
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): **November 14, 2019**

ARTELO BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

<u>Nevada</u> (State or other jurisdiction of incorporation)	<u>333-199213</u> (Commission File Number)	<u>33-1220924</u> (IRS Employer Identification No.)
<u>888 Prospect Street, Suite 210, La Jolla, CA USA</u> (Address of principal executive offices)		<u>92037</u> (Zip Code)

Registrant's telephone number, including area code **760-943-1689**

(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))

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 7.01. Regulation FD Disclosure.

On November 14, 2019, Artelo Biosciences, Inc. (“Artelo”) issued a press release announcing that Gregory D. Gorgas, President and Chief Executive Officer of Artelo, is scheduled to present at the Annual Investival Showcase at 11:30 a.m., GMT, to be held on November 19, 2019 at the Waldorf Hilton Hotel in London, England. During the conference and in separate sessions with analysts and investors, Mr. Gorgas will refer to an updated slide presentation. A copy of this updated slide presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Investor Presentation.

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.

/s/ Gregory Gorgas

Gregory Gorgas
President & CEO

Date November 15, 2019



Artelo

BIOSCIENCES

A clinical stage biopharmaceutical company developing and commercializing a portfolio of novel therapeutic candidates targeting the endocannabinoid system

Nasdaq: ARTL

November 2019

Forward Looking Statements

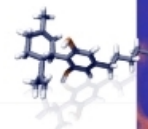
Statements in this presentation of Artelo Biosciences, Inc. (the "Company") that are not historical facts are "forward-looking statements" subject to risks/uncertainties. Such statements are based on current facts/analyses and other information that are based on forecasts of results, estimates of amounts not yet determined, and assumptions of management. Such statements are generally, but not always, identified by the words "expects", "plans", "anticipates", "believes", "intends", "estimates", and similar expressions or that events or conditions "will", "would", "may", "can", "could" or "should" occur. Information concerning reserve estimates may also be deemed to be forward looking statements, as it constitutes a prediction of what might be present when/if a project is actually developed.

It is important to note that actual outcomes and results could differ materially from those in such statements due to numerous factors beyond the Company's control including misinterpretation of data, inaccurate estimates of timelines, uncertainty of the requirements demanded by governmental agencies, Company's ability to raise funds in future financings, breach of agreements by third-parties, inability to retain employees/consultants, competition for equipment, inability to obtain permits, delays in operations, inability to maintain licensing agreements, the likelihood that no commercial markets exist for the Company's products, and our ability to develop products.

This presentation and the information contained in this presentation are confidential and proprietary and are being given to you on a confidential basis. No part of this presentation or the information contained herein may be reproduced, photocopied, redistributed or passed on, directly or indirectly, to any other person (whether within or outside your organization/firm) or published, in whole or in part, for any purpose.

This presentation is for informational purposes only. This presentation does not constitute an offer to sell or a solicitation of an offer to buy any securities of the Company, which offer or solicitation shall only be made by means of a prospectus filed with the U.S. Securities and Exchange Commission, nor shall it or any part of it, or the fact of its distribution, form the basis of or be relied on in any way in connection with any sale of securities of the Company.

Artelo Biosciences, Inc.



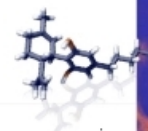
Clinical stage biopharmaceutical company developing and commercializing a portfolio of novel therapeutic candidates targeting the Endocannabinoid System (ECS)



- The ECS is a family of receptors and neurotransmitters that form a biochemical communication network throughout the body
- The ECS maintains a healthy state in response to environmental changes
- For the treatment of disease, stress, and adverse medical conditions, modulating the vast potential of the ECS may lead to new and significantly improved medical treatments

*“Modulating ECS activity holds therapeutic promise for a broad range of diseases, including neurodegenerative, cardiovascular and inflammatory disorders, obesity/metabolic syndrome, cachexia, chemotherapy-induced nausea and vomiting, tissue injury and pain, among others.”**

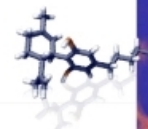
Pipeline



Product Candidate	Pre-clinical	Phase 1	Phase 2	Market Size
ART 27.13 Cannabinoid Agonist	Anorexia associated with Cancer			Cancer Anorexia Cachexia Syndrome: \$2B
ART 12.11 CBD Cocystal	Inflammatory Bowel Disease PTSD			IBD (Crohn's & Colitis): \$9B Post-Traumatic Stress Disorder: \$7B
ART 26.12 FABP5 Inhibitor	Prostate Cancer Breast Cancer			Prostate Cancer: \$8B Breast Cancer: \$13B

