



# Artelo

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***Company Presentation***

March 2018

# Forward Looking Statements

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Statements in this Artelo Biosciences presentation 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 financing, breach by third-parties, inability to retain employees/consultants, competition for equipment, inability to obtain permits, delays in operations, problems with licensing agreements, the likelihood that no commercial markets exist for our products, and our ability to development products.

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**Company**

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## Introduction

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Company: **Public quoted in the US**

Sector: **Cannabinoid-based pharmaceuticals**

Focus: **Endocannabinoid system modulation**

Therapeutic areas: **Pain, Inflammation, Cachexia, Cardiovascular, Cancer**

Stock symbol: **ARTL**

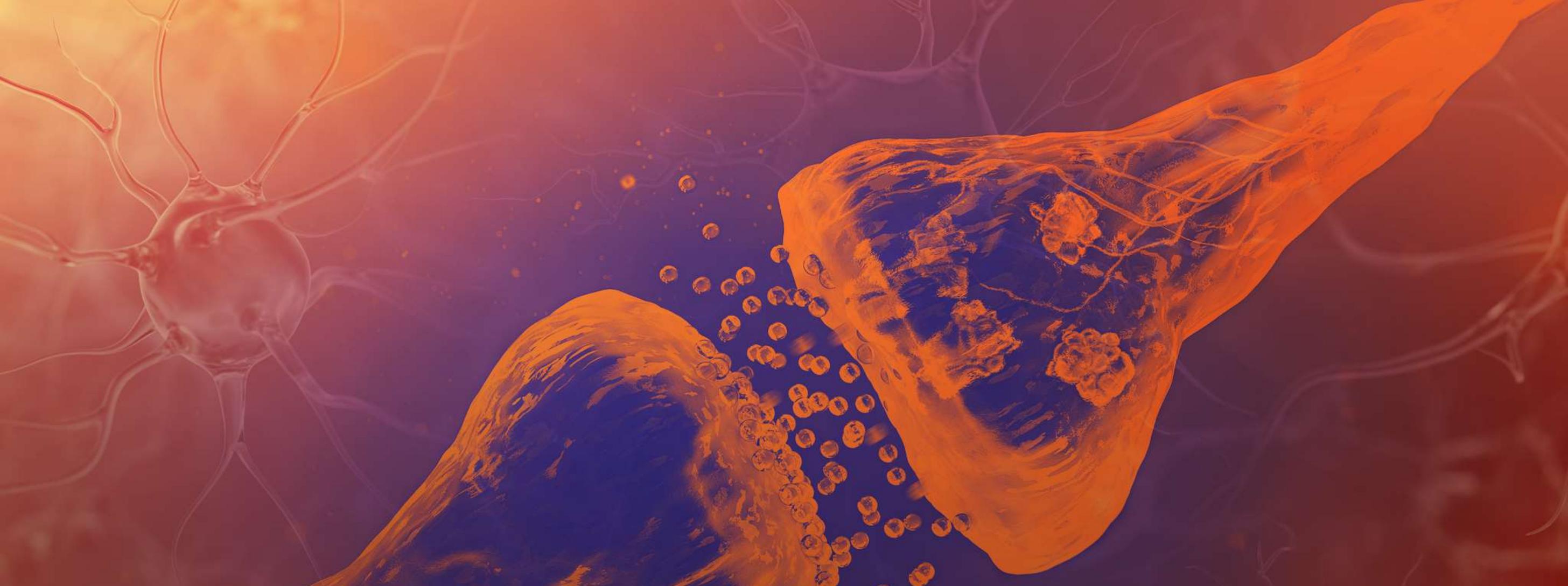
Exchange: **OTC**

Liabilities: **No debt**



**US Headquarters: San Diego, California**

**European Hub: Dublin, Ireland**



**Leading Science**

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## Potential of the Endocannabinoid System (ECS)

