

Forward-Looking Statements

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The Company's SEC filings are available at artelobio.com.



Artelo Biosciences, Inc.

Clinical stage biopharmaceutical company developing a portfolio of lipid-signaling modification product candidates to treat people living with cancer, pain, anxiety, and other serious diseases





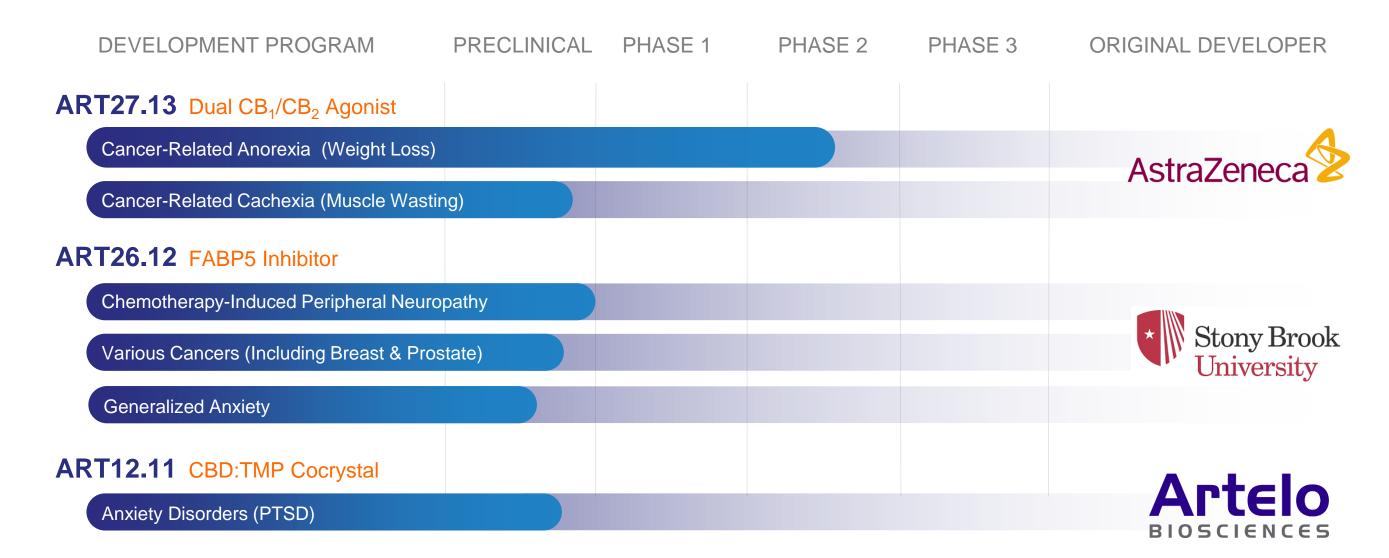




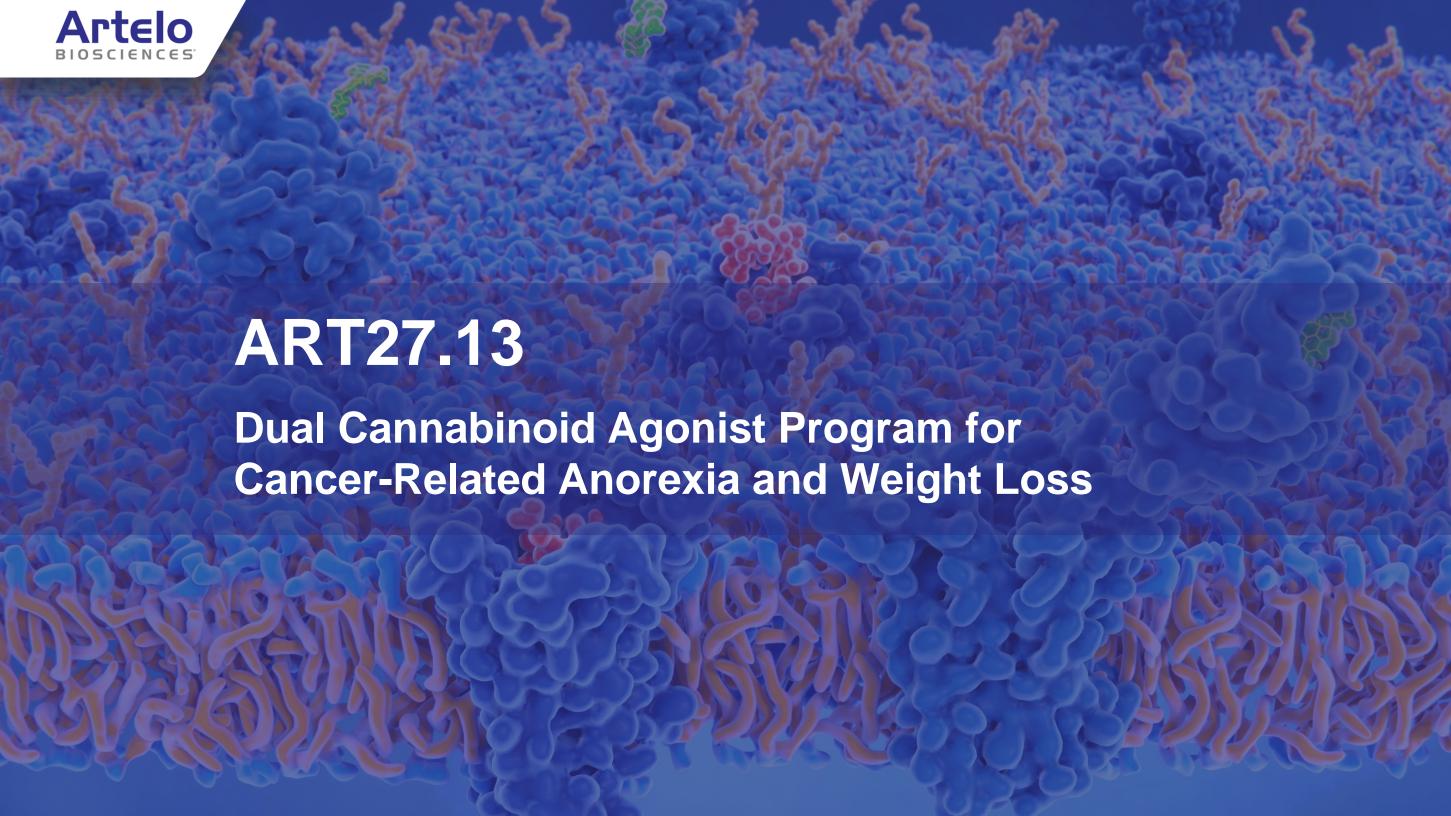




Lipid-Signaling Modification Pipeline







Cancer Anorexia Cachexia Syndrome (CACS)

CACS is often a devastating and debilitating aspect of any stage of malignancy that can alter the course of treatment



Edinburgh Cancer Centre 2022. Used with permission.

"When you pull a pair of trousers up and they just fall right back down again, it sort of hits home how quickly the weight dropped off. That was scary."



Global Opportunity to Impact Cancer Care

High Unmet Need

Cancer-related anorexia affects >60% of advanced stage cancer patients^{1,4,5}



"It is characterized by loss of appetite, weight loss and tissue wasting, accompanied by a decrease in muscle mass and adipose tissue, impoverishing quality of life and often preceding the patient's death." 6

No Standard of Care



Management of Cancer Cachexia: ASCO Guideline 2020

"In the absence of more robust evidence, no specific pharmacological intervention can be recommended as the standard of care;" ⁵

No therapeutic is approved for the treatment of CACS in North America, United Kingdom, or Europe



European Society for Clinical Nutrition and Metabolism

"To counter malnutrition in patients with advanced cancer there are few pharmacological agents and pharmaconutrients with only limited effects."

Large Global Market

Therapeutic market for CACS is estimated to be \$2 billion globally and expected to increase significantly with a proprietary new market entry²



