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Artelo Biosciences Reports Fiscal 2023 Year-End Financial Results and Provides Business Update

Major achievements in 2023 lay the foundation for key upcoming milestones

SOLANA BEACH, Calif., March 25, 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 fiscal year ended December 31, 2023 and provided a business update.

Key Program Accomplishments in 2023:

- Completed phase 1b and initiated phase 2a of the Cancer Appetite Recovery Study (CAReS) with ART27.13;
- Advanced ART 26.12 toward IND submission in 2024 for the treatment of painful neuropathies following positive pre-IND meeting with the FDA; and
- Presented data demonstrating improved efficacy and bioavailability of ART12.11 compared to cannabidiol in well-established models of anxiety and depression.

“We made substantial progress on multiple programs last year,” commented Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. “Notably, CAReS progressed from the dose-ranging phase 1b to the randomized phase 2a where we will assess the safety and efficacy of ART27.13 in terms of lean body mass, weight gain, activity, and improvement of anorexia versus placebo. Importantly, with ART27.13 now being studied in approximately a dozen clinical sites in five countries, we are on track to fully enroll the phase 2a of CAReS before the end of 2024.”

“Additionally, following the positive pre-IND meeting held with the FDA and five preclinical animal studies in painful neuropathies, we completed the critical toxicology studies and important manufacturing steps with ART26.12 necessary for an IND filing in the first half of this year. The momentum from last year and our cash, projected to support operations into the second half 2025, give us confidence in achieving several important clinical milestones that hold the potential to drive significant value for shareholders,” stated Gorgas.

Additional Recent Business Highlights:

- Presented safety results for ART27.13 from the 1b phase of CAReS at the Cancer Cachexia Society annual conference by leading investigator, Dr. Barry Laird, where it

was noted there were no grade 3 or 4 adverse events related to ART27.13 in the cancer population.
- Published peer-reviewed research in the journal, Pharmaceuticals, demonstrated protective properties of ART27.13 against muscle degeneration caused by cancer. This data suggests the dual mechanism of ART27.13 is relevant for both the anorexia and the cachexia associated with advanced stage cancer.
- Announced pre-clinical research demonstrating ART26.12's positive effects in multiple models of neuropathic pain, as well as effectiveness in treating and preventing Oxaliplatin-induced peripheral neuropathy.
- Strengthened patent estate across the entire portfolio with a new total of 52 issued patents and 37 pending applications in US and foreign territories.

Fiscal 2023 Year-End Financial Results

- **Cash and Investments**: Cash and investments totalled $10.4 million as of December 31, 2023.
- **R&D Expenses:** Research and development expenses were $5.7 million for the year ended December 31, 2023, compared to $4.3 million for the same period in 2022.
- **G&A Expenses:** General and administrative expenses were $4.2 million for the year ended December 31, 2023, compared to $6.0 million for the same period in 2022.
- **Net Loss:** For the year ended December 31, 2023, net loss was $9.3 million, or $3.14 per basic and diluted common share, which included $0.4 million of non-cash expenses, compared to a net loss of $10.1 million, or $3.56 per basic and diluted common share for the year ended December 31, 2022, which included $2.3 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 CB1and 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.

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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