27 August 2024

Argent BioPharma Ltd.

(**Argent BioPharma** or the **Company**)

Letter From the CEO

Dear Shareholders,

We are pleased to share an update on Argent BioPharma's recent progress, strategic direction, and key developments. Our mission remains unwavering: to deliver an innovative approach that enhances patient outcomes by offering effective treatments for conditions where options are currently limited or non-existent.

Argent BioPharma will continue its journey as a specialised biopharmaceutical company with a primary research focus on the central nervous system (CNS) and the immune system, two pivotal and promising areas in the future of medicine. By advancing its existing portfolio of drugs and integrating new, innovative biological and chemical therapies, Argent BioPharma is dedicated to addressing unmet medical needs and pioneering advancements in healthcare.

As part of the final stages of our restructuring process, which began earlier this year, we have achieved significant milestones, including raising US$2.5m in a non-brokered placement in July at AU$1.20 per share (US$0.80) and the appointment of new brokers in the UK. This restructuring allows us to focus more effectively on the UK, Europe, and the US markets.

Below, we outline our achievements and future plans to continue delivering value to our shareholders and advancing our mission.

