August 13, 2025

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

Multiple Announcements of Clinical Data Results Anticipated in Q3 2025

SOLANA BEACH, Calif., Aug. 13, 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 June 30, 2025.

Business Highlights:

ART26.12 –Advancing Toward Multi-dose Phase 1 Safety Study

- Successfully completed a Phase 1 Single Ascending Dose (SAD) study in 49 healthy volunteers. Data confirmed positive safety results, with only mild, transient adverse events, no drug-related issues, and predictable, dose-linear pharmacokinetics. The wide therapeutic window supports dose titration flexibility and advancement to the next clinical stage.
- Preparations are underway for a Multiple Ascending Dose (MAD) study to start in Q4 2025
- Presented new data at the British Pain Society Conference, validating the therapeutic potential of FABP inhibitors in osteoarthritis (OA). In a surgical rat model of OA, both single and repeat oral doses of ART26.12 significantly improved weight-bearing function, with effects sustained up to four weeks.
- Announced publication of a comprehensive review in Neurobiology of Disease, titled "Fatty acid binding proteins and their involvement in anxiety and mood disorders" underscoring the potential of FABP inhibitors in treating mood and anxiety disorders, expanding ART26.12's therapeutic relevance beyond pain.

ART27.13 –Phase 2 Readout Anticipated in Q3 2025

- On track to report initial data from the Phase 2 CAReS study of ART27.13, its peripherally acting cannabinoid receptor agonist, in Q3 2025. Following a successful Phase 1 trial demonstrating safety in cancer patients, ART27.13 is positioned to address significant unmet needs in cancer anorexia-cachexia syndrome, a condition currently lacking any FDA-approved therapies.

ART12.11 – Progress Targeting Depression and Anxiety

- At the 35th Annual International Cannabinoid Research Society (ICRS) Symposium, presented compelling preclinical data for ART12.11, a novel Cannabidiol:Tetramethylpyrazine (CBD:TMP) cocrystal, highlighting dual-action efficacy in alleviating depressive-like behaviors and restoring cognitive function in animals. The results support ART12.11's potential entry into the multi-billion-dollar antidepressant market.
- 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 2026.

Gregory D. Gorgas, President and CEO of Artelo Biosciences, commented on the results of the second quarter, "We are very pleased with the momentum across our pipeline, highlighted by the growing body of evidence supporting our first-in-class FABP5 inhibitor, ART26.12. The successful completion of our Phase 1 SAD study demonstrated positive safety and pharmacokinetics, laying the groundwork for our upcoming MAD study."

"We are also on track to report Phase 2 data from our CAReS study of ART27.13 during the current third quarter and to collect data demonstrating dual-action efficacy of our preclinical candidate ART12.11 in treating depression and cognitive decline to support our plans to initiate human trials early next year. These achievements reflect our commitment to addressing large unmet medical needs through novel science and thoughtful clinical development," concluded Mr. Gorgas.

Q2 2025 Financial Results (Unaudited)

- **R&D Expenses:** Research and development expenses were $1.9 million for the quarter ended June 30, 2025, compared to $1.7 million for the same period in 2024.
- **G&A Expenses:** General and administrative expenses were $1.3 million for the quarter ended June 30, 2025, compared to $0.8 million in 2024.
- **Net Loss:** For the quarter ended June 30, 2025, net loss was $3.2 million, or $5.61 per basic and diluted common share, which included $0.2 million of non-cash expenses, compared to a net loss of $2.4 million, or $4.52 per basic and diluted common share for the quarter ended June 30, 2024, which included $0.1 million of non-cash expenses.
- **Cash and Investments**: Cash and investments totaled $2.1 million as of June 30, 2025.
- In May 2025, the Company issued $0.9 million at-market convertible notes.
- On June 26, 2025, the Company completed a private placement for gross proceeds of $1.425 million.
- Subsequent to June 30, 2025, the Company completed an at-the-market PIPE (private investment in public equity) for gross proceeds of $9.475 million.
- In connection with the two PIPE transactions, the Company has adopted a Digital Asset Treasury strategy whereby it plans to purchase the digital currency **known as Solana ("SOL")** complementing the Company's expectation to hold and maintain at least one year of cash in traditional instruments to fund its biopharmaceutical develop operations.

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 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 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 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. Complementing its scientific innovation, Artelo has adopted a forward-looking corporate finance initiative whereby it is deploying a portion of its excess capital into Solana under a newly authorized digital asset treasury strategy. As the first publicly traded pharmaceutical company to designate Solana as a core reserve asset, Artelo intends to leverage Solana's high-performance, decentralized blockchain to diversify its balance sheet, enhance liquidity management, and position the Company for long-term value creation in parallel with its therapeutic programs. Guided by disciplined risk controls and staged investments approved by the Board of Directors, this Solana-centric strategy is designed to preserve working capital for the continued advancement and commercialization of Artelo's product candidates while affording shareholders exposure to a next-generation monetary network. Led by an experienced executive team collaborating with world-class researchers and digital-asset technology partners, Artelo applies rigorous scientific, regulatory, commercial, and treasury management practices 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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