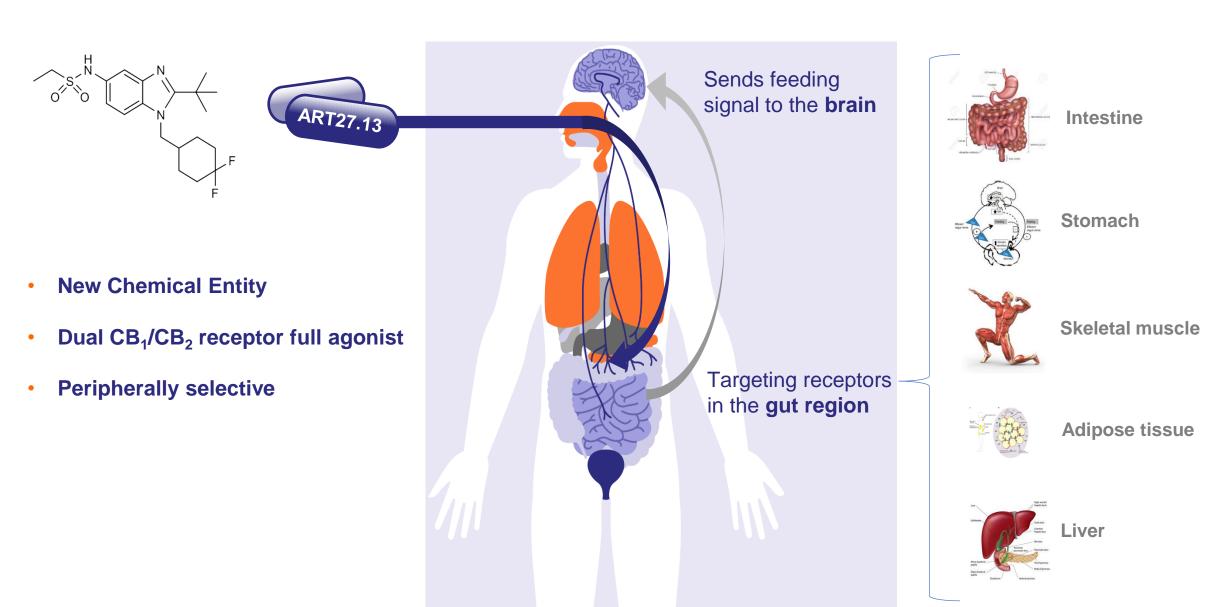
Drugs are used off-label with limited success 3, 5

- Short-term (weeks) corticosteroids
- Appetite stimulants
- Anabolic agents
- Progesterone analogs
- Cytokine & metabolic inhibitors



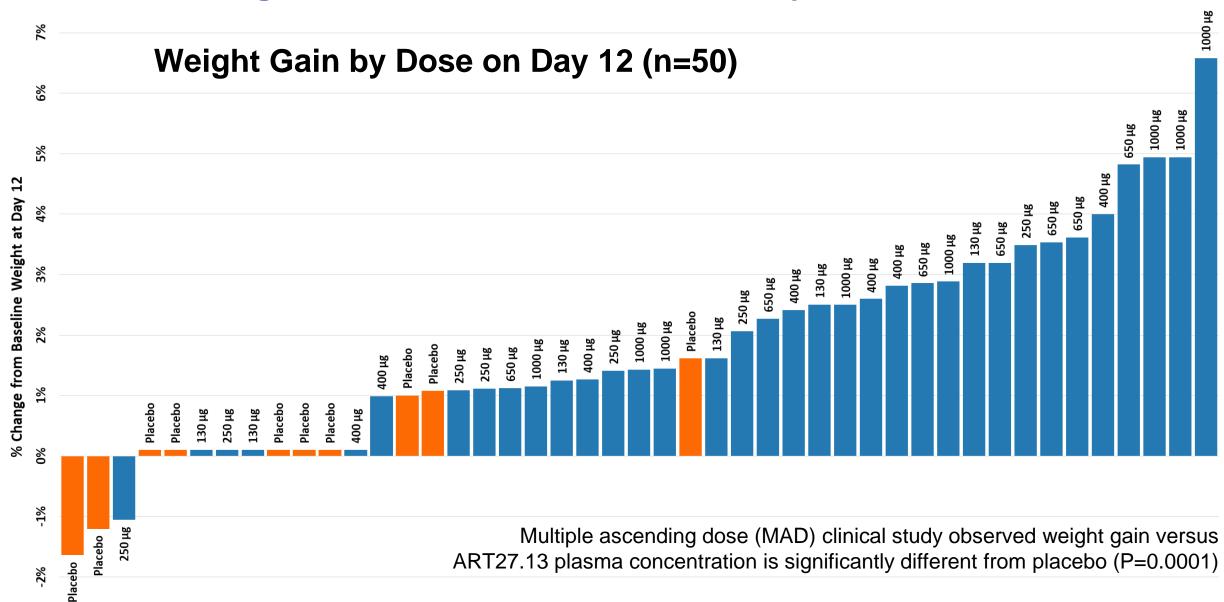
Sources: 1: Nonsteroidal selective androgen receptor modulator Ostarine in cancer cachexia. Zilbermint MF, Dobs AS, Future Oncol. 2009 Oct; 5(8):1211-20; 2: Data from Market Intel Reports 2016 as quoted in Innovus Pharma to Enter the Oncology Supportive Care Market With an Exclusive License to Two GRAS-Listed OTC Compounds for Cachexia and Muscle Growth and Repair From the University of Iowa Research Foundation. Innovus Press Release June 6, 2017, ex-US estimate based upon market forecast model from US sales figures; 3: Pharmacological management of cachexia in adult cancer patients: a systematic review of clinical trials. Advani, Shailesh M et al., *BMC cancer* vol. 18,1 1174. 27 Nov. 2018, doi:10.1186/s12885-018-5080-4; 4. Sánchez-Lara K, Ugalde-Morales E, Motola-Kuba D, Green D. Gastrointestinal symptoms and weight loss in cancer patients receiving chemotherapy. Br J Nutr 2013;109:894-7, 5. Management of Cancer Cachexia: ASCO Guideline, May 2020; 6. Megestrol acetate for treatment of anorexia-cachexia syndrome. *Cochrane Database of Systematic Reviews* 2013, Issue 3. Art. No.: CD004310. 7: Arends J, Bachmann P, Baracos V, Barthelemy N, Bertz H, Bozzetti F, Fearon K, Hütterer E, Isenring E, Kaasa S, Krznaric Z, Laird B, Larsson M, Laviano A, Mühlebach S, Muscaritoli M, Oldervoll L, Ravasco P, Solheim T, Strasser F, de van der Schueren M, Preiser JC. ESPEN guidelines on nutrition in cancer patients. Clin Nutr. 2017 Feb:36(1):11-48, doi: 10.1016/i.clnu.2016.07.015. Epub 2016 Aug 6. PMID: 27637832.