Therapeutics market size based upon total global annual Rx sales in 2016, 2017 or 2018

Patent Estate & Licenses



Product Candidate	Patent Status	License
ART 27.13 Cannabinoid Agonist	Two (2) issued patents (US & Intl) including composition of matter, term 11/3/25	Worldwide exclusive license
ART 12.11 CBD Cocystal	Pending composition of matter applications (US & Intl), filed 12/10/18, priority 12/11/17	N/A (owned by Artelo)
ART 26.12 FABP5 Inhibitor	Two (2) patents issued (US), term 7/19/30 and 7/19/33, and three (3) pending (Intl) covers the target, composition of matter, and utility claims, filed 7/19/10, 7/19/13, and 3/10/17	Worldwide exclusive license

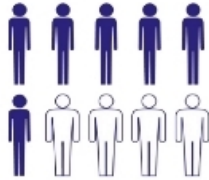


ART 27.13

CANCER ANOREXIA CLINICAL PROGRAM



Cancer Anorexia and Cachexia Syndrome (CACS) Remains a High Unmet Need



Cancer-related anorexia affects about 60% of advanced stage cancer patients

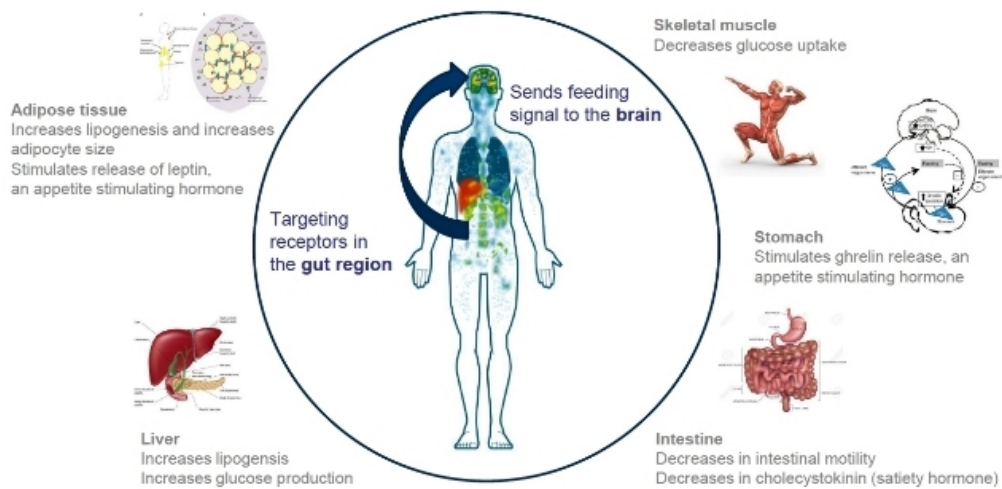
CACS therapy market currently exceeds \$2 billion globally and could increase significantly with proprietary new market entries



Although there are no FDA approved drugs for CACS, several agents are used off-label with limited success

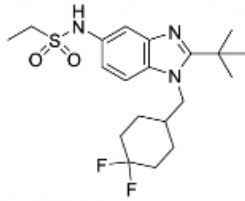
- Appetite stimulants
- Anabolic agents
- Cytokine & metabolic inhibitors

Link Between Cannabinoid Receptor Activation and Appetite is Well Established



Cannabinoid-Based Drug is Unique Among Late Stage Agents Targeting CACS

ART27.13 is differentiated from other current clinical programs



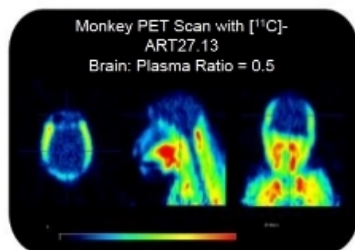
- Peripherally restricted synthetic new chemical entity
- High-potency dual CB₁/CB₂ cannabinoid agonist
- Established mechanism of action

