

A drug discovery company dedicated to addressing unmet medical needs

Focusing on the Central nervous system (CNS) and Autoimmune systems



**June 2025**Company Presentation

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Argent BioPharma is a specialized Biopharmaceutical company focused on developing and marketing innovative drugs.

Committed to providing accessible medical treatments for unmet medical needs with Nano Neuro-Immune Modulation.

# **Innovative Technology Platform:**

Utilizing advanced nanotechnology and a multidisciplinary approach in its in-house R&D platform to develop innovative therapies. This approach mainly targets the central nervous system (CNS) and the Autoimmune System.



# Vision

Argent BioPharma aspires to become a **biopharmaceutical company** recognized globally for its **innovative treatments** that address **unmet medical needs**, particularly in the **central nervous system (CNS)** and **immune-related diseases**. The company aims

to be a key player in **transforming patient outcomes** by providing **advanced**, **effective therapies** for conditions with limited or no treatment options.

# Mission

Argent BioPharma aims to **improve patient outcomes** by providing **effective**, **cutting-edge treatments** for conditions with limited or no existing therapeutic options. This involves leveraging its **EU GMP manufacturing facilities**, **robust drug pipeline**, and **experienced management team** to bring these **innovative therapies** to market as quickly and efficiently as possible.





# R&D Center and Manufacturing Capabilities

# In house Research, Development & Production

Wholly owned and Operated EU GMP Sites

- Slovenia R&D hub is staffed with highly experienced pharmaceutical industry professionals dedicated to developing advanced drug formulations and delivery systems.
- Slovenia Quality team, expertly navigates regulatory pathways to secure marketing approvals from both the US FDA and EMA markets.
- Malta, Hal Far Fully automated EU GMP site, possesses advanced production capabilities, enabling efficient manufacture of drugs and generating sales.



# Slovenia – EU Research and Development site

Integrated research hub ensuring innovation, patient access, long-term value, and a strong market position.

- Advanced R&D Operations: Operates with a team of skilled professionals, ensuring continuous innovation and progress in drug development
- ➢ Early Patient Access: Capable of developing and producing products for Early Patient Access, ensuring critical therapies reach patients swiftly.
- Long-term Value: The R&D center drives innovation, expanding Argent's drug portfolio and generating long-term value.
- > **Investment and Market Position:** Ongoing innovation attracts investment, enhances market position, and addresses unmet medical needs, providing substantial returns to shareholders.



# Malta – Manufacturing site

A fully built, modern EU GMP-certified Boutique manufacturing facility, operational for less than three years and supported by multi-million dollar grants from the Maltese government<sup>1</sup>.

- Automated Production Capabilities: The facility features fully automated production capabilities, producing tens of thousands<sup>2</sup> of drug units per shift, ensuring high-volume, high-quality output.
- ➤ Versatile Drug Manufacturing: The facility supports Argent BioPharma's diverse therapeutic portfolio by being equipped to manufacture a wide range of drugs, including flagship products like CannEpil® and CimetrA®.
- > Potential Contract Manufacturing Organization (CMO) services for non-sterile oral liquid dosage forms.



<sup>2.</sup> Malta GMP certificate. Based on 30ml bottle size



# **Key products**

We utilize advanced nanotechnology and a multidisciplinary approach in our in-house R&D platform to develop innovative therapies for unmet medical needs.



# Refractory Epilepsy Seizure Control Management

#### **Early-Stage Revenue Generating**

- Approximately **30% of generalized seizure epilepsy patients** have **Refractory Epilepsy,** aka "Drug-Resistant Epilepsy" (DRE)<sup>1</sup>, representing **15,000,000 patients** around the world.
- **CannEpil®** is now available to patients in the **Germany, UK, Ireland and Australia** by **Named Patient Request or SAS**, to be prescribed by **clinicians and general doctors**.
- CannEpil® is accepted by the Irish Health Product Regulatory Authority (HPRA), and full health insurance coverage is obtained through the Medicinal Cannabis access program (MCAP).
- The first UK patient has access to **CannEpil®** through the **NHS RESCAS pathway** and the **"I am Billy Foundation"**, they have been using CannEpil® for **over 1.5 years.**
- Orphan Drug designation (ODD) was Submitted to the FDA





<sup>1.</sup> Fattorusso A, et al. (2021) The Pharmacoresistant Epilepsy: An Overview on Existent and New Emerging Therapies. Front. Neurol.