Leveraging a Well-Established Appetite Pathway



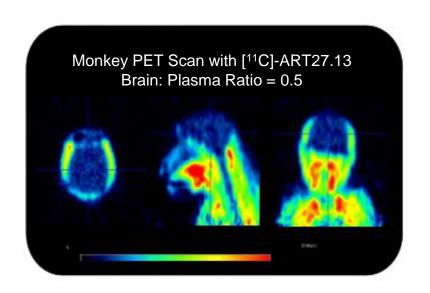


Observed Weight Gain in Prior Phase 1 Study



Peripherally Selective Targeting of Receptors in the Body, not the Brain

ART27.13 is designed to minimize undesired CNS effects of CB₁ agonism



Adverse Events Observed in Clinical Studies

Prior Phase 1 (MAD study)¹

Subjects with AEs	Placebo N = 10	130 μg N = 8	250 μg N = 8	400 μg N = 8	650 μg N = 8	1000 μg N = 8
Mild	4 (40.0%)	4 (50.0%)	-	1 (12.5%)	5 (62.5%)	8 (12.5%)
Moderate	4 (40.0%)	2 (25.0%)	5 (62.5%)	2 (25.0%)	2 (25.0%)	4 (50.0%)
Severe	-	1 (12.5%)	1 (12.5%)	5 (62.5%)	1 (12.5%)	3 (37.5%)
Subjects with any AE	8 (80.0%)	7 (87.5%)	6 (75.0%)	8 (100.0%)	8 (100.0%)	8 (100.0%)

CAReS Phase 1b

ART27.13 has been well-tolerated with no serious adverse events attributable to the investigational drug in patients suffering from anorexia associated with cancer, up to 650µg.²



Currently Enrolling the CAReS Study



Title: A Phase 1b/2a, Randomized, Placebo-Controlled Trial of the Synthetic Cannabinoid ART27.13 in

Patients with Cancer Anorexia and Weight Loss

Objectives: Phase 1b - Determine the most effective and safe dose to be used in Phase 2a

Phase 2a - Determine point estimates of activity of ART27.13 in terms of lean body mass, weight

gain, activity, and improvement of anorexia

Status: Phase 1b completed; Phase 2a enrolling

Size: 64 patients

Region: UK & Ireland, and Norway

Lead Investigator: Barry J. A. Laird, M.D., Institute of Genetics and Cancer, University of Edinburgh, Scotland

