Argent BioPharma

A drug discovery company dedicated to addressing unmet medical needs

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

September 2024
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.

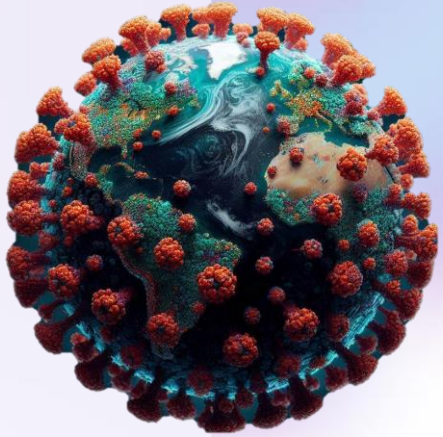
Innovative Technology Platform:

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

Argent BioPharma Vision and Mission

Vision: Argent BioPharma aspires to become a leading 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 Centers and Manufacturing Capabilities

(3 sites in total)

In-house Research, Development & Production

Wholly owned and Operated EU GMP Sites

- **Slovenia, Emonska R&D hub** is staffed with over 40 highly experienced pharmaceutical industry professionals dedicated to developing advanced drug formulations and delivery systems.
- **Slovenia, Emonaka Quality and medical site,** expertly navigates regulatory pathways to secure marketing approvals from both the US FDA and EMA markets.
- **Slovenia, Kmaniska IMP EU GMP site**, where the formula is taken to production for clinical trials and early patient access.
- **Malta, Hal Far Fully automated EU GMP site,** possesses advanced production capabilities, enabling efficient manufacture of drugs and generating sales.

*In accordance with the European Medicines Agency, Federal Drug Administration, ICH Good Clinical Practice, and Israeli health regulations

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.

*In accordance with the European Medicines Agency, Federal Drug Administration, ICH Good Clinical Practice, and Israeli health regulations

Malta Manufacturing site

Fully built EU GMP manufacturing facility

A modern EU GMP-certified manufacturing facility, operational for less than three years and supported by multi-million dollar grants from the Maltese government[1].

- **Automated Production Capabilities**: The facility features fully automated production capabilities, producing tens of thousands[2] of drug units per shift, ensuring high-volume, high-quality output.

- **Versatile Drug Manufacturing**: The facility supports Argent BioPharma's therapeutic portfolio by being equipped to manufacture a wide range of drugs, including flagship products like CannEpil® and CimetrA®.

1. Refer to ASX Announcement dated 2 November 2021
2. 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.

CannEpil®

Refractory Epilepsy

Early-Stage Revenue Generating Refractory Epilepsy Seizure Control Treatment

- Approximately 30% of generalized seizure epilepsy patients have Refractory Epilepsy, aka “Drug-Resistant Epilepsy" (DRE)[1], representing 15,000,000 patients around the world.
- CannEpil® is now available to patients in the UK by **Named Patient Request**, to be prescribed by clinicians listed on the **GMC Specialist** Register.
- 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.

Total Addressable

Global Market: £15B[2]

1. Fattorusso A, et al. (2021) The Pharmacoresistant Epilepsy: An Overview on Existent and New Emerging Therapies. Front. Neurol.
2. https://www.biospace.com/epilepsy-therapeutics-market-worth-15-1-bn-by-2030-at-a-cagr-of-4-5-percent
Date on file – CannEpil Driving Performance
Data on file – CannEpil vs. MXP100 study

CannEpil®

Refractory Epilepsy

Market potential

Worldwide Potential Patients with DRE	15M	UK Potential Patients with DRE	150K	CannEpil Treatment Estimate per patient per annum	£7000[3]

Forwards Looking:

- Commercial strategy is a combination of 3rd party distribution supported by in-house Medical Scientific Liaison
- Key wholesaler partners in the UK and Europe: PCCA and Medisonal clinic
- 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[4]
- Initiate CannEpil® IND submission to the US FDA

