

Artelo Biosciences Reports Second Quarter 2022 Financial Results and Provides Business Update

CAReS Study Evaluating ART27.13 in Cancer Anorexia Progresses to Fourth Cohort

ART26.12 Program to Target Chemotherapy-Induced Peripheral Neuropathy

\$21.3 Million in Cash and Investments as of June 30, 2022

15-for-1 Reverse Stock Split to be Effective August 10, 2022

SOLANA BEACH, Calif., Aug. 09, 2022 (GLOBE NEWSWIRE) -- <u>Artelo Biosciences</u>, <u>Inc.</u> (Nasdaq: ARTL), a clinical stage pharmaceutical company developing therapeutics that modulate lipid-signaling pathways, including the endocannabinoid system, today reported financial and operating results for the three months ended June 30, 2022.

"During this past quarter we completed enrollment of the first three cohorts in our Cancer Appetite Recovery Study (CAReS) evaluating ART27.13 for the treatment of cancer-related anorexia," stated Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. "Based upon the CAReS safety review committee's conclusion that ART27.13 was well-tolerated with no serious adverse events attributable to the investigational drug, we initiated a fourth cohort at a 650-microgram dose. With the momentum from an increasing number of clinical sites, we expect to complete the Phase 1b stage and to commence enrollment in the Phase 2b stage of CAReS in the fourth quarter of 2022."

"Furthermore, we maintained a solid balance sheet with over \$21.3 million in cash and cash equivalents. This capital is anticipated to support our operations through the end of 2023, enabling Artelo to deliver on important clinical and preclinical milestones," concluded Mr. Gorgas.

Artelo's Board of Directors approved a 15-for-1 reverse stock split of the Company's common stock. The Company's common shares will begin trading on a split-adjusted basis on the Nasdaq Capital Market commencing at the market open, August 10, 2022. The Board of Directors determined the 15-for-1 ratio to be appropriate in order to improve the marketability and liquidity of Artelo's common stock and to regain compliance with all of Nasdaq's continued listing requirements.

As a result of the reverse split, each fifteen shares of the Company's issued and outstanding common stock will be automatically combined and converted into one issued and outstanding share of common stock. Each shareholder's pro-rata percentage ownership will remain unchanged as a result of the reverse split and no further action is required by

shareholders. All of the Company's current outstanding warrants to purchase shares of common stock and other derivatives automatically adjust per their terms to reflect the reverse split. Immediately after the reverse split becomes effective, there will be approximately 2.8 million shares of common stock issued and outstanding. For further details, all shareholders are invited to review the 8-K regarding this reverse split filed today, August 9, 2022.

Other Business Highlights

In its review of data from the first three Phase 1b cohorts, the safety review committee for CAReS affirmed that ART27.13 has been well-tolerated with no serious adverse events (SAEs) related to ART27.13 in study patients suffering from anorexia associated with cancer. In addition, ART27.13's safety profile appears more benign among cancer patients participating in CAReS than observed in healthy volunteers in prior Phase 1 studies with ART27.13 while the pharmacokinetics remained consistent between the two studies. This more recent safety profile plus an observed improvement in anorexia from each dose escalation led to the decision to expand to the fourth cohort at a 650-microgram dose.

Pre-clinical research of ART26.12, Artelo's lead FABP5 inhibitor, indicated that chronic, oral treatment was effective at preventing and treating both oxaliplatin- and paclitaxel-induced pain sensitivity without any sedating effects in rats. In addition, prevention studies of ART26.12 minimized acute weight loss caused by oxaliplatin. These findings support further development of ART26.12 in neuropathies including neuropathy associated with chemotherapy which represents a significant unmet need for which there are no approved treatments in the US, UK, or Europe.

Financial Results Ended June 30, 2022

Operating expenses for the three months ended June 30, 2022, were \$2.4 million compared to \$2.3 million for the same period in 2021. The increase in operating expenses for the three months ended June 30, 2022, was primarily related to increases in payroll and in subcontractor expenditures relating to the Company's ART27.13 clinical trial.

Net loss was approximately \$2.4 million, or \$0.87 per basic and diluted common share, for the three months ended June 30, 2022, compared to a net loss of \$ 2.3 million, or \$1.45 per basic and diluted common share, for the three months ended June 30, 2021.

As of June 30, 2022, the Company had approximately \$21.3 million in cash and investments, compared to \$25.6 million as of December 31, 2021.

About ART27.13

ART27.13 is a highly potent, peripherally restricted synthetic, dual G-Protein Coupled Receptor agonist believed to target the cannabinoid receptors CB_1 and CB_2 , which has the potential to increase appetite and food intake. Originally developed by AstraZeneca plc, ART27.13 has been in five Phase 1 clinical studies including over 200 subjects where it demonstrated a statistically significant and dose-dependent increase in body weight in healthy subjects. Importantly, the changes in body weight were not associated with fluid retention and the distribution of the drug enables systemic metabolic effects while minimizing central nervous system-mediated toxicity. Artelo is advancing ART27.13 as a supportive care therapy for cancer patients suffering from anorexia and weight loss, where the current annual

global market is estimated to be valued in excess of \$2 billion.

About CAReS

The Cancer Appetite Recovery Study (CAReS) is a Phase 1b/2a randomized, placebocontrolled trial of the Company's lead clinical program, ART27.13, in patients with cancer anorexia and weight loss. Anorexia, or the lack or loss of appetite in cancer patients, may result from the cancer and/or its treatment with radiation or chemotherapy. It is common for patients 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 1b portion of the CAReS study is designed to determine the most effective and safest dose of ART27.13 for dosing in the Phase 2a stage. The Phase 2a 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 ART26.12

Fatty Acid Binding Proteins (FABPs) are a family of intracellular proteins that chaperone lipids including endocannabinoids and fatty acids. Various inhibitors of FABPs may be particularly useful for the treatment of specific cancers, neuropathic and nociceptive pain, and anxiety disorders. ART26.12, Artelo's lead FABP inhibitor compound, is a selective inhibitor of FABP5. While developing our lead molecule for Chemotherapy-Induced Peripheral Neuropathy, additional compound(s) from our extensive library of potent and selective inhibitors of FABPs have been identified and selected for advancement towards regulatory-enabling studies in cancer and other areas of high-unmet need where inhibition of FABPs show significant promise.

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 including the endocannabinoid system. Artelo is advancing a portfolio of broadly applicable product candidates designed to address significant unmet needs in multiple diseases and conditions, including anorexia, cancer, anxiety, pain, neuropathy, and inflammation. Led by proven biopharmaceutical executives collaborating with highly respected researchers and technology experts, the company applies leading edge scientific, regulatory, and commercial discipline to develop high-impact therapies. More information is available at <u>www.artelobio.com</u> and Twitter: <u>@ArteloBio</u>.

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.

Investor Relations Contact:

Crescendo Communications, LLC Tel: 212-671-1020 Email: <u>ARTL@crescendo-ir.com</u>



Source: Artelo Biosciences