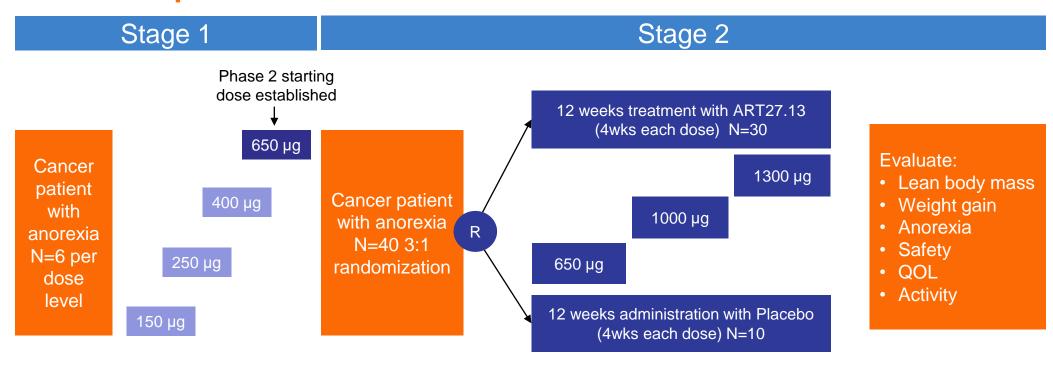
Expected Completion: Phase 2a enrollment in 2H - 2024



CAReS Study Design



Establishing safety, an optimized dose, and a proof-of-concept in cancer patients with anorexia



QOL = Quality of Life R = Randomization





FABP Inhibitor Platform

Fatty Acid Binding Proteins (FABPs) are intracellular proteins that serve as carriers for lipids including endocannabinoids and fatty acids with potential for broad application in therapeutics development.

Pain and Inflammation

Inhibition of FABP5 can cause a direct analgesic effect via cannabinoid receptors as well as reducing inflammation via altering fatty acid metabolism.

Anxiety Disorders

Inhibition of FABP5 is capable of modulation of the CB₂ receptor in the CNS, which is involved in the control of both fear and anxiety.

Cancer

Inhibition of FABP5 suppresses the growth and migration of several cancers.

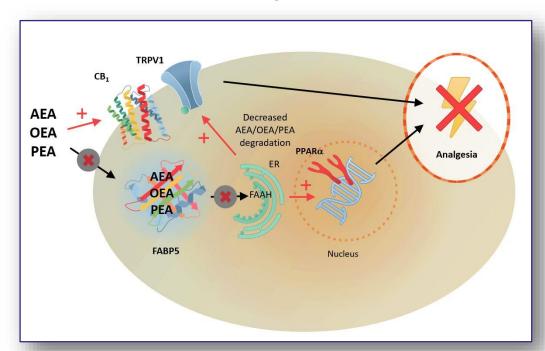
Artelo has a worldwide exclusive license to multiple FABP inhibitors under pre-clinical evaluation.



Lipid Signaling Pathways as a Key Mechanism for the Treatment of Pain

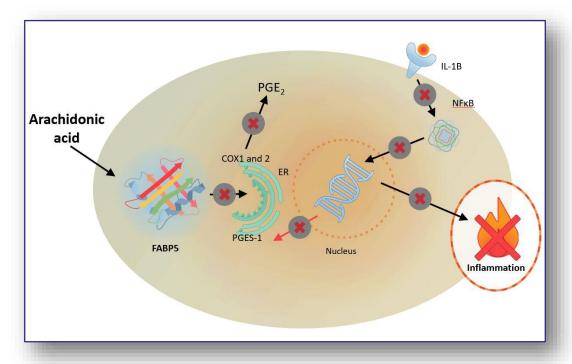
Inhibiting Fatty Acid Binding Protein 5 (FABP5) has potential as a next-generation, non-opioid, non-psychoactive, dual mechanistic approach to pain and inflammation

Pain



FABP5 inhibition is capable of increasing levels of endocannabinoids (AEA, OEA, and PEA) and in turn these can cause a direct analgesic effect via cannabinoid receptors (CB1, TRPV1, and PPARα)

Inflammation

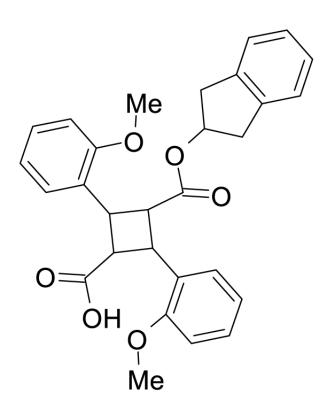


FABP5 inhibition is believed to disrupt fatty acid metabolism resulting in reduced inflammatory prostaglandins reducing inflammation