<sup>2.</sup>https://www.biospace.com/epilepsy-therapeutics-market-worth-15-1-bn-by-2030-at-a-cagr-of-4-5-percent



Refractory Epilepsy
Seizure Control Management

**Early-Stage Revenue Generating** 

## **Market potential**

- > Worldwide Potential Patients with DRE 15,000,000
- > USA Addressable Market 1,135,200
- Germany Addressable Market 180,000

# **Key points**

- ➢ CannEpil® already sold in the Germany, UK, Ireland and Australia
- > There are **50 million epilepsy sufferers** of which **6.21 million in Europe and the UK**
- Approximately 30% of generalized seizure epilepsy patients
   have Refractory Epilepsy aka "Drug-Resistant Epilepsy" (DRE)¹











# Refractory Epilepsy Seizure Control Management

**Early-Stage Revenue Generating** 

# **Forward-looking**

- Commercial strategy is a combination of 3rd party distribution supported by in-house Medical Scientific Liaison.
- Continuing the work with the 'I am Billy' Foundation and the pathway to NHS RESCAS for Paediatric Refractory Epilepsy.
- Dedicated in-house Neurology and Paediatrician collaboration with the European Paediatric Neurology Society<sup>1</sup>.
- Initiate CannEpil® IND submission to the US FDA.
- Exploring novel mechanisms for IP claims and ODD.
- Studies are underway. Followed by early-phase efficacy trials.





Total Addressable Global Market:

US\$20.30B<sup>2</sup>

<sup>1.</sup> http://dpnsee.org/2019/01/22/treatment-with-medicines-derived-from-cannabis/

<sup>2.</sup> https://www.biospace.com/epilepsy-therapeutics-market-worth-15-1-bn-by-2030-at-a-cagr-of-4-5-percent



# Multi-target anti-inflammatory & immunomodulatory therapy

## **Early-Stage Revenue Generating**

**CimetrA®:** a multi-target immunomodulator meeting **critical unmet medical needs** from **acute ARDS to chronic autoimmune gaps** (RA, IBD, lupus) where **current therapies fall short**.

CimetrA® delivered **50,000** units to the **USA** market (Under Special Access) and over **100,000** worldwide, representing over **US\$2,500,000** in sales to date.

## Results of Preclinical and Clinical program, meeting FDA guidelines, to date:

- Effective **blocking of the IL-32mRNA** expression<sup>1</sup>, the pro-inflammatory cytokine related to Autoimmune diseases, lupus, rheumatoid arthritis, inflammatory bowel disease, asthma, and chronic obstructive pulmonary disease<sup>1</sup>.
- Clinically proven mechanism: Studies show CimetrA blocks the IL-32  $\rightarrow$  NF-κB / p38 cytokine cascade and boosts protective HO-1, sharply reducing tissue inflammation<sup>1</sup>.
- Preclinical studies showed CimetrA® significantly reduced IL-1β, TNF-α, IL-6, and other key inflammatory markers. The focus on IL-32 reflects its relevance to autoimmune diseases, but the research highlights a broader effect on cytokines<sup>3</sup>.
- Preclinical studies in rodents (rats, mice) and non-rodent (swine) confirm the safety profile, with **no formulation-related toxicity detected**<sup>3</sup>.





