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Artelo Biosciences Provides Business Update Highlighting Clinical Progress and Reports Fiscal 2025 Year-End Financial Results

Positive human data and upcoming clinical catalysts across portfolio

SOLANA BEACH, Calif., Feb. 24, 2026 (GLOBE NEWSWIRE) -- **Artelo Biosciences, Inc. (Nasdaq: ARTL)** ("Artelo" or the "Company"), a clinical-stage pharmaceutical company focused on modulating lipid-signaling pathways to develop treatments for people living with cancer, pain, dermatological, or neurological conditions, today provided a business update and announced its financial and operational results for the fiscal year ended December 31, 2025.

Business Highlights:

Successful Phase 1 study with ART26.12: Reported positive first-in-human Phase 1 single ascending dose (SAD) clinical data demonstrating a favorable safety profile, predictable pharmacokinetics, and dosing flexibility. As a result, the Company is working to complete preparations to open enrollment to the multiple ascending dose (MAD) study in the third quarter of 2026.

Positive interim Phase 2 results with ART27.13: Announced positive interim Phase 2 CArES data demonstrating improvements in body weight, lean body mass, and physical activity alongside a favorable side-effect profile compared to placebo in patients with cancer anorexia-cachexia syndrome.

Streamlined regulatory pathway for ART12.11: Received favorable UK MHRA regulatory guidance supporting Phase 1 study plans and potential accelerated pathways. Pending outcome of toxicology study results in 2026, the Company plans to initiate human clinical studies with an oral solid dosage form during the first half of 2027.

"2025 was a pivotal year clinically for Artelo, marked by meaningful progress across all our core programs," stated Gregory D. Gorgas, Chief Executive Officer of Artelo, "We successfully completed a first-in-human Phase 1 SAD study for ART26.12 and validated our FABP5 inhibition approach to pain management. These results were further strengthened by positive preclinical efficacy data with ART26.12 which demonstrated sustained analgesic effects without tolerance in an osteoarthritis pain model, with efficacy comparable to naproxen and a potentially safer profile. We are excited to be progressing this program as a differentiated, non-opioid, non-steroidal alternative for pain"

“We were very pleased to report positive interim Phase 2 CARES data for ART27.13. These results reinforced ART27.13’s potential as a meaningful therapeutic strategy to address the significant unmet medical need in patients with cancer anorexia-cachexia syndrome. In addition, we received a Notice of Allowance from the European Patent Office covering the intended commercial formulation of ART27.13 and extending patent protection through December 2041. Together, the clinical progress and enhanced intellectual property position have advanced partner interest in supporting the program’s next stage of development.”

“In parallel, we were pleased with the UK MHRA’s favorable regulatory guidance supporting our Phase 1 clinical plans for ART 12.11. As presented at the 35th Annual International Cannabinoid Research Society Symposium, ART12.11’s positive preclinical efficacy was confirmed by its robust antidepressant-like activity in a stress-induced depression model, with efficacy comparable to sertraline (Zoloft) and differentiated cognitive benefits not observed with leading SSRIs. Our team is therefore preparing to initiate first-in-human studies with an oral solid dosage form early next year.” Gorgas concluded by stating that “Looking ahead, we are firmly focused on disciplined clinical execution, strategic collaboration, and prudent capital management to drive shareholder value.”

Fiscal 2025 Year-End Financial Results

- **R&D Expenses:** Research and development expenses were \$5.4 million for the year ended December 31, 2025, compared to \$6.0 million for the year ended December 31, 2024.
- **G&A Expenses:** General and administrative expenses were \$6.0 million for the year ended December 31, 2025, compared to \$4.1 million in the prior year.
- **Net Loss:** For the year ended December 31, 2025, net loss was 12.9 million, or \$12.52 per basic and diluted common share, compared to a net loss of \$9.8 million for the year ended December 31, 2024.
- **Cash and Investments:** Cash and investments totaled \$0.6 million as of December 31, 2025.

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, with a diversified pipeline addressing significant unmet needs in anorexia, cancer, anxiety, dermatologic conditions, pain, and inflammation. Led by an experienced executive team collaborating with world-class researchers and technology partners, Artelo applies rigorous scientific, regulatory, commercial, and treasury management practices, including digital assets, to maximize stakeholder value. More information is available at www.artelobio.com and X: @ArteloBio.

About ART26.12

ART26.12, Artelo’s lead Fatty Acid Binding Protein 5 (FABP5) inhibitor, is under development as a novel, peripherally acting, non-opioid, non-steroidal analgesic, initially for the treatment of chemotherapy-induced peripheral neuropathy (CIPN). Human studies with ART26.12 have demonstrated a favorable safety profile with no serious adverse events, as well as predictable, linear pharmacokinetics and dosing flexibility in both fed and fasted

states. Fatty Acid Binding Proteins (FABPs) are a family of intracellular proteins that chaperone lipids important to normal cellular function. In addition to ART26.12, 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 cannabinoid receptor agonist being developed as supportive care for people with cancer experiencing anorexia and cachexia. Administered orally once daily, the treatment goals with ART27.13 are to improve appetite, body weight, and activity levels while preserving muscle and elevating quality of life. Initially developed by AstraZeneca plc, ART27.13 selectively targets peripheral cannabinoid (CB₁ and CB₂) receptors to avoid the psychoactive side effects typically associated with some cannabinoids. While exhibiting a favorable safety profile at all doses in the CAREs trial, interim analysis from the blinded and randomized Phase 2 study demonstrated a mean weight gain of over 6% for participants that received the top dose of ART27.13 compared to a 5% loss in the placebo group. A weight loss of more than 5% can predict a poor outcome for cancer patients and a lower response to therapy. Currently, there is no FDA approved treatment for cancer anorexia cachexia syndrome.

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 people with cancer experiencing 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. Interim data from the Phase 2 portion of CAREs showed improvements in lean body mass, weight gain, and activity among patients treated with all doses of ART27.13, particularly at the highest dose, compared to the participants administered placebo. (ISRCTN registry: <https://www.isrctn.com/ISRCTN15607817>)

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. Artelo has received favorable UK MHRA regulatory guidance supporting Phase 1 study plans and potential accelerated pathways with plans to initiate human clinical studies in the first half of 2026. 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 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 and has now been granted or validated in 21 additional countries.

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 statements 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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