Lead Development Candidate from FABP Inhibitor Platform

- Sub-micromolar FABP binding affinity showing selective binding to FABP5
- Attractive Non-Clinical Safety Profile
 - No off-target liability against a broad panel of enzymes and receptors of concern
 - No in-vitro safety pharmacology of concern
 - NOAEL* of 1,000 mg/kg/day in a 14-day dog and rodent toxicology study
 - Non-controlled substance
- GLP IND enabling studies & GMP drug-substance scale-up (6kg) complete
- Intended for development as an orally dosed prevention and treatment with an initial indication for chemotherapy-induce peripheral neuropathy (CIPN), and other forms of neuropathy (e.g., diabetic)



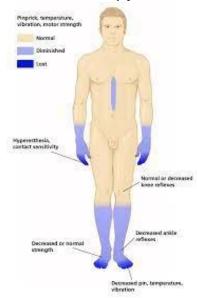
ART26.12



Chemotherapy-Induced Peripheral Neuropathy (CIPN)

Impacts Ability to Treat

Up to 40% of cancer patients treated with chemotherapy will develop neuropathic pain¹ which often requires dose reduction or cessation of therapy.²



For many patients, CIPN is one of the least expected and most upsetting side effects of cancer treatment. Symptoms described as "pins and needles" on feet, legs, hands and arms.³

No Approved Therapy



Prevention and Management of CIPN: ASCO Guideline 2020

"Clinicians should assess, and discuss with patients, the appropriateness of dose delaying, dose reduction or stopping chemotherapy (or substituting with agents that do not cause CIPN) in patients who develop intolerable neuropathy and/or functional nerve impairment." ⁴

As of January 2024, no therapeutic is approved for the treatment of CIPN in North America, United Kingdom, or Europe.

Growing Market

The global CIPN market held a market value of \$1 Billion in 2021 and is forecasted to reach \$1.5 Billion by the year 2030 without any new marketed product.⁵



According to the National Cancer Institute, as of 2020, around 1,806,590 new cancer cases were estimated to be diagnosed in the United States, many of which will also experience CIPN.

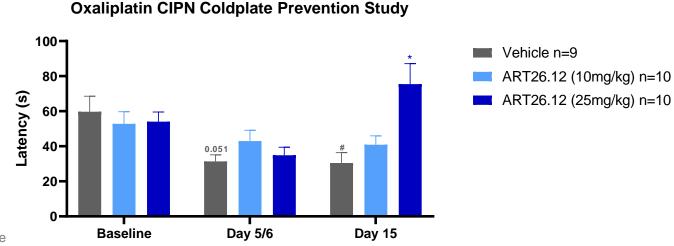


ART26.12: Non-Clinical Evidence for the Prevention and Treatment of Neuropathies

Prevention of CIPN

Prophylactic daily treatment with 25 mg/kg p.o. BID ART26.12 in multiple CIPN animal models

- Significantly reversed cold allodynia latencies in oxaliplatin induced CIPN by day 15
- Reduced mechanical and cold allodynia associated with paclitaxel induced CIPN by day 15[^]

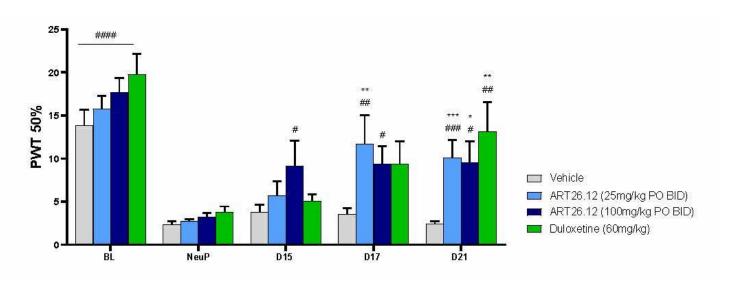


Values are presented as mean ± s.e.m. (n=9-11). Study was performed in male Sprague Dawley Rats. ^Data on file

Treatment of Diabetic Neuropathy (DN)

Oral treatment with 25 or 100 mg/kg, BID ART26.12 for seven days⁺ in male Wistar rats with streptozotocin (STZ) induced DN

- Significantly increased withdrawal thresholds[∓] over baseline <u>after first dose of 100mg/kg</u>
- Significantly increased withdrawal thresholds in both 25 and 100 mg/kg on third and seventh days of dosing
- Duloxatine delayed significant effect until seventh day







Can Anxiety be Treated Better?

Anxiety

- Most common mental health condition in the US**
 - Prevalence of 40 million adults
 - Incidence of ~19% of the adult population each year
 - Anxiety disorders include generalized anxiety disorder (GAD), panic disorder, social anxiety disorder (SAD), obsessive-compulsive disorder (OCD), and post-traumatic stress disorder (PTSD), among others
- 2021 \$11b WW market, \$16.25b by 2029 ⁺
- Most commonly used drugs are suboptimal
 - Issues of slow onset, dependance and drug interactions leave many unmet needs

Can CBD be Improved?