Total Addressable Global Market:

US\$18.3B4

<sup>1.</sup> Data on file – CimetrA in-vitro study

<sup>2.</sup> Data on file - Interim results - CimetrA Dose Finding Study

<sup>3.</sup> Data on file - CimetrA pre-clinical study

<sup>4.</sup> https://www.mordorintelligence.com/industry-reports/acute-respiratory-distress-syndrome-treatment-market



Immunomodulation Treatment for Acute lung injury and ARDS

**Early-Stage Revenue Generating** 

# **Market potential**

Cases of severe illness of influenza worldwide 3 – 5M Respiratory deaths per annum 650,000 – 850,000

# **Key Points**

- Sales strategy is to license and distribute through 3rd party distribution supported by in-house Medical Scientific Liaison
- Key wholesaler partners in the USA and MENA
- Initiate CimetrA® IND submission to the US FDA

# **Strategic Milestones**

- A series of preclinical studies to further evaluate CimetrA®'s efficacy for new indications is set to begin before the end of the year. These studies, conducted in collaboration with a renowned German institute, will include ex vivo testing across various indications and in vivo testing on a complex animal model.
- This will be accompanied with a potential future **ODD** and **IP claims**.





US\$18.3B<sup>2</sup>



Improving quality of life in Dementia and Alzheimer's

#### **Early-Stage Revenue Generating**

- > 55 million people worldwide suffering from Dementia and Alzheimer's<sup>1</sup>
- Approved in Germany under Special Access Scheme
- CogniCann® designed as a treatment for the symptoms associated with Dementia and Alzheimer's
- Patients in the Placebo group experienced
   a deterioration in their condition, compared with the stable
   neuropsychiatric profile of those patients in the treatment group with
   CogniCann<sup>®2</sup>
- This important finding indicates not only improvement in the health status of the patients and also the improved quality of life of the families and caregivers taking care of dementia patients





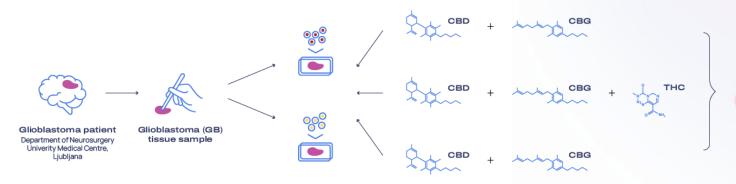
Oromucosal Spray

Pharmaceutical Dosage Form



# Improving quality of life in Dementia and Alzheimer's

- Innovative pre-clinical stage drug targeting **Glioblastoma Multiforme** (GBM) Stem Cells, one of the **deadliest forms of brain cancer**, with the potential to transform treatment outcomes for this aggressive disease
- > An estimated **250,000 new cases** of GBM per year worldwide.<sup>1</sup>
- The preclinical studies demonstrated that IrniCan® was cytotoxic to Glioblastoma tumor and stem cells, reducing cell viability, which could establish a new benchmark in treating GBM by improving safety and efficacy profiles.<sup>2</sup>



Cell viability
Apoptosis
Cell invasion





**Tablets** 

Pharmaceutical Dosage Form



#### Pre-Clinical Stage for Chronic Wounds Treatment



- Chronic wounds are a major global health issue, costing billions in treatment annually (e.g., £3.2 billion in the UK¹ in 2015; \$28.1 to \$96.8 billion in the USA in 2014²). These wounds cause extreme suffering with severe symptoms, often complicated by antibiotic-resistant infections, impenetrable biofilms, and deteriorating local tissue health.
- The aim is to develop a nano-formulated product with antimicrobial, biofilm-disrupting, symptom-controlling, and wound-healing properties to address chronic wounds lacking effective treatment.