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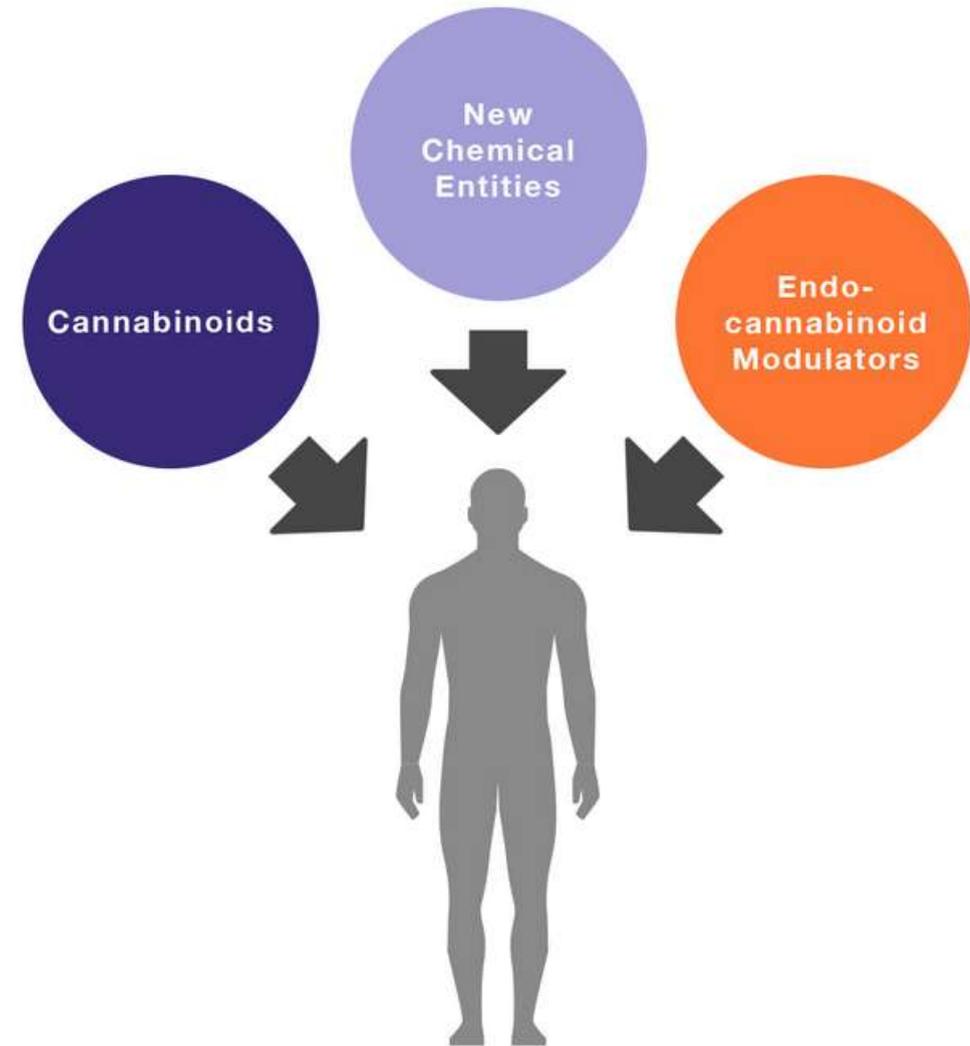
***“Modulating the ECS activity may have therapeutic potential in almost all diseases affecting humans, including obesity/metabolic syndrome, diabetes and diabetic complications, neuro-degenerative, inflammatory, cardiovascular, liver, gastrointestinal, skin diseases, pain, psychiatric disorders, cachexia, cancer, chemotherapy-induced nausea and vomiting, among many others.”***

Laboratory of Physiologic Studies, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Bethesda, Maryland, USA – May, 2013

## Artelo's Approach to Modulating the ECS

**We are developing a portfolio of novel pharmaceuticals that address serious medical conditions**

**Our programs are based on multiple mechanisms to target and modulate the ECS**





# Pipeline

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# Full Spectrum ECS Modulation Pipeline

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Cannabinoids

## ART12.11 Novel CBD Composition

- Provisional patent filed in December 2017 claiming improved composition
- Addresses physical polymorphism challenges with CBD
- Invented by Artelo scientists in collaboration with US-based top-tier CRO
- Planning development in inflammation, pain, and cardiovascular diseases



Endo-cannabinoid Modulators

## ART26.12 FABP5 Inhibitor

- FABP5 inhibitor program is designed to increase endogenous anandamide levels
- Pre-IND research stage program
- Licensed from Stony Brook University (NY)
- Planning development in cancer, pain and inflammation



New Chemical Entities

## ART27.13 High-Potency Dual Agonist

- High-potency, dual CB1/CB2 agonist designed to be peripherally restricted
- Safety data on over 200 subjects from five clinical studies; notable weight gain observed
- Licensed from The NEOMED Institute (Montreal, Canada)
- Clinic ready for cachexia and direct anti-tumor screening *in vitro* studies underway

