

# Artelo Biosciences Reports Third Quarter 2023 Financial Results and Provides Business Update

\$12.9 Million in Cash and Investments as of September 30, 2023; Runway Expected to Reach Meaningful Development Milestones

On Track to Submit IND Application with the FDA for ART26.12 During the First Half of 2024

SOLANA BEACH, Calif., Nov. 13, 2023 (GLOBE NEWSWIRE) -- <u>Artelo Biosciences</u>, <u>Inc.</u> (Nasdaq: ARTL), a clinical-stage pharmaceutical company focused on modulating lipidsignaling pathways to develop treatments for people living with cancer, pain, and neurological conditions, today reported financial and operating results for the three months ended September 30, 2023 and provided a business update.

"We are pleased to report continued progress toward achieving meaningful milestones," commented Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences. "Specifically, we are on track to complete patient enrollment in our Cancer Appetite Recovery Study (CAReS) Phase 2a trial, evaluating our lead clinical program ART27.13 for the treatment of cancer-related anorexia and weight loss, in the second half of next year."

Artelo also has two product candidates, ART26.11 and ART12.11 advancing toward the clinic. New data on ART26.12, a Fatty Acid Binding Protein 5 (FABP5) inhibitor, and ART12.11, the Company's proprietary cocrystal of cannabidiol (CBD) and tetramethylpyrazine (TMP), were presented at prominent conferences including the Gordon Research Conference, the 6<sup>th</sup> Cannabinoid-Derived Drug Development Summit, and the 13<sup>th</sup> Congress of European Pain Federation during the quarter. Notably, ART12.11 demonstrated improved pharmaceutical properties in preclinical chronic stress models due to its novel co-crystallization. These improved properties result in better solubility, dissolution, and absorption compared to CBD alone. In addition, ART26.12 shows promise as a potential treatment for pain resulting from peripheral neuropathy based on its ability to activate multiple receptors implicated in pain signaling. The Company intends to submit its IND (Investigational New Drug) application to the Food and Drug Administration (FDA) during the first half of 2024 to support first-in-human clinical trials of ART26.12.

"Furthermore, we maintained a strong balance sheet with over \$12.9 million in cash and cash equivalents, which we believe will support operations into the first quarter of 2025. We continue to carefully manage our resources in order to reach significant development milestones and attract partner interest across our entire portfolio," Mr. Gorgas concluded.

## Financial Results Ended September 30, 2023

Operating expenses for the three months ended September 30, 2023, were \$2.6 million compared to \$2.4 million for the same period in 2022. The increase in operating expenses for the three months ended September 30, 2023, was primarily related to an increase in research and development expense as a result of increased salaries to internal research and development staff along with increased payments to third-party service providers offset by a decrease in general and administrative expenses associated with a decrease in the year-over-year service cost of stock-based compensation, a non-cash expense.

Net loss was approximately \$2.4 million, or \$0.83 per basic and diluted share, for the three months ended September 30, 2023, compared to a net loss of \$2.3 million, or \$0.82 per basic and diluted share, for the three months ended September 30, 2022.

As of September 30, 2023, the Company had approximately \$12.9 million in cash and investments, compared to \$17.5 million as of December 31, 2022.

## **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>.

# 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. 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 1b portion of the CAReS study was designed to determine the most effective and safest dose of ART27.13 for dosing in the Phase 2a stage. Currently enrolling, 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)

# 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 statements 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