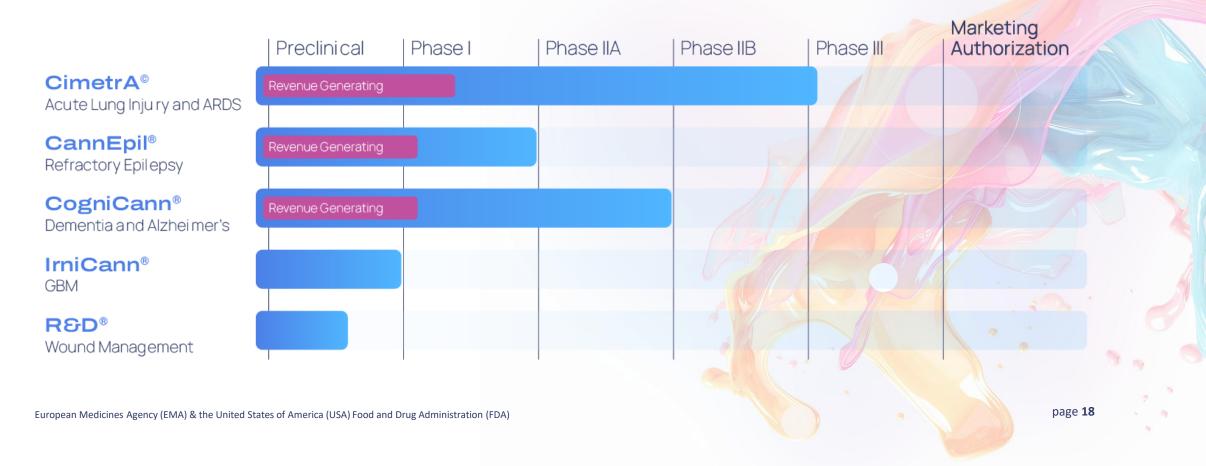
## **Goals of Preclinical Studies**

- > Identify and Select Novel Repurposed Antimicrobial Agents
- Optimize Combinations for tissue health and relief
- > Enhance Nano-Formulation to maximize therapeutic benefits

# **Research and Development Product Pipeline**

**US FDA & EMA Registration plan** 

Actively pursuing FDA approval with potential Orphan Drug Designation.







Roby Zomer
Chief Executive Officer

Roby Zomer is an accomplished executive with extensive experience in the biopharmaceutical and biotech industries. As the CEO of the company, Roby has demonstrated strong leadership in driving strategic growth, managing financial operations, and ensuring compliance with industry-specific standards. He also serves as the Chairman of the Board for Graft Polymer, overseeing the implementation of advanced polymer solutions in the Biotech, Automotive and Recycling sectors. Roby's entrepreneurial background includes founding and leading Green City Urban Recycling, a pioneering Israeli company focused on biofuel production. His innovative work in this field contributed to national energy independence initiatives and led to the company's acquisition by Rafael Advanced Defense Systems. With a solid industrial engineering and management foundation, Roby Zomer brings a unique blend of technical and strategic skills to his professional endeavors.



Igor Bluvstein
Chief Financial Officer

Igor is a seasoned Chief Financial Officer with extensive experience across diverse industries, including digital health, e-commerce, biotechnology, petrochemicals, and medical cannabis. He has held leadership roles as CFO at G Medical Innovations Holdings Ltd., MDD Group of Companies, and an e-commerce retailer. Igor also served as Regional CFO at Frutarom Industries Ltd. and Financial Controller at Mirland Development Corporation PLC, beginning his career as a Senior Auditor at Ernst & Young. He holds a Bachelor of Arts in Accounting and Economics from the Open University in Israel and is a Certified Public Accountant (CPA). Igor leads the finance and compliance department. His international business experience and strong financial management skills make him an exceptional CFO, particularly in publicly traded companies.













Dr. Jonathan Grunfeld

Vice president of Medical Development

Dr. Jonathan Grunfeld is a highly experienced neurologist and neuro-oncologist with a career spanning over two decades. He completed his medical degree at Tel Aviv University, followed by a fellowship in neuro-oncology at the prestigious MD Anderson Cancer Center. Dr. Grunfeld has dedicated much of his career to the management of oncological symptoms and palliative care, particularly exploring the therapeutic potential of cannabis in these areas. His extensive experience and innovative approach have equipped him with exceptional clinical observations and unique insights, which he brings to bear in translational initiatives.