Key points

- CannEpil® already sold in the UK, Ireland and Australia
- There are 501 million epilepsy sufferers of which 6.21 million in Europe and the UK

Approximately 30% of generalised seizure epilepsy patients have Refractory Epilepsy aka "Drug-Resistant Epilepsy" (DRE)2

1. https://www.who.int/news-room/fact-sheets/detail/epilepsy Fattorusso A, et al. (2021) The Pharmacoresistant Epilepsy
2. Overview on Existant and New Emerging Therapies. Front. Neurol. 12:674483.
3. Alacrita Report 2019
4. http://dpnsee.org/2019/01/22/treatment-with-medicines-derived-from-cannabis/

CimetrA®

Acute Lung Injury and ARDS

Early Stage Revenue Generating Immunomodulation Treatment for ARDS

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:

- Demonstrated **suppression of cytokine storm** in Phase II Clinical Trials[1]
- Demonstrated significant reduction in **C-reactive protein (CRP)**, a major inflammatory marker[2].
- The biological markers in the blood tests further proved a **reduction of inflammation**, enterohepatic involvement, and liver reactant proteins[1].
- Effective **blocking of the IL-32mRNA** expression[1], the pro-inflammatory cytokine related to Autoimmune diseases, lupus, rheumatoid arthritis, inflammatory bowel disease, asthma, and chronic obstructive pulmonary disease[1]
- Preclinical studies in rodents (rats, mice) and non-rodent (swine) confirm the safety profile, with no formulation-related toxicity detected[3].

Total Addressable Global Market: £13.6B[4]

1. Data on file – CimetrA in-vitro study
2. Data on file – Interim results – CimetrA Dose Finding Study
3. Data on file – CimetrA pre-clinical study
4. https://www.mordorintelligence.com/industry-reports/acute-respiratory-distress-syndrome-treatment-market

CimetrA®

Acute Lung Injury and ARDS

Market potential

Cases of severe illness of influenza worldwide[1] **3-5M** Per annum

Respiratory deaths **290-650K** Per annum

Potentially, CimetrA® can be used to treat **inflammatory** conditions with **£100B**[2] total addressable market.

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 — AMC
- Initiate CimetrA® IND submission to the US FDA

Strategic Milestones

CimetrA® IND submission to the US FDA

1. https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal)
2. https://www.precedenceresearch.com/anti-inflammatory-therapeutics-market

CogniCann®

Dementia and Alzheimer's

Improving quality of life in Dementia and Alzheimer's

- **55 million people worldwide** suffering from Dementia and Alzheimer's[1]
- **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®**[2]
- This important finding indicates **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

1. https://www.who.int/news-room/fact-sheets/detail/dementia
2. Data on file : CogniCann Phase II study, Australia

IrniCann®

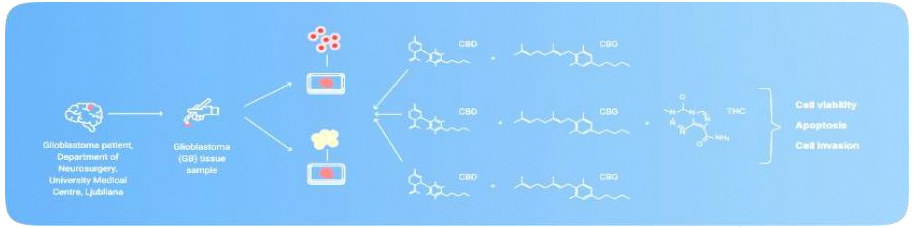
Glioblastoma

Pre-Clinical Stage Glioblastoma

- 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.[1]

- The preclinical studies demonstrated that IrniCan® was cytotoxic to Glioblastoma tumor and stem cells, reducing cell viability and inducing), which could establish a new benchmarkcaspase-dependent cell apoptosis (or cell death in treating GBM by improving safety and efficacy profiles.[2]



Tablets
Pharmaceutical Dosage Form

1. https://www.sciencedaily.com/releases/2024/02/240215113623.htm
2. Lah, T. . et al. The Cytotoxic Effects of Cannabidiol and Cannabigerol on Glioblastoma Stem Cells May Mostly Involve GPR55 and TRPV1 Signalling. Cancers 2022, 14, 5918T

DerNaPol Chronic Wounds

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 UK [1] in 2015; $28.1 to $96.8 billion in the USA in 2014[2]). 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.