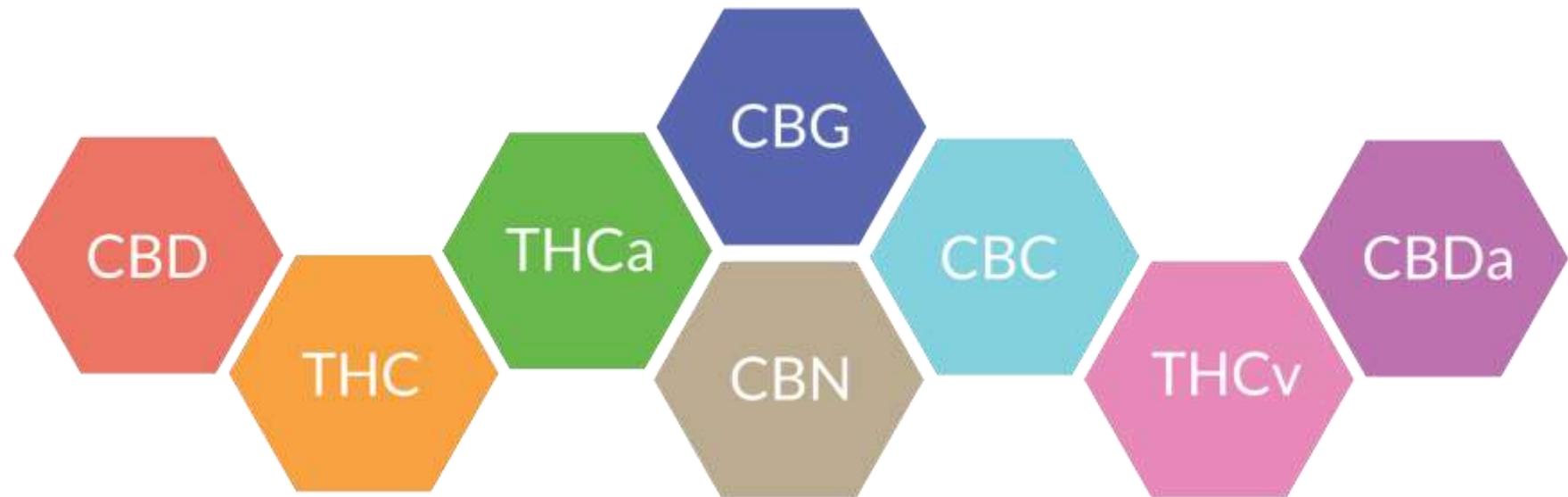


**ART 12.11**  
**Proprietary CBD Composition**

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## What is Cannabidiol (CBD)?

- **Second most abundant chemical found in the flowering bud of the cannabis plant**
- **Does not cause the same psychotropic effects as THC**
- **Has a multiple effects in the body:**
  - anti-inflammatory
  - anti-oxidant
  - anxiolytic
  - analgesic
  - anti-epileptic
  - anti-tumoral
  - neuroprotectant
  - vasodilator



## Therapeutic Potential of Cannabidiol (CBD)

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### Beyond current clinical use in multiple sclerosis and epilepsy, non-clinical evidence supports CBD's potential for multiple therapeutic applications:

- Inducing tumor-cell specific cell death *in vitro* and *in vivo* in breast, lung and colon cancer, limiting cancer cell migration and metastases, reducing new blood vessel formation at tumors
- Reducing the onset and pancreatic inflammation associated with type 1 diabetes and reducing symptoms (cardiac and endothelial dysfunction, pain (neuropathy) and eye problems (retinopathy) associated with type 1 and 2 diabetes
- Improving cardiac and vascular function and reducing blood pressure
- Offsetting the effects of ischemia/reperfusion damage (lack of oxygen) in models of stroke, acute liver or kidney damage, and global hypoxia
- Reducing gastrointestinal inflammation and reducing nausea and vomiting and colonic hypermotility
- Reducing pain and inflammation in models of arthritis

