

September 3, 2025



Artelo Biosciences Affirms Strong Partnering Outlook for ART27.13 Following Positive Interim Phase 2 CAREs Results

SOLANA BEACH, Calif., Sept. 03, 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, affirms that, based on the strength of the positive interim results from its Phase 2 CAREs trial of ART27.13 for cancer anorexia-cachexia syndrome (CACS) and the strong interest expressed by multiple pharmaceutical companies awaiting these results, it is well positioned to secure a development partner for ART27.13. CACS, a leading cause of death in cancer patients and affecting up to 80% of those living with cancer, currently has no FDA-approved treatment.

This morning, Artelo announced positive interim Phase 2 results demonstrating compelling improvements in weight, lean body mass, and activity in patients treated with ART27.13. That full release is available here: [Artelo Biosciences Announces Positive Interim Phase 2 CAREs Results](#).

As a result of ongoing discussions with potential partners and the supportive clinical profile of ART27.13 for CACS, Artelo does not envision the need to internally fund a Phase 3 trial and believes a licensing transaction represents the most value-accretive path forward for shareholders.

“This morning’s interim results highlight the potential of ART27.13 to become an FDA and internationally approved therapy for cancer anorexia-cachexia syndrome, an underserved, multi-billion-dollar potential market,” said Gregory D. Gorgas, President and CEO of Artelo. “Based on strong interest from multiple pharmaceutical companies, and given the strength of our newly released data, our immediate strategy is to secure a development partner to efficiently advance ART27.13 through registrational trials. We plan to provide further updates as soon as practical.”

About ART27.13

ART27.13 is a novel benzimidazole derivative being developed as a once-daily, orally administered agent selectively targeting peripheral CB₁ and CB₂ 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. The Phase 1 portion of the CAREs study was designed to determine the most effective and safest initial dose of ART27.13 in the Phase 2 stage. 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 compared to placebo.

(ISRCTN registry: <https://www.isrctn.com/ISRCTN15607817>)

About CACS

Cancer Anorexia-Cachexia Syndrome (CACS) is a condition marked by loss of appetite, weight loss, and the breakdown of muscle and fat, affecting up to 80% of patients with advanced cancer- representing a greater than \$3 billion addressable market. This loss of appetite, known as anorexia, may result from the cancer itself or from treatments such as radiation and chemotherapy. The resulting weight loss can weaken the immune system, cause discomfort and dehydration, and lower a patient's ability to tolerate treatment. Losing more than 5% of body weight is associated with poorer outcomes and reduced response to chemotherapy. While drugs that stimulate appetite have been used to help manage cancer-related anorexia, there are currently no approved treatments in the US, UK, or EU for this condition.

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 its digital asset treasury strategy. 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, including future plans in respect to ART27.13, potential transactions with pharmaceutical companies or other strategic counterparties in

respect of ART27.13, 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