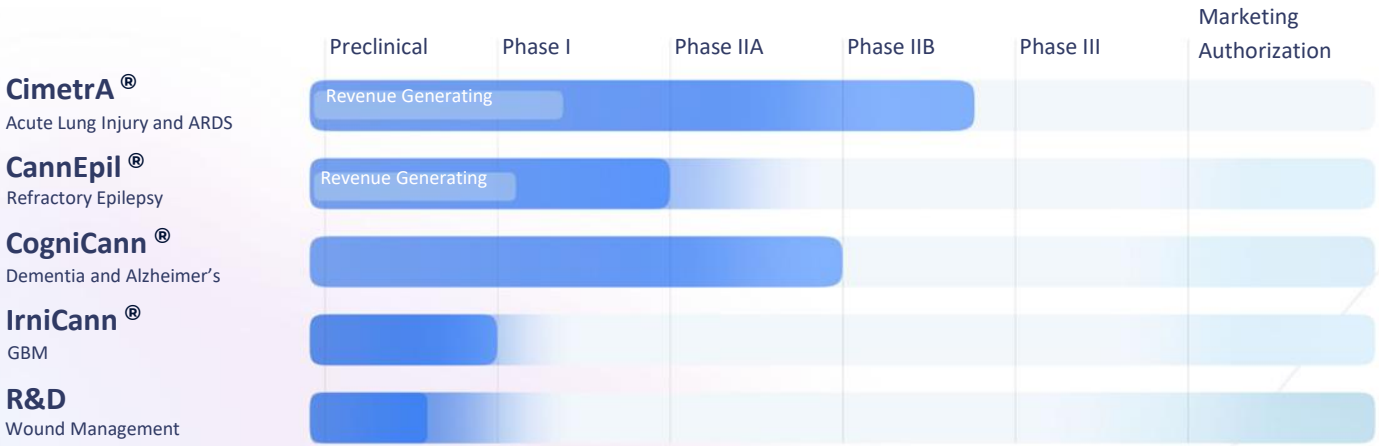
- Goals of Preclinical Studies:
    - Identify and Select Novel Repurposed Antimicrobial Agents
    - Optimize Combinations for tissue health and relief
    - Enhance Nano-Formulation to maximize therapeutic benefits

1 Guest, J.F., et al., Health economic burden that different wound types impose on the UK's National Health Service. International Wound Journal, 2017. 14(2): p. 322-330.
2 Nussbaum, S. R., t al., Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value in Health, 21(1), 27-32.

Research and Development Product Pipeline

US FDA & EMA Registration Plan

Actively pursuing FDA approval with potential Orphan Drug Designation.



European Medicines Agency (EMA) & the United States of America (USA) Food and Drug Administration (FDA)

Qualified team with versatile industry experience and expertise

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 served 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.

Yifat Steuer

Chief Operating Officer

Yifat is a seasoned executive with over 20 years of experience at GSK, J&J, and various biopharmaceutical and medical device SMEs. With expertise in financial strategy and corporate management, she excels in optimizing cash flows, improving efficiency, and driving large-scale corporate transformations. Yifat holds an MBA in Finance and Strategy and CPA credentials from Deloitte. Yifat leads operational functions, guiding the company's work plans towards sustainable growth. She adeptly manages strategic initiatives, risk mitigation, and corporate relations, significantly boosting company growth and efficiency. Her leadership continues to elevate the company's performance and strengthen its market position.

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.

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.

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.

Medical advisors

Dr. Jonathan Grunfeld

Vice President 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.

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.