## ART12.11 Cannabidiol (CBD) Composition Superiority

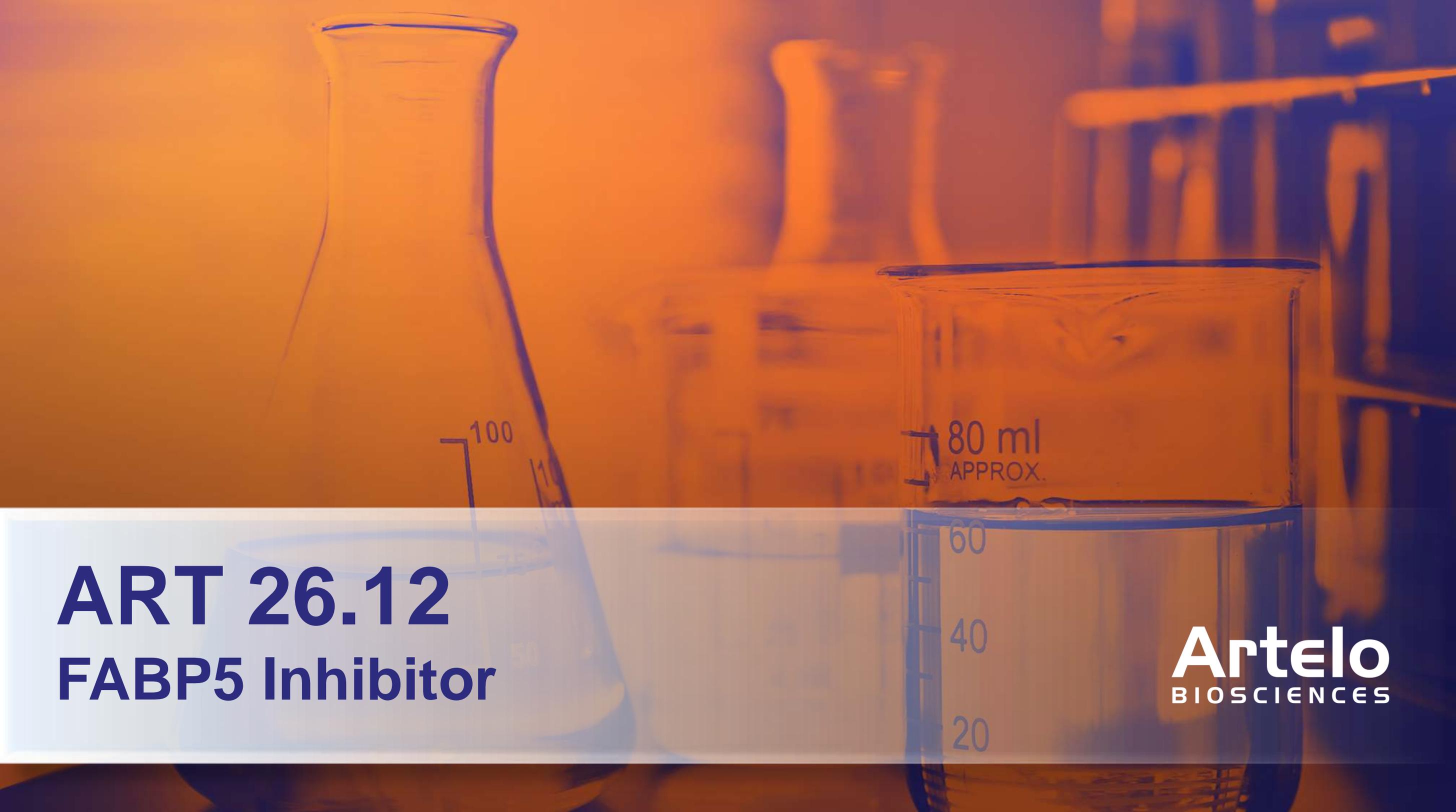
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- What is so medicinally enticing about CBD?
  - There is strong evidence supporting CBD's therapeutic activity
  - The WHO has designated CBD as safe\*
  - Epidiolex (GWPH) PDUFA date: June 27, 2018\*\*
- What opportunities are there to make CBD more pharmaceutically attractive?
  - CBD is in the public domain
  - Plant-extracted and synthetic CBD exhibits significant physical polymorphism leading to high variability in drug absorption and consistency of exposure

**ART12.11 successfully addresses both the proprietary challenge and the opportunity for a more consistent and stable formulation**

World Health Organization, Expert Committee on Drug Dependence, Thirty-ninth Meeting Geneva, 6-10 November 2017. [http://www.who.int/medicines/access/controlled-substances/5.2\\_CBD.pdf](http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf)

\*\*<https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-announces-acceptance-nda-filing-epidiolex%C2%AE-cannabidiol-treatment/>

A background image of laboratory glassware, including a large Erlenmeyer flask on the left and a beaker on the right, both containing a light-colored liquid. The scene is lit with a warm, orange-red glow. The beaker has markings for 20, 40, 60, and 80 ml, with the text '80 ml APPROX.' visible. The Erlenmeyer flask has a '100' marking.