Other investigational approaches

Cannabix SR 5 mg (Cannabix)	Macimorelin (Aeterna Zentaris)	Ruxolitinib (Novartis)	Anamorelin/ONO-7643 (Helsinn)
<ul style="list-style-type: none"> • Oral, small-molecule THC • Delivery via a proprietary, sustained-release capsule • Phase 2A CACS trial completed April 2018 (NCT02359123) 	<ul style="list-style-type: none"> • Brand name: Macrilen • Ghrelin mimetic (also known as growth hormone secretagogue) • FDA approved in 2017 for the diagnosis of adult growth hormone deficiency • Currently in Phase 2 study for cachexia in adults with incurable solid tumors (NCT01614990) 	<ul style="list-style-type: none"> • Brand name: Jakafi • A selective, orally available JAK1/2 inhibitor • FDA approved in 2011 for myelofibrosis; supplemental approval for polycythemia vera in 2014 • Currently in Phase 2 trial for adults with cachexia and confirmed tumors of any site (NCT02072057) 	<ul style="list-style-type: none"> • Brand name: Adlumiz • Ghrelin-receptor agonist, targets the growth hormone secretagogue receptor 1a • Two CACS studies are ongoing: <ul style="list-style-type: none"> • Phase 2: Fatigue in solid tumors (NCT03035409) • Phase 2/3: Anorexia in NSCLC (NCT03637616)

Synthetic Cannabinoid Rationally Designed for an Attractive Safety Profile

Peripheral acting ART27.13 avoids undesired cannabis “high” by targeting the body not the brain



Enables systemic metabolic effects while minimizing central nervous system mediated toxicity

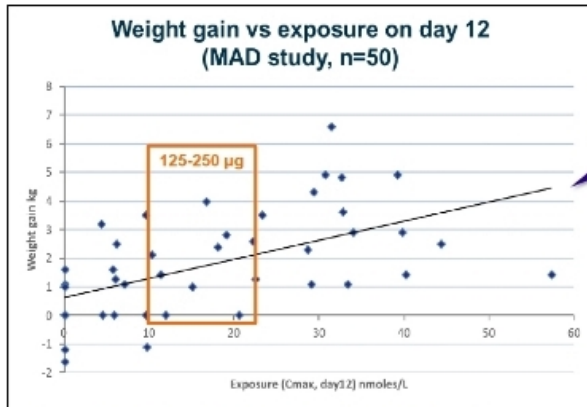
Acceptable side effect profile at the intended dose for the planned phase 2 study in cancer anorexia

Side effects	Placebo	ART27.13 (250 µg)
Mild	91%	89%
Moderate	9%	10%
Severe	0%	1%
# Events/subjects	121/10	169/8

MAD = Multiple Ascending dose study with 8 subjects receiving ART27.13 at 250 µg and 10 receiving placebo

Correlation of Exposure to Weight Gain Observed in Phase 1 Study

Feeding and weight gain effect significantly different between ART27.13 and placebo



Multiple ascending dose (MAD) clinical study observed weight gain slope is significantly different from flat line of placebo (p=0.0001)

Over 12 days, 25% of subjects at the target dose for the planned phase 2 study gained 3% or greater of their baseline body weight

ART27.13 Planned Phase 1b/2a Study

Study:	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, safe dose (recommended Phase 2 dose, or RP2D) to be used in Stage 2 Phase 2a - Determine point estimates of activity of ART27.13 in terms of weight gain, lean body mass, and improvement of anorexia at the RP2D
Regulatory:	Clinical Trials Application required in UK. FDA and Health Canada have already reviewed protocol concept and had no objections (option to file IND or equivalent in Canada as needed).
Size:	Up to 49 subjects
Sites:	All clinical sites in UK (option to expand with potential sites in Canada and US)
Cost:	~\$3 M
Duration:	Estimated at 12 months Expecting to open study upon successful manufacture clinical supply and regulatory clearance



ART 12.11
PROPRIETARY CBD COCRYSTAL PROGRAM

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Creating a Better Cannabidiol (CBD)

We are developing a more attractive CBD for pharmaceutical development

What is good about CBD?

Chemical has known medical applications

Potential for broad application due to multiple effects in the body

- anti-inflammatory
- anxiolytic
- neuroprotectant

Sole active ingredient in a product that was recently FDA approved for childhood epilepsy

What could be better?