Cannabidiol (CBD)

- FDA approved Epidiolex® as safe and effective
 - Indicated for two forms of childhood epilepsy
 - Developed by Greenwich Biosciences and acquired by Jazz Pharmaceuticals for \$7.2b
 - 2022 revenue of \$736m
- Known therapeutic potential for the treatment of anxiety, depression, sleep, pain and inflammation
- Therapeutic utility is limited by its properties
 - High lipophilicity
 - Poor solubility and stability
 - Low oral bioavailability



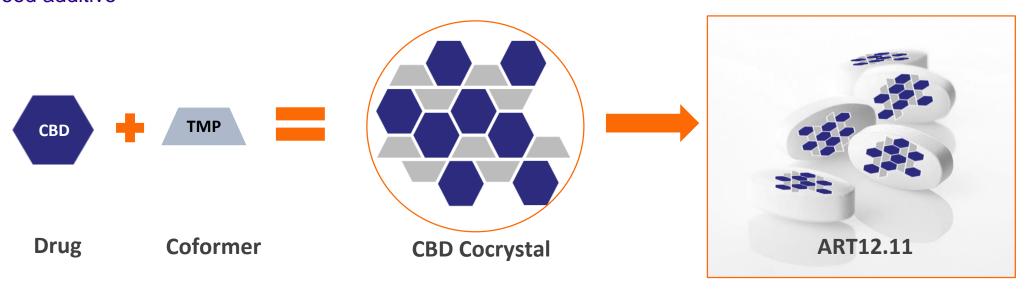
ART12.11 Leverages Cocrystalization to Improve CBD

Cocrystalization of CBD with TMP

- A validated pharmaceutical method for overcoming problematic drug properties
- A 1:1 ratio of CBD and tetramethylpyrazine (TMP; also called ligustrazine)
- Allows for precise control over purity, potency, and consistency
- TMP is a plant-derived compound from the Ligusticum species
- European Food Safety Authority (EFSA) approved TMP as a safe food additive

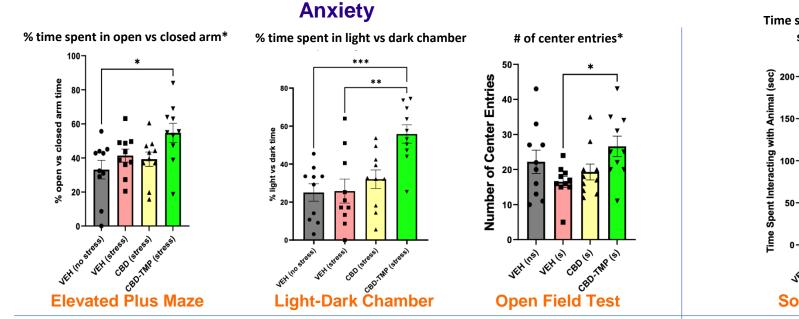
ART12.11

- Delivers higher levels of CBD and its major metabolite CBD-7COOH compared to CBD alone
- More soluble in Fasted State Simulation Intestinal Fluid (FaSSIF) and Fed State Simulated Intestinal Fluid (FeSSIF)
- CBD dissolution is improved in FaSSIF and FeSSIF
- A single crystalline melt and higher melting point (91 °C) than either individual component (CBD 65 °C)
- US Patent issued composition of matter and use Dec 10, 2038;
 PCT National phase filings WW underway

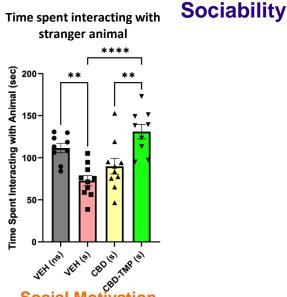


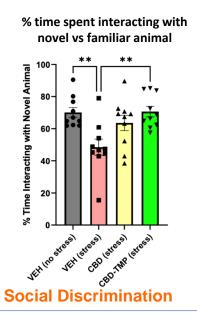


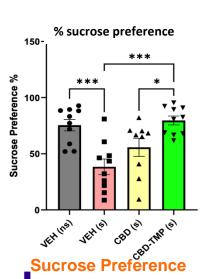
ART12.11 Data Shows Superior Preclinical Efficacy Compared to CBD