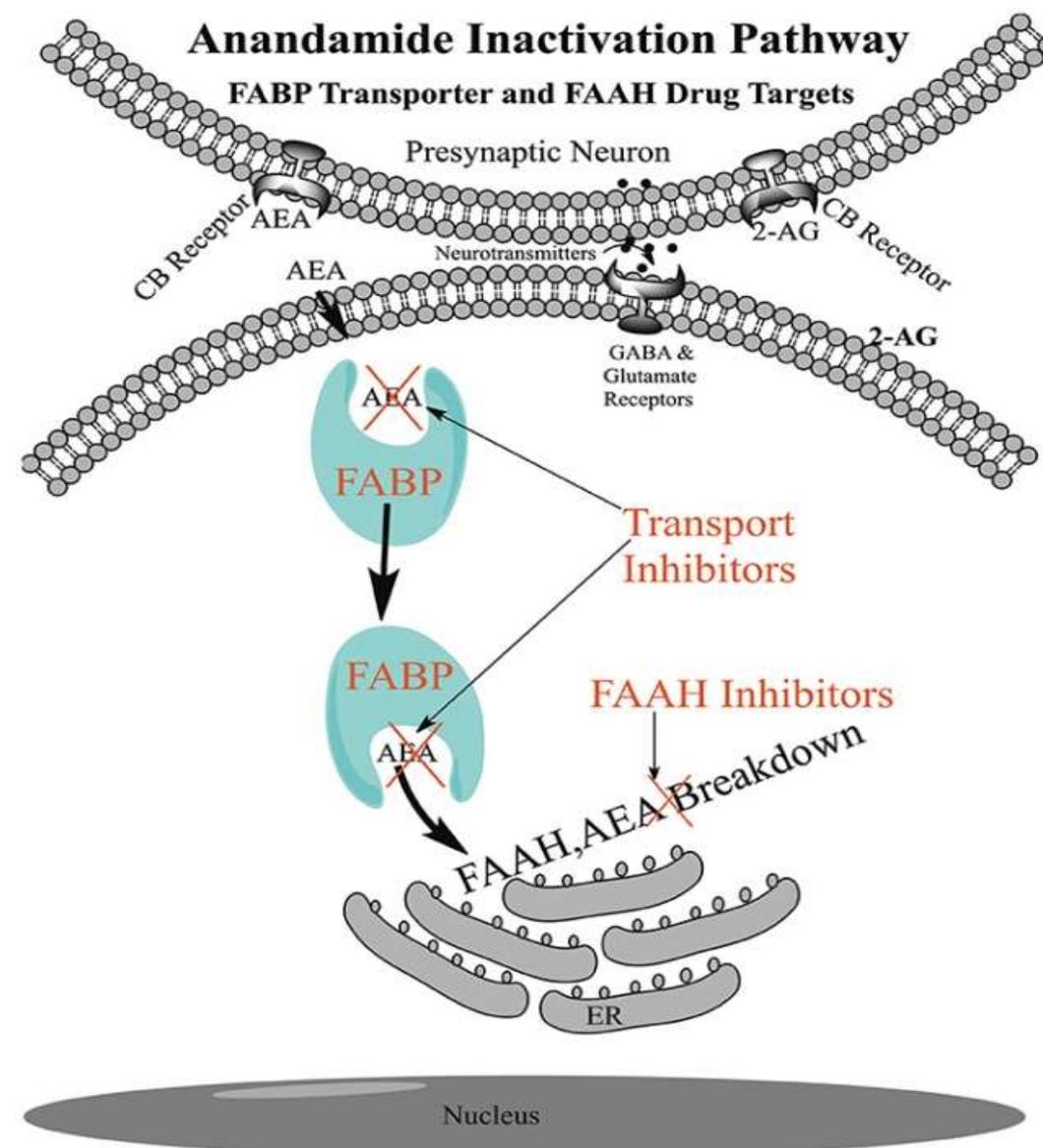
# ART 26.12

## FABP5 Inhibitor

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## FABP5 and the Endocannabinoid System

- Overexpression of FABP5 increases the hydrolysis of anandamide (AEA) and FABP inhibition decreases AEA hydrolysis
- FABP5 inhibition increases AEA levels i.e. alternative mechanism to increase endocannabinoid tone (similar to FAAH inhibition)
- FABP5 inhibition leads to CB<sub>1</sub>-mediated analgesia



## FABP5 and Cancer

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- FABP5 is upregulated in **breast cancer (including triple-negative)** and correlated with tumor grade and poor prognosis and FABP5 silencing decreases breast cancer cell growth and tumor growth in mouse models, and decreases epidermal growth factor receptor (EGFR) expression (Liu et al., 2011; Levi et al., 2013; Powell et al., 2015)
- FABP5 is upregulated in **prostate cancer** and FABP5 silencing decreases tumor size in mice (Forootan et al., 2010)
- FABP5 is upregulated in **cervical cancer**, expression correlates with metastasis and tumor size and independent risk factor for poor diagnosis, silencing decreases tumor growth and metastasis in mouse models, MMP-2 and MMP-9 (Wang et al., 2016)
- How is FABP5 pro-cancerous and why may an inhibitor be useful?
  - EGFR signalling upregulates FABP5 which then delivers PPAR $\beta/\delta$  activating ligands to the nucleus that result in the upregulation of cell growth and survival genes (Kannan-thulasiraman et al., 2009; Levi et al., 2013)
  - FABPs deliver PPAR $\gamma$  ligands which increase VEGF transcription promoting angiogenesis (Forootan et al., 2016)