CBD is in the public domain with market exclusivity challenges

Address manufacturing and delivery issues

Improve consistency of exposure affected by polymorphism



Our solution

CBD cocrystal

Proprietary CBD with composition of matter patent protection

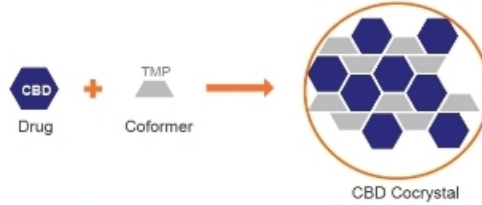
Enhanced pharmaceutical properties



Cocrystals are Accepted in Pharmaceuticals and New to CBD

CBD cocrystal leverages an innovative, USPTO and FDA supported pharmaceutical strategy

CBD Cocrystalization



Blockbuster cocrystals

Therapeutic	Innovator	FDA Approval	Indication	Annual Sales
Entresto®	Novartis	2015	Heart Failure	>\$1B global (2018)
Lexapro®	Forest Labs	2002	Depression Anxiety	>\$2B US (2005)

Competitive Advantages of Next-Generation CBD Cocystal

Potential next-generation benefits are derived from multiple proprietary features

Proprietary Features

- ✓ Unique new chemical entity
- ✓ Addresses issues associated with polymorphism to improve pharmaceutical properties
- ✓ Synthetic manufacture of solid-state dosage form
- ✓ Leverages known uses of two active chemicals
- ✓ Composition of matter patent pending

Expected Benefits

- Proprietary to Artelo with worldwide market exclusivity
- Greater consistency of exposure resulting in improved safety/efficacy
- Favorable manufacturing costs with high margins
- Human data from clinical and commercial use indicates favorable efficacy and safety profile
- Multiple protected large pharmaceutical markets



ART12.11 CBD Cocystal

Priority Indications for Development of Proprietary CBD Cocystal

CBD activity in PTSD and IBD support ART12.11's development strategy

Post-Traumatic Stress Disorder

- Anxiety disorder caused by very stressful, frightening or distressing events
- Affects almost 7% of American adult population
- Often manifests in anxiety symptoms, insomnia, isolation
- Common treatments include antidepressants, anxiolytics, CBD-rich cannabis, sleep medications, mood stabilizers, narcotics, and non-narcotic pain drugs
- CBD cocystal's cofomer (TMP) has preclinical efficacy evidence in PTSD as a single agent
- Planning to study CBD cocystal as treatment for symptoms of PTSD, particularly anxiety and sleep disturbances

Inflammatory Bowel Diseases

- Illnesses characterized by chronic inflammation of the gastrointestinal tract, including ulcerative colitis and Crohn's disease
- Current treatment exposes patients to risks of opportunistic infections, bone marrow suppression, adrenal suppression, gastric ulceration and pancreatitis
- CBD was able to reduce increases in epithelial permeability secondary to inflammation
- Cannabinoids help induce remission in Crohn's disease
- IBD patients using cannabis report symptomatic relief
- CBD had a permeability-reducing effect in the small bowel and colon in Phase 1 study



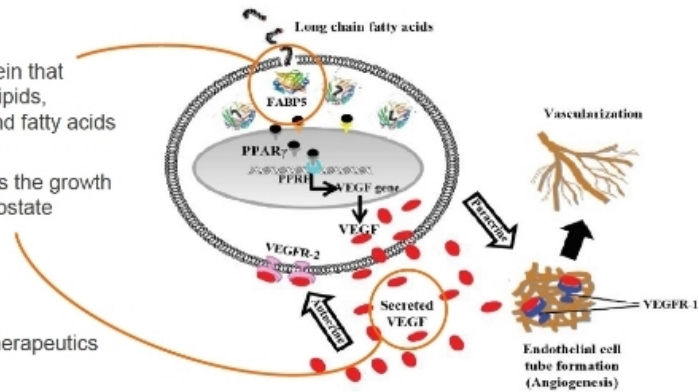
ART 26.12
FABP5 INHIBITOR PROGRAM

Artelo
BIOSCIENCES

Lipid Signaling Pathways are a Next-Generation Target for Cancer Therapeutics

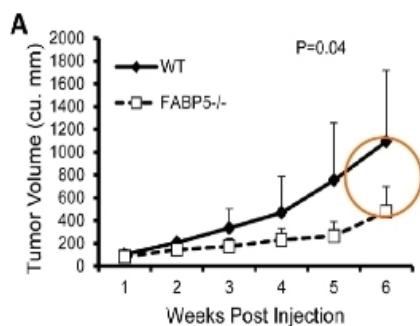
FABP5 inhibitor was developed at Stony Brook University with multi-million dollar NIH funding

