBD) and tetramethylpyrazine (TMP). Isolated as a single crystalline form, ART12.11 has exhibited better pharmacokinetics and improved efficacy compared to other forms of CBD in

nonclinical studies. Superior pharmaceutical properties, including physicochemical, pharmacokinetic, and pharmacodynamic advantages have been observed with ART12.11. Artelo believes a more consistent and improved bioavailability profile may ultimately lead to increased safety and efficacy in humans, thus making ART12.11 a preferred CBD pharmaceutical composition. The US issued composition of matter patent for ART12.11 is enforceable until December 10, 2038.

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, 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 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.

Investor Relations Contact:

Crescendo Communications, LLC

Tel: 212-671-1020

Email: ARTL@crescendo-ir.com



Source: Artelo Biosciences