## ART26.12 Next Generation Endocannabinoid Modulator

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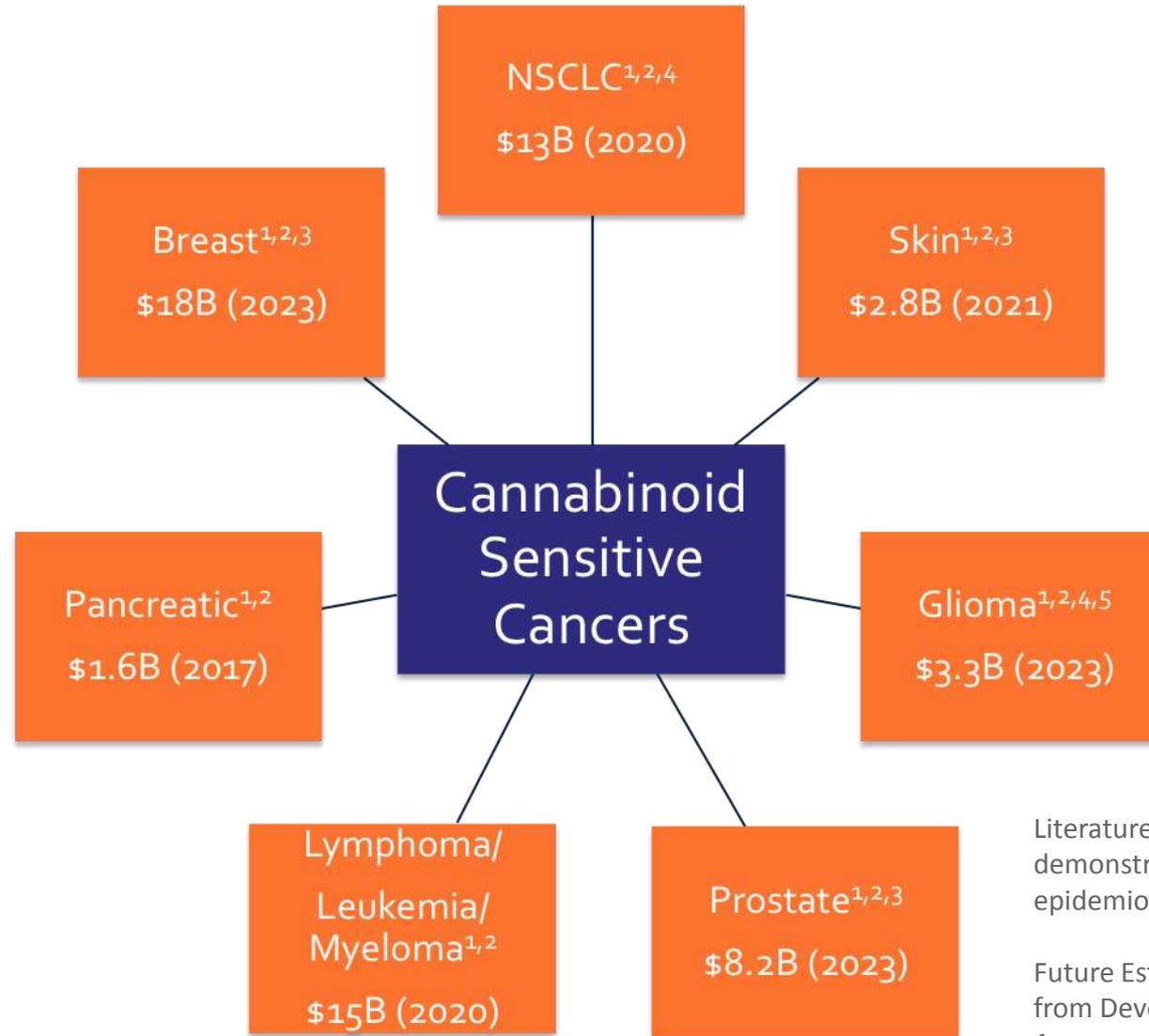
- ART26.12 is a highly-selective, highly-potent FABP5 inhibitor
- FABP5 inhibitors represent a novel and exciting mechanism of modulating the endocannabinoid system
- FABP5 inhibitors are likely candidates in pain and oncology
- Artelo intends to develop ART26.12 for indications in pain, inflammation, and cancer (breast and prostate)
- In the next 8-12 months, in collaboration with Stony Brook University, we expect to develop, formulate and test a novel, selective lead FABP5 inhibitor to take forward into IND-enabling studies



