

September 29, 2025



Artelo Biosciences Announces Presentation of Positive Interim Phase 2 CAREs Data on ART27.13 at the 2025 Cancer Cachexia Society Conference

Patients treated with ART27.13 showed consistent improvements in weight, lean body mass, and activity

While clinical benefits were observed in all treated cohorts, the best outcomes in CAREs were observed in patients titrated to the highest dose

SOLANA BEACH, Calif., Sept. 29, 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 announced the first public presentation of the interim data from its Phase 2 Cancer Appetite Recovery Study (CAREs) evaluating ART27.13 in patients with cancer anorexia-cachexia syndrome (CACS). The data were presented by Barry Laird, Professor of Palliative Medicine, Oslo University Hospital - Radium Hospital and University of Oslo, Norway, and Chief Investigator in CAREs, at the [8th Cancer Cachexia Society \(CCS\) Conference](#) held September 25–27, 2025 in Turin, Italy.

The CCS presentation showed the actual interim data underlying previously announced summary results of ART27.13's potential to meaningfully impact weight gain, lean body mass, and daily activity in patients with CACS. Importantly, Professor Laird's presentation introduced new insights from digital wearable data, which showed that patients treated with ART27.13 had greater frequency and intensity in daily activity compared to placebo, reinforcing the therapy's potential to improve both physical outcomes and quality of life in cancer patients suffering from this debilitating condition.

Interim Data Highlights

- **Weight Gain:** Patients who had lost at least 5% of body weight to be included in CAREs and titrated to the highest ART27.13 dose (1300 µg) achieved an average +6% weight gain over 12 weeks, while patients on placebo lost an additional ~5%.
- **Lean Body Mass:** Improvements in lean body mass were aligned with total weight gains, suggesting preservation or accrual of muscle, consistent with pre-clinical research with ART27.13.
- **Activity:** Digital wearable data confirmed greater daily activity metrics among treated patients compared to placebo.
- **Safety:** ART27.13 continued to exhibit a favorable safety profile, with adverse events

mostly mild to moderate and no serious drug-related events reported.

Steven D. Reich, MD, Chief Medical Officer at Artelo commented, “These interim findings provide strong evidence that ART27.13 can help address the profound weight and activity loss experienced by patients with cancer anorexia-cachexia syndrome. With ART27.13 we are seeing consistent improvements not just in weight, but also in lean body mass and activity—outcomes that are highly meaningful to patients’ daily lives.”

In addition to CCS participants hearing Professor Laird’s presentation, Artelo’s Senior Vice President and Chief Scientific Officer, Andy Yates, PhD, attended CCS 2025 to engage with global thought leaders and advance partnering discussions with pharmaceutical companies that have expressed interest in ART27.13. These efforts are aligned with the Company’s strategy to maximize the therapeutic and commercial potential of its lead program.

“Discussing the interim CAREs results at CCS 2025 allowed us to engage with the global research community, foster collaboration, and advance partnering discussions for a much-needed therapy in this area of critical unmet need,” added Dr. Yates.

Data from Professor Laird’s presentation have been added to Artelo’s corporate presentation available on the Company’s website [here](#).

About ART27.13

ART27.13 is a novel benzimidazole derivative and dual cannabinoid agonist 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 the Phase 1 portion of the CAREs study in cancer patients where ART27.13 demonstrated an excellent safety profile, Artelo is conducting the Phase 2 portion of the 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 stage 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 off-label 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. 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, 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 candidate development strategies, clinical and regulatory timelines or results, market opportunity, competitive positions, possible or assumed future results of operations or research, business strategies, potential growth opportunities, treasury strategies, 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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Source: Artelo Biosciences