UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **September 3, 2025**

ARTELO BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-38951**	**33-1220924**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

505 Lomas Santa Fe, Suite 160 Solana Beach, CA USA	**92075**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(858) 925-7049**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ARTL	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Information

Announcement of Interim Phase 2 CAReS Results for the Treatment of Cancer Anorexia-Cachexia Syndrome (CACS)

On September 3, 2025, Artelo Biosciences, Inc. **(the "Company")** announced interim results from its Phase 2 Cancer Appetite Recovery Study (CAReS) trial with ART27.13, the Company's peripherally acting cannabinoid receptor agonist for the treatment of cancer anorexia-cachexia syndrome (CACS). Affecting up to 80% of people living with cancer, CACS is marked by loss of appetite, weight loss, and breakdown of muscle and fat. This leading cause of death in cancer patients has no FDA-approved treatment. The Company believes the CAReS interim data comparing ART27.13 to placebo supports acceleration of the Company's partnering initiatives with its lead clinical program.

The Phase 2 CAReS study is evaluating ART27.13 as a once-daily oral treatment aimed at improving weight, appetite, activity, and quality of life in cancer patients who had lost a minimum of 5% of their body weight in the prior six months. Effectiveness was measured by changes in lean body mass, weight, appetite, and activity over 12 weeks and at a 30-day follow-up. Activity and quality of life were assessed using wearable monitors and standardized questionnaires, while safety was closely tracked through adverse event reporting, laboratory tests, vital signs, visual analogue scales, and ECGs.

In the interim analysis, 18 evaluable patients—primarily with lung and gastrointestinal cancers not receiving cyclic chemotherapy—were included. After 12 weeks of treatment in patients who titrated to the top dose evaluated of 1300 micrograms (n=5), ART27.13 demonstrated compelling increases in mean body weight of 6.38% (Standard Deviation or SD 9.50) compared to patients on placebo (n=6) who lost -5.42% (SD 8.17). The maximum weight gain in the ART27.13 group reached 18.5%, versus only 0.4% in placebo. The maximum weight loss in the placebo arm was -17.4%, compared to just -3.0% in the ART27.13 group. Additional benefits were seen in lean body mass, with a +4.23% increase (SD 5.37) in the treatment group versus a -3.15% loss (SD 4.89) in placebo at one month, as well as qualitative improvements in total and weekly activity scores.

Safety results were consistent with prior findings. Among the 32 participants enrolled in the CAReS Phase 2 trial to date, 7 patients (22%) experienced adverse events that may be related to ART27.13. All were mild or moderate, with the exception of a single case of severe malaise, and no drug-related serious adverse events were reported. These data are aligned with safety outcomes observed in Phase 1 of CAReS, supporting ART27.13's overall favorable tolerability and acceptable safety profile.

As a result of these discussions and the supportive clinical profile of ART27.13, the Company does not plan to internally fund a Phase 3 trial and believes a licensing transaction represents the most value-accretive path forward for stockholders.

Forward Looking Statements

This report 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 report. 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARTELO BIOSCIENCES, INC.

Date: September 3, 2025

/s/ Gregory D. Gorgas
Gregory D. Gorgas
President & Chief Executive Officer