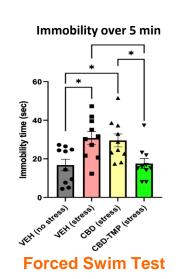


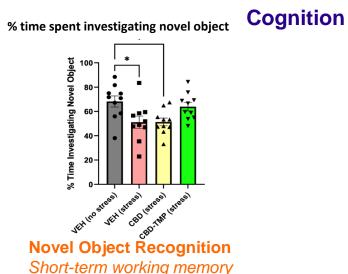
Depression

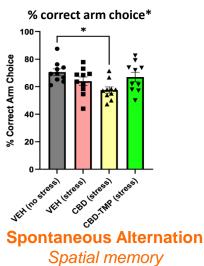












ART12.11 Summary of Superior Preclinical Efficacy Compared to CBD

Clinical Behavior	Behavioral Test	ART12.11 (3.5 mg/kg CBD + 1.5 mg/kg TMP p.o.)	CBD-alone (10 mg/kg p.o.)
Anxiety	Elevated plus maze	Anxiolytic	No effect
	Light-dark chamber	Anxiolytic	No effect
	Open field test	Anxiolytic	No effect
Depression	Sucrose preference	Anti-depressive (reversed stress effect)	No effect
	Forced swim test	Anti-depressive (reversed stress effect)	No effect
Sociability	Social motivation	Pro-social (reversed stress effect)	No effect
	Social discrimination	Pro-social (reversed stress effect)	No effect
Cognition	Novel-object recognition	Protected short term memory (reversed stress effect)	No effect
	Spontaneous alternation	Protected spatial memory (reversed stress effect)	Impaired spatial memory



Positive Effect



No Effect



Negative Effect





Accomplished and Anticipated Near-Term Milestones

2H 2022 ✓ ART26.12 Results from key non-clinical studies

1H 2023 ✓ ART27.13 Initiate Phase 2a CAReS cancer anorexia study

✓ ART12.11 Results from key non-clinical studies

2H 2023 ✓ ART26.12 Pre-IND meeting minutes from FDA

1H 2024 ART26.12 IND Submission

☐ ART12.11 Results from key non-clinical studies

2H 2024 ART27.13 Complete enrollment of Phase 2a CAReS cancer anorexia study



Company Capitalization (Nasdaq: ARTL)



Capitalization (as of 11/30/2023)	
Common Shares Outstanding	3,188,959
Warrants (WAEP \$55.60)	252,964
Options (WAEP \$15.79)	519,105
Total	3,961,028
Cash, Cash Equivalents, and Marketable Securities (As of 9/30/2023)	\$12.9M
No Debt	

Fully diluted ownership: 6% Officers/Directors



Proven Leadership

MANAGEMENT TEAM



Gregory Gorgas President & CEO, DirectorBiogen IDEC, Chiron, Cetus,
Upjohn, MAST



Steven D. Reich, MD Chief Medical Officer Pfizer, Ligand, Biogen, PAREXEL



Andrew Yates, PhD Chief Scientific Officer UK Pharmacist, AstraZeneca, Bristol Myers



Saoirse O'Sullivan, PhD VP, Translational Science Professor, University of Nottingham, UK



Jason Baybutt SVP, Finance PubCo Reporting

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Artelo Biosciences Summary



Cutting edge science focused on lipidsignaling and endocannabinoid system modulation

Risk mitigated by:

- Development stage
- Probability of success
- Mechanism of action



Well-capitalized to achieve multiple nonclinical and clinical achievements

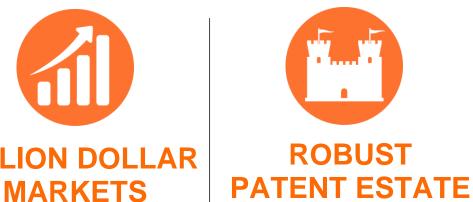
Planning ART26.12 IND submission in 1H2024

Expecting completion of enrollment of CAReS Phase 2a clinical study in 2H2024



Target indications for the portfolio are in multibillion dollar markets

- CIPN \$1B+
- Cancer anorexia \$2B+
- Prostate cancer \$9B
- Breast cancer \$18B
- Anxiety \$11B
- PTSD \$7B



Issued (38) and pending (37) patents (includes owned, licensed, and partnered)

Granted composition of matter and broad method claims ensure strong prospects for meaningful worldwide market exclusivity



Experienced team of biopharmaceutical executives, drug developers, and top tier researchers

Proven track records in developing and commercializing highimpact federally regulated therapeutics







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