**ART 27.13**  
**High-Potency Dual Agonist**

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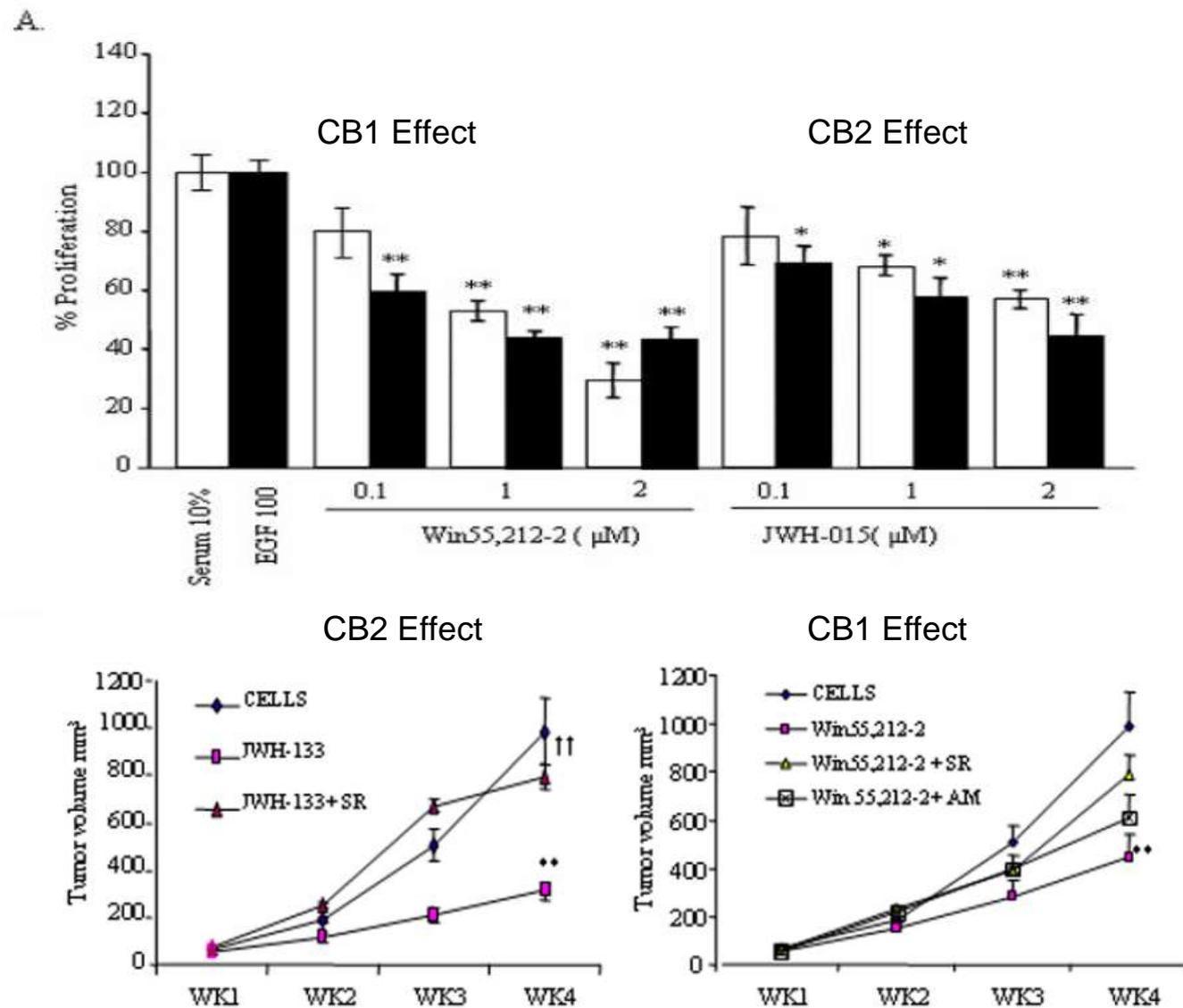
# Multiple Cancer Types are Sensitive to Cannabinoids



Literature CB1 and/or CB2 directed anti-tumour activity demonstrated in 1) ex-vivo, 2) in-vitro, 3) in-vivo, 4) human epidemiology 5) human clinical data

Future Estimates for total worldwide sales in cancer types obtained from Developments in Cancer Treatments, Market Dynamics, Patient Access and Value Global Oncology Trend Report 2015 IMS

## Supportive Activity Data for CB1/CB2 Agonists as Anti-Tumor Agents



- Synthetic cannabinoids have anti-tumor effects as a monotherapy
- Effects are blocked by cannabinoid antagonists
- Driven by both CB<sub>1</sub> and CB<sub>2</sub> effects
- >50% inhibitory effects observed for cell killing, tumor shrinkage and reduction in metastasis
- JWH (CB<sub>2</sub>) and Win (CB<sub>1</sub>) are not suitable for the clinic and very few dual CB<sub>1</sub>/CB<sub>2</sub> agonists have been designed to be peripherally restricted; reducing CNS side effects

*Cancer Prev Res (Phila)* . 2011 January ; 4(1): 65–75.

