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Artelo Biosciences Provides Business Update and Reports Fiscal 2024 Year-End Financial Results

Multiple Clinical Readouts Due in 2025

SOLANA BEACH, Calif., March 03, 2025 (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, or neurological conditions, today provided a business update and announced its financial and operational results for the fiscal year ended December 31, 2024.

Business Highlights:

- **ART26.12**: Phase I study is on track for completion in Q2 2025.
- **ART27.13**: Initial data from the Phase 2 CAReS trial anticipated by the end of Q2 2025.
- **ART12.11**: Substantial progress has been made toward initiation of human studies with an oral solid dosage form in 2H 2025.

“Each of our programs is slated to reach important clinical milestones in 2025,” said Gregory D. Gorgas, President and CEO of Artelo Biosciences. “Notably, enrollment in our Phase 1 study of ART26.12, a Fatty Acid Binding Protein (FABP) inhibitor, has progressed rapidly and is expected to conclude in the second quarter of this year. Designed to harness the power of lipid signaling with broad therapeutic potential, ART26.12 is the first selective FABP5 inhibitor from our proprietary FABP platform to enter human studies. Modulation of lipid-signaling remains Artelo’s key strategy to develop innovative medicines to treat significant unmet needs.”

“In Q2 2025, we also look forward to initial data from our Phase 2 CAReS study of ART27.13 in cancer anorexia. The promising safety and efficacy profile of ART27.13 observed in our Phase 1 study reinforced its potential to address debilitating appetite and weight loss in cancer patients. Additionally, ART12.11, our innovative CBD-TMP cocrystal, is well positioned to begin clinical trials this year. Targeting anxiety and depression, ART12.11 offers a much-needed alternative to drugs with addictive properties or with slow onset of activity. All these developments highlight our progress in advancing transformative therapies with operational efficiency,” Mr. Gorgas concluded.

Fiscal 2024 Year-End Financial Results

- **R&D Expenses:** Research and development expenses were $6.0 million for the year

ended December 31, 2024, compared to $5.7 million for the same period in 2023.
- **G&A Expenses:** General and administrative expenses were $4.1 million for the year ended December 31, 2024, compared to $4.2 million in 2023.
- **Net Loss:** For the year ended December 31, 2024, net loss was $9.8 million, or $3.05 per basic and diluted common share, which included $0.6 million of non-cash expenses, compared to a net loss of $9.3 million, or $3.14 per basic and diluted common share for the year ended December 31, 2023, which included $0.4 million of non-cash expenses.
- **Cash and Investments**: Cash and investments totaled $2.3 million as of December 31, 2024.

About ART26.12
ART26.12, Artelo's lead Fatty Acid Binding Protein 5 (FABP5) inhibitor, is being developed as a novel, peripherally acting, non-opioid, non-steroidal analgesic. Cleared by the FDA for a first-in-human study in the US, a Phase 1 trial with ART26.12 was initiated in late 2024. The initial clinical development planned is 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. In addition to 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 ART27.13
ART27.13 is a novel benzimidazole derivative being developed as a once-daily, orally administered agent selectively targeting peripheral $CB_1$and CB_2 receptors, with the potential to improve body weight, appetite, muscle degeneration, and quality of life in cancer patients. Initially developed by AstraZeneca plc, ART27.13 has been in six clinical studies with over 250 participants. A statistically significant and dose-dependent increase in body weight was observed in people 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 Phase 2 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 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. Greatly enhanced pharmaceutical properties, including physicochemical, pharmacokinetic, and pharmacodynamic advantages have been observed with ART12.11. Artelo believes a more consistent and improved bioavailability profile in a solid dosage form may ultimately lead to increased safety and efficacy in humans, thus making ART12.11 a preferred CBD pharmaceutical composition. The U.S. issued composition of matter patent for ART12.11 is enforceable until December 10, 2038.

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. 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 1 portion of the CAReS study was designed to determine the most effective and safest dose of ART27.13 for dosing in the Phase 2 stage. Currently enrolling, the Phase 2 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 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 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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