Dr. Shlomo Sadoun

Strategic Business Development

Dr. Shlomo Sadoun has over 18 years of experience in the pharmaceutical industry. As co-founder 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.

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 Syqe 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. His company received two NOFAR grants for cancer and lupus projects, and he assisted with two Kamin grants from Hadasit/Yissum and BGNegev/Hadasit.

Financials[1]

1. **30 June 2024 Preliminary Financial Report** https://www.investi.com.au/api/announcements/rgt/ba7eeb34-10e.pdf

PROFIT AND LOSS (USD)	JUN 23- JUL 24*	JUN 22- JUL 23
Revenue	894,263	2,241,621
Gross profit	315,845	959,620
Operating loss	(10,957,390)	(13,149,334)
Loss for the year	(11,523,050)	(13,984,482)

BALANCE SHEET (USD)	JUN 23- JUL 24*	JUN 22-JUL 23
Total assets	7,074,104	6,606,382
Total liabilities	10,778,676	11,921,208
Total equity	(3,704,572)	(5,314,826)

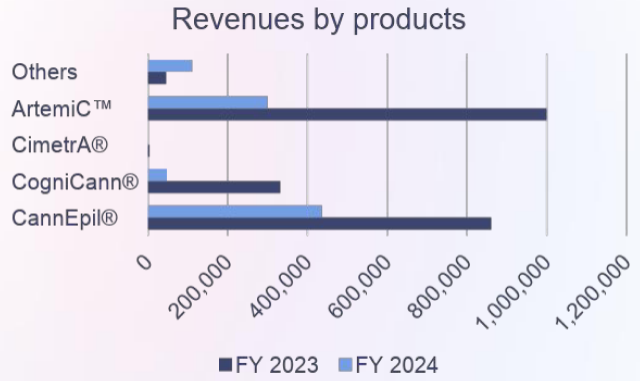
CASH FLOW (USD)	JUN 23- JUL 24	JUN 22- JUL 23
Net cash used in operating activities	(9,511,069)	(7,930,829)
Net cash used in investing activities	(93,448)	401,131
Net cash provided by financing activities	9,913,763	6,440,159
Cash and cash equivalents at the end of the year	468,744	158,694

(*) USD 300k revenue reclassification from Sept 2024 due to the timing of invoice

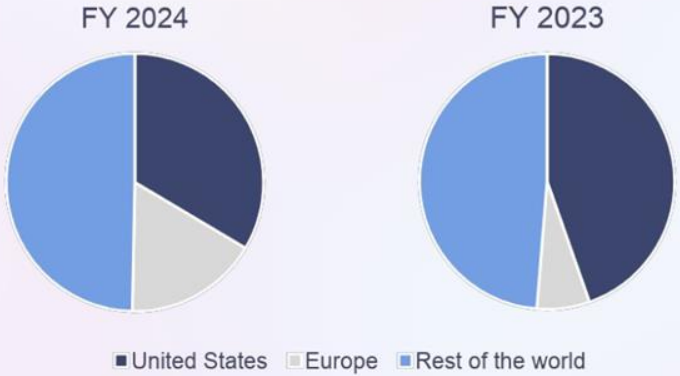
1. **30 June 2024 Preliminary Financial Report** https://www.investi.com.au/api/announcements/rgt/ba7eeb34-10e.pdf

Revenues by products

Sales by products (USD)	JUN 23- JUL 24	JUN 22 – JUL 23
CannEpil®	436,334	860,699
CogniCann®	47,300	331,615
CimetrA®	-	3,862
ArtemiC™	* 300,000	1,000,000
Others	110,629	45,445
SUM	**894,263**	**2,241,621**



Sales by GEO region(USD)	JUN 23 – JUL 24	JUN 22 – JUL 23
United States	* 300,000	1,000,000
Europe	149,961	149,627
Rest of the world	444,302	1,091,994



(*) USD 300k revenue reclassification from Sept 2024 due to the timing of invoice

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Argent BioPharma

Addresses unmet Medical needs

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