August 13, 2024

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

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

“Artelo is entering an unprecedented phase of productivity in clinical development,” commented Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. “Specifically, we look forward to multiple clinical readouts over the next 18 months across our portfolio. Most recently, we received clearance from the U.S. Food and Drug Administration (FDA) to initiate clinical trials for ART26.12 for the treatment of chemotherapy-induced peripheral neuropathy and Phase 1 trial results are expected during the first half of 2025. In addition, we anticipate full enrollment in the Phase 2a portion of the CAReS trial with our lead clinical asset, ART27.13, for the treatment of cancer-related anorexia near the end of 2024 or early 2025. To date, there have been no serious adverse events reported related to the study drug in CAReS. Finally, ART12.11, our proprietary cocrystal of CBD and TMP intended for the treatment of anxiety and depression, is in the final stages of product formulation as an oral solid, creating the potential to enter a clinical study early next year.”

“With over $5.6 million of cash and cash equivalents as of June 30, 2024, and the receipt of approximately $1.3 million in cash from the UK government from R&D tax credits on July 10, 2024, we have the momentum to meaningfully advance our asset portfolio over the coming months,” concluded Mr. Gorgas.

Other Company Highlights:

- Presented data from multiple preclinical studies at the 34th Annual International Cannabinoid Research Society Symposium
  - Efficacy of ART26.12 in Breast Cancer-Induced Bone Pain
  - Results supporting broad potential utility of FABP Inhibitor platform
  - Multiple studies confirming ART12.11’s potential advantages as a product candidate for the treatment of anxiety related disorders
- Presented highly encouraging data towards developing a solid dosage form of ART12.11, including comparative data to the Epidiolex formulation of CBD. Epidiolex

had annual sales in excess of $700 million in 2023

- Announced publication of peer-reviewed article highlighting FABP7 as a promising novel target in cancer therapy

Financial Results for Quarter Ended June 30, 2024

- **Cash and Investments**: Cash and investments totaled $5.6 million as of June 30, 2024.
- **R&D Expenses:** Research and development expenses were $1.7 million for the three months ended June 30, 2024, compared to $0.8 million for the same period in 2023.
- **G&A Expenses:** General and administrative expenses were $0.8 million for the three months ended June 30, 2024, compared to $1.0 million for the same period in 2023.
- **Net Loss:** For the three months ended June 30, 2024, net loss was $2.4 million, or $0.75 per basic and diluted common share, which included $0.1 million of non-cash expenses, compared to a net loss of $1.6 million, or $0.56 per basic and diluted common share for the three months ended June 30, 2023, which included $0.2 million of non-cash expenses.
- **R&D Tax Credit:** Subsequent to the end of the quarter, the Company received approximately $1.3 million in cash on July 10, 2024, 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_1 and CB_2 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 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 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, dermatologic conditions, 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 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.

Investor Relations Contact:
Crescendo Communications, LLC
Tel: 212-671-1020
Email: ARTL@crescendo-ir.com

Source: Artelo Biosciences