November 12, 2025

Artelo Biosciences Provides Business Update and Reports Third Quarter 2025 Financial Results

Encouraging Clinical Progress, Including Positive Interim Phase 2 Results for the Treatment of Cancer Anorexia Cachexia Syndrome

SOLANA BEACH, Calif., Nov. 12, 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 three months ended September 30, 2025.

“We continue to deliver on our clinical and strategic objectives, advancing three differentiated programs with strong potential to address large, underserved markets,” said Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. “We were very pleased with the interim Phase 2 data with ART27.13 showing restoration in body weight versus continued weight loss in people suffering from cancer-related anorexia. Importantly, this data has attracted meaningful partnering interest from several pharmaceutical companies. In addition, partnering interest continues to expand for ART26.12, our lead FABP5 inhibitor, as more companies become aware of its broad therapeutic potential. With ART26.12’s progress toward a multiple ascending dose study, we believe our clinical pipeline is well-positioned to create substantial value for patients and shareholders.”

Business Highlights:

ART26.12 – Following Successful Single Ascending Dose (SAD) Study, Multiple Ascending Dose (MAD) Study Protocol being Finalized

- The MAD study aims to confirm the favorable safety profile and dose-linear pharmacokinetics observed in the SAD study under multiple dose scenarios while providing further information on dosing frequency and biomarker strategy.
- Preliminary food-effect results support future development with dosing in either fed or fasted states.

ART27.13 –Positive Interim Phase 2 CAReS Data Driving Partnering Interest

- Interim Phase 2 Cancer Appetite Recovery Study (CAReS) results demonstrated meaningful efficacy, safety, and functional benefit in cancer-related anorexia and weight loss.

    - Patients receiving top dose ART27.13 achieved an average +6.4% weight gain versus a -5.4% loss on placebo, showed +4.2% lean body mass increase, and improved activity levels aligned with potential regulatory endpoints.
    - ART27.13 was well tolerated with predominantly mild or moderate adverse events.
- Following positive Phase 2 results and coverage by UK and USA media outlets, Artelo has received multiple expressions of potential collaboration interest from global and regional pharmaceutical companies.
- European Patent Office issued a Notice of Allowance covering the intended commercial formulation of ART27.13 through 2041.

ART12.11 – First-in-Human Study Expected to Commence in 1H 2026

- Received clear guidance from MHRA, the regulatory authority in the UK, on a streamlined pathway to the clinic. First-in-human study anticipated to start in first half of 2026.
- Presentation of new preclinical data at the 35th Annual International Cannabinoid Research Society Symposium demonstrating an antidepressant-like activity on par with and improved cognitive benefits over sertraline (Zoloft®); a leading standard-of-care therapy.
- Publication of new preclinical data conducted in collaboration with researchers at Western Ontario University in Progress in Neuro-Psychopharmacology and Biological Psychiatry, which highlighted that ART12.11 significantly outperformed cannabidiol (CBD) alone in reducing stress-induced depression and anxiety symptoms, while also achieving superior oral bioavailability.

Q3 2025 Financial Results (Unaudited)

- **R&D Expenses:** Research and development expenses were $1.3 million for the quarter ended September 30, 2025, compared to $0.3 million for the same period in 2024, during which $1.3 million of UK tax credits were received.
- **G&A Expenses:** General and administrative expenses were $1.8 million for the quarter ended September 30, 2025, compared to $0.9 million in 2024.
- **Net Loss:** For the quarter ended September 30, 2025, net loss was $3.1 million, or $3.97 per basic and diluted common share, which included $0.4 million of non-cash expenses, compared to a net loss of $1.1 million, or $2.10 per basic and diluted common share for the quarter ended September 30, 2024, which included $0.2 million of non-cash expenses.
- **Cash and Investments**: Cash and investments totaled $1.7 million as of September 30, 2025.
- In July 2025, the Company entered into an At-The-Market Offering Agreement under which the Company can offer and sell up to $6.5 million of shares of common stock from time to time through an “at the market” offering program. During the quarter ended September 30, 2025, common stock was sold under the agreement for gross proceeds of $0.4 million.
- In September 2025, the Company completed a confidentially marketed public offering of common stock with gross proceeds of $3.0 million.

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) under an investigational new drug application opened with the FDA. 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 seven clinical studies with over 280 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 conducting a Phase 2 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 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 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 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 19 additional countries.

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.

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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