- FABP5 is an intra-cellular protein that serves as a carrier for certain lipids, including endocannabinoids and fatty acids
- Inhibition of FABP5 suppresses the growth and migration of breast and prostate cancers
- Modulating lipid signaling has the potential to be the next revolution in cancer therapeutics

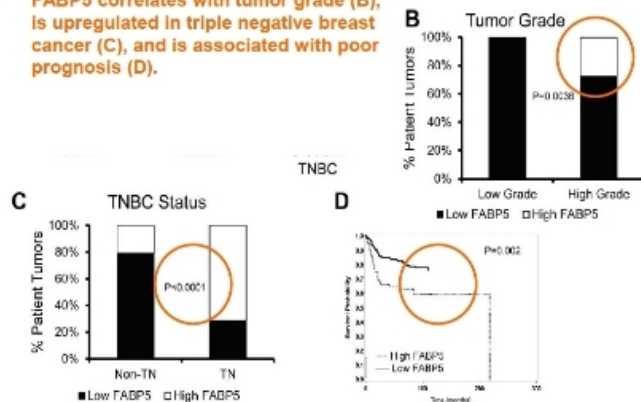


FABP5 is a Validated Target in Breast, Prostate, and Cervical Cancer

Genetic silencing of FABP5 is anti-tumor (A)



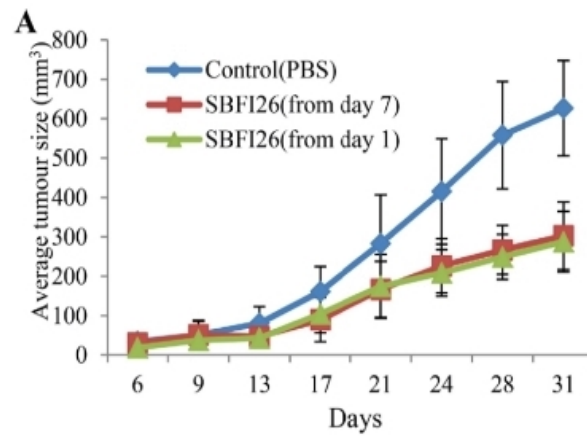
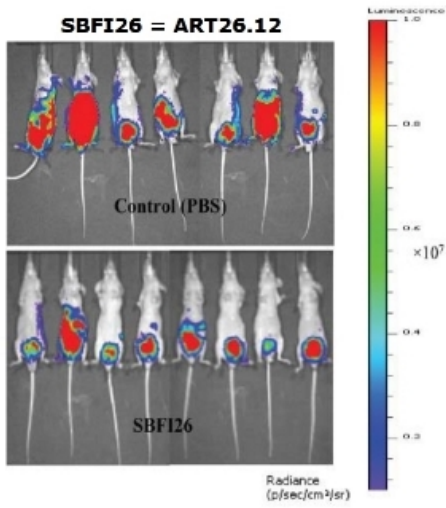
FABP5 correlates with tumor grade (B), is upregulated in triple negative breast cancer (C), and is associated with poor prognosis (D).



WT = Wild Type. Powell et al., 2015 Oncotarget vol 6, no. 6 p6373-6385

Data above from breast cancer. Liu et al., 2011; Levi et al., 2013; Powell et al., 2015; Guaila Esteruelas et al., 2017. Similar findings published in prostate and cervical cancer. Forootan et al., 2010; Jeong et al., 2012.

FABP5 Inhibitor Decreases Tumor Growth in Prostate Cancer Model

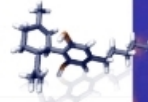


Inhibitor SBFI26 suppresses the malignant progression of castration-resistant PC3-M cells by competitively binding to oncogenic FABP5. *W. Al-Jameel, Oncotarget, 2017, Vol. 8, (No. 19), pp. 31041-31061*



COMPANY

Artelo
BIOSCIENCES



Proven Leadership

MANAGEMENT TEAM



GREGORY GORGAS
President & CEO, Director
 BiogenIdec, Chiron, Cetus, Upjohn
Proven global biopharma success with four first-in-class launches



STEVEN D. REICH, MD
Chief Medical Officer
 Pfizer, Ligand, Biogen, PAREXEL
Demonstrated clinical track record in academia, service provider and pharmaceutical industry