Amir Polak
Chief Pharmaceutical
Development Officer

Amir is a seasoned professional with over 18 years of experience in the pharmaceutical and chemical industries. Currently serving as the Pharmaceutical Development Officer at Argent Biopharma LTD, Amir has a strong background in strategic planning, project management, and intellectual property management, with a proven track record of bringing innovative treatments to market. His prior roles include leadership positions at Nano-Dimension Tech, where he spearheaded advanced manufacturing lines for nano-particles, and Green City-Urban Recycling, where he co-founded and led technological advancements. Amir holds an M.Sc. in Organic Chemistry and a B.Sc. in Physical Chemistry from the Hebrew University of Israel. Amir leads the full lifecycle of pharmaceutical product development, from ideation to commercialization.



Making Cancer History®





Sabina Suljaković
Chief Quality and
Commercial Officer

Sabina is an accomplished quality professional with over 10 years of experience, specializing in establishing systems that ensure regulatory compliance and drive commercial success. Sabina led the company to become the only EU GMP-certified entity by JAZMP. As the primary liaison with Health Authorities worldwide, she expertly navigates complex regulatory landscapes, develops strategies for market entry, and leads diverse teams. Her expertise spans regulatory compliance, auditing, production, quality control, and batch certification, with a strong focus on aligning quality initiatives with business goals. Sabina oversees quality, business development, and commercial activities. She is dedicated to fostering continuous improvement and driving both quality and commercial success within the organization.



Yair Tal
Chief Information Security
Officer

With 30 years of extensive experience, Yair Tal specializes in providing comprehensive security solutions. His expertise spans across various aspects of security, ensuring that businesses and organizations operate with confidence in an increasingly complex global environment. He covers security management, data protection, and physical cyber security, from the company's facilities to its online operations and most significantly, patient data. Yair Tal's dedication to security excellence and his broad expertise make him a trusted partner for organizations looking to safeguard their operations and assets.









**Dr. Shlomo Sadoun**Strategic Business Development

Dr. Shlomo Sadoun has over 18 years of experience in the pharmaceutical industry. As cofounder and leader of SK-Pharma Group, he has expanded the company into 18 countries, specializing in generic, specialty, and biosimilar products. He also serves as CEO of Arphio, focusing on orphan drugs. Dr. Sadoun has forged strategic alliances with over 200 companies and launched more than 300 products globally, making SK-Pharma one of Israel's fastest-growing pharmaceutical groups. He holds a master's degree in Global Management and a Doctorate in Business Administration with a focus on public health.



Prof. Uri Kramer
Head of Neurology

Professor Uri Kramer is a renowned neurologist, epileptologist, a leading specialist in Israel in the diagnosis and treatment of childhood neurological disorders. Graduated from Medical University in Tel Aviv. Improved his qualifications in childhood epilepsy and clinical neurophysiology in Boston. He is a researcher and creator of several methods in the diagnosis and treatment of epilepsy. He has written over 80 scientific medical papers on pediatric neurology. Created a special EpiLert bracelet with a transmitter that notifies children or adults of an approaching seizure. Member of the European, American and Israeli Associations of Epileptology. He has over 50 years of professional experience.



Yossi Mograbi
Strategic R/D

Mograbi is a seasoned biotech entrepreneur, having initiated eight projects with top scientists from leading academic and healthcare institutions. Four projects involved NCEs from the Hebrew University of Jerusalem, and another was a drug collaboration with Hadassah Medical Organization. Currently, he's engaged in three projects with Tel-Aviv University, focusing on CSS, COVID-19, and bone applications. As an inventor or co-inventor on seven patents, Yossi has also consulted for Teva, Yissum, and Syge Medical. He's mentored MBA-Biomed students at the Hebrew University and participated in the SPARK Program. Beyond biotech, Yossi is an expert in dietary supplements, advising companies like Teva and aiding patients with severe rare diseases.















# Addressing unmet medical needs

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