

November 12, 2024



# Artelo Biosciences Reports Third Quarter 2024 Financial Results and Provides Business Update

SOLANA BEACH, Calif., Nov. 12, 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 its financial and operating results for the three months ended September 30, 2024, and provided a business update.

“With the ongoing, rapid progress of our pipeline, we anticipate multiple clinical readouts over the next 15 months,” stated Gregory D. Gorgas, President and CEO of Artelo Biosciences. “Starting with ART26.12, our promising Fatty Acid Binding Protein 5 (FABP5) inhibitor drug candidate, we received FDA clearance to begin trials in chemotherapy-induced peripheral neuropathy. This debilitating condition, for which there is no approved treatment, affects up to 40% of people experiencing chemotherapy. Phase 1 results are expected in the first half of 2025. Additionally, we presented data at several conferences during the quarter highlighting the promising effects of inhibiting FABP5 across multiple cancer types and cancer bone pain.”

Artelo’s Phase 2 CARES trial is on track for completion of patient enrollment in early 2025 and for announcement of results as soon as all required safety data is collected on ART27.13, which is designed to treat cancer-related anorexia. “We are encouraged by the trial’s progress and safety profile to date, with no serious adverse events reported. This positions ART27.13 as a potential new therapy to improve the quality of life of people struggling with significant and severe loss of appetite and weight associated with their cancer and cancer treatment,” added Mr. Gorgas.

Simultaneously, Artelo’s ART12.11, an innovative and proprietary CBD-TMP cocrystal is expected to initiate clinical trials for anxiety and depression in 2025. This unique cocrystal composition offers a novel approach to mental health treatment.

## Financial Results for Quarter Ended September 30, 2024

- **Cash and Investments:** Cash and investments totaled \$4.9 million as of September 30, 2024.
- **R&D Expenses:** Research and development expenses were \$0.3 million for the three months ended September 30, 2024, compared to \$1.6 million for the same period in 2023.
- **G&A Expenses:** General and administrative expenses were \$0.9 million for the three

months ended September 30, 2024, compared to \$1.0 million for the same period in 2023.

- **Net Loss:** For the three months ended September 30, 2024, net loss was \$1.1 million, or \$0.35 per basic and diluted common share, which included \$0.2 million of net non-cash expenses, compared to a net loss of \$2.4 million, or \$0.83 per basic and diluted common share for the three months ended September 30, 2023, which included \$0.1 million of net non-cash expenses.
- **R&D Tax Credit:** During the three months ended September 30, 2024, the Company received approximately \$1.3 million in cash from the UK government related to qualified prior research and development expenses.

### **About ART27.13**

ART27.13 is a G-Protein Coupled Receptor (GPCR) agonist, a highly potent, peripherally restricted new chemical entity, targeting CB<sub>1</sub> and CB<sub>2</sub> 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**

ART26.12, Artelo's lead Fatty Acid Binding Protein 5 (FABP5) cleared by FDA to initiate first-in-human studies, is a potent and selective inhibitor of FABP5 being developed as a novel, peripherally acting, non-opioid, non-steroidal analgesic, with initial clinical development planned for chemotherapy-induced peripheral neuropathy (CIPN). Fatty Acid Binding Proteins (FABPs) are a family of intracellular proteins that chaperone lipids important to normal cellular function. FABP is overexpressed and associated with abnormal lipid signaling in a number of pathologies. Beyond ART26.12 in CIPN, Artelo's extensive library of small molecule inhibitors of FABPs has shown therapeutic promise for the treatment of

certain cancers, neuropathic and nociceptive pain, psoriasis, 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. 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, dermatologic conditions, 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](http://www.artelobio.com) and Twitter: @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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