JASON BAYBUTT
SVP, Finance
 PubCo Reporting
US and Canadian public company experience



PETER O'BRIEN
SVP, European Operations
 HSBC, Medical Staff Ireland, SPR
 Global Technologies, Nursing Station
Serial entrepreneurial performance with multiple positive exits

BOARD OF DIRECTORS



CONNIE MATSUI
Chair of the Board
Nominating & Governance Committee Chair
 BiogenIdec, Wells Fargo, Board Chair Halozyme



STEVEN KELLY
Compensation Committee Chair
 Carisma, Theracrine, Amgen, IDEC, Sanofi



DOUGLAS BLAYNEY, MD
 ASCO President, Stanford Cancer Center,
 University of Michigan, NCI



GEORGIA ERBEZ
Audit Committee Chair
 Jefferies, Cowen, H&Q, Raptor Pharmaceuticals



R. MARTIN EMANUELE, PhD
 DuPont, Avanir, DaVita

SCIENTIFIC COLLABORATORS



SAOIRSE O'SULLIVAN, PhD
 Cannabinoid Professor, University
 of Nottingham, UK,



ANDREW YATES, PhD
 UK Pharmacist, AstraZeneca



STEVE LAVIOLETTE, PhD
 University of Western Ontario,
 Canada

Company Capitalization (Nasdaq: ARTL)

Market Cap	USD \$7.39M
Shares Outstanding	3,415,016
Warrants	2,143,875
Options	231,500
Fully Diluted	5,790,376

Data from October 16, 2019



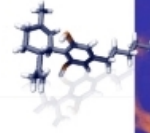
Series A warrant strike price - \$8.00 (# 244,042)
Series B warrant strike price - \$12.00 (# 163,620)
Series C warrant strike price - \$14.00 (# 87,644)
Series D warrant strike price - \$14.00 (# 209,665)
Series E Warrant strike price - \$16.00 (# 33,984)

Options strike price - \$10.80 (# 50,000)
Option strike price - \$1.99 (# 181,500)

Tradable Warrant (ARTLW) price - \$6.45 (# 1,491,915)

S-1 Registrations were made effective for selling stockholders May 30, 2018 and October 5, 2018

Ownership – fully diluted:
Officers, Directors (15%)
Shareholders (85%)



Accomplished and Anticipated Milestones

- 1H 2019**
 - ✓ Raised \$1.6M in private placements
 - ✓ Public offering \$8M (net \$7.3M)
 - ✓ Nasdaq listing
- 2H 2019**
 - ✓ ART27.13 Licensing payment fully paid
 - ✓ ART26.12 Milestone one payment made for accomplishing lead optimization
 - ✓ ART26.12 Publication of non-clinical research combination of FABP5 inhibitor and chemotherapy
- 1H 2020**
 - ❑ ART27.13 Manufacture clinical material for cancer anorexia study
 - ❑ ART26.12 and ART12.11 Initiate regulatory enabling non-clinical studies
 - ❑ ART12.11 Composition of matter patent for CBD cocrystal from USPTO
- 2H 2020**
 - ❑ ART27.13 Initial clinical data from cancer anorexia study

Company Summary



NOVEL DRUG PIPELINE

Developing federally regulated therapeutics from cutting edge science focused on the endocannabinoid system

- Cannabinoid Agonist
- CBD Cocrystal
- Novel Protein Inhibitor

Optimized for development stage, probability of success, and mechanism of action



ROBUST PATENT ESTATE

Comprehensive issued (4) and pending (4) patents (includes owned and licensed)

Anticipating filing additional patent applications / receiving issued patents in 2019-2020

Composition of matter and broad claims ensure meaningful worldwide market exclusivity



NEAR-TERM MILESTONES

Clinical milestone readout expected for lead program in 2020

Multiple pre-clinical achievements planned over next 12-18 months



BILLION DOLLAR MARKETS

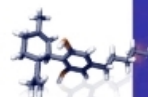
Target indications for the portfolio are in multi-billion dollar markets

- Cancer anorexia \$2B
- IBD \$9B
- PTSD \$7B
- Prostate cancer \$8B
- Breast cancer \$13B



PROVEN LEADERSHIP

Experienced team of pharmaceutical executives and cannabinoid researchers with proven track records in developing and commercializing high-impact federally regulated therapeutics





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For more information:
www.artelobio.com