## ART27.13 Advancing as an Anti-Cancer Agent

- Cachexia and treatment of cancer are both attractive opportunities
- A key focus will be understanding the novel anti-tumor potential
- We intend to fully explore cachexia with additional investment into supporting research
- First clinical PoC study could test hypothesis of both cachexia and effects on tumors

**2005-2009**

### AZD1940

- Potent *peripherally restricted* CB1/CB2 agonist (AZ12368920)
- 5 clinical trials conducted under IND1
- Pain

**2012**

### NEO1940

- IP transferred to The NEOMED Institute
- Cachexia

**2018**

### ART27.13

- MDTA exclusivity with Artelo
- Artelo's option to trigger full license before Q1 2019
- Cachexia
- Cancer



# Proven Leadership

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## Executive Management

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### **Gregory Gorgas, President & CEO**

Over 30 years of high-impact commercial and development experience as biotech veteran and entrepreneur, including global marketing leadership of Biogen's worldwide cancer business, commercial officer at Mast Therapeutics with orphan disease expertise, Theragence co-founder and director, and four significant first-in-class launches in addition to more than a dozen successful product launches at IDEC, Chiron, Cetus and Upjohn.



### **Peter O'Brien, Senior Vice President, European Operations**

Over 20 years in healthcare industry as entrepreneur founding and leading several successful recruitment firms including Driver & Labour Recruit and Hanrahan & O'Brien Consultants. Founded and sold Nursing Station to Medacs Healthcare (Impellam Group). Founder of the the Medical Job Board, a leading medical staffing firm in Ireland.

## Scientific Advisors

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### **Saoirse O'Sullivan, PhD**

Professor and noted researcher in development of cannabinoids for cancer, stroke, inflammation, and pain at the University of Nottingham, UK. Over 26 original research articles, 6 reviews and 3 book chapters on the topic of cannabinoid pharmacology. Named the International Cannabinoid Research Society Young Investigator of the Year.



### **Andrew Yates, PhD**

A UK registered pharmacist who received his PhD in cannabinoid medicinal chemistry from the University of Nottingham, with more than 15 years experience in the pharmaceutical industry including 10 years as an executive at AstraZeneca. Extensively involved in the life-cycle management of key multi-billion dollar products leading to the funding and initiation of significant development programmes.



### **Steven Laviolette, PhD**

Professor in the Schulich School of Medicine, Univ. of Western Ontario, Canada. Research focuses on the neurobiological and molecular mechanisms underlying various neuropsychiatric disorders and how cannabinoids can differentially control brain pathways. Recipient of numerous national and international research awards. Currently serves on several Review Panels for the Canadian Institutes for Health Research. Former Chair of the Review Committee for the Ontario Mental Health Foundation.

## Board of Directors

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### **Connie Matsui, Chair**

Serves on multiple pharmaceutical and nonprofit boards bringing executive leadership and general management expertise to her responsibilities. Chaired collaboration for the late stage development and commercialization of rituximab (MabThera/Rituxan) in partnership with Roche and Genentech as well as Project Leader for Zevalin, the first radioimmunotherapy approved by the FDA.



### **Steven Kelly**

Founding CEO of Pinteon Therapeutics, an early stage Oncology and CNS development company. Held the position of CEO and CCO of three other biopharmaceutical companies including Theracrine, Biovex and Innovive. Deeply involved in all phases of the business across multiple therapeutic categories over last 30 years.



### **Douglas Blayney, MD**

Professor of Medicine at Stanford and former Medical Director of Stanford Cancer Center. Dr. Blayney is a past president of the American Society of Clinical Oncology (ASCO) and a founder of the ASCO Quality Symposium. He has over 70 scientific publications with expertise on clinical trial development, use of oncology drugs in clinical practice, and information technology use.

## Board of Directors

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### **Georgia Erbez**

Currently CBO/CFO of Zosano Pharma. Formerly CFO at Raptor Pharmaceuticals during growth phase including first drug approval and commercial drug launch. Performed strategic consulting and financial management leadership for several public and private biotech companies. Over 20 years experience as an investment banker focused on emerging life sciences companies.



### **Martin Emanuele, PhD**

More than 30 years of bio-pharmaceutical industry experience including over 20 years at the senior executive level at companies including CytRx Corp., Avanir Pharmaceuticals, Kemia Inc, Da Vita Inc and Mast Therapeutics. Awarded several US patents and drug development grants from the NIH and the US Food & Drug Administration. Led four original IND's for new chemical entities and been a key participant in the NDA approval for two first-in-class drugs.

## Accomplishments and Highlights

Filed patent on novel cannabidiol (CBD) composition

Pioneering the next-generation ECS modulating pharmaceuticals in a sector which is projected to surpass \$20 billion by 2020

Planning for clinical development in rare and orphan diseases

Clinic ready high potency CB1/CB2 peripherally restricted agonist originally developed at Astra Zeneca

Worldwide, exclusive rights to intellectual property covering the FABP program and the dual CB1/CB2 agonist

Portfolio of programs demonstrates differentiated commitment to full spectrum endocannabinoid system modulation

FABP5 Inhibitor licensed from Stony Brook University (NY) is our leading endocannabinoid modulator

GMP/DMF supported supply in place

Research collaborations with leading institutes worldwide: University of Nottingham (UK) NEOMED Institute (CAN) Stony Brook University (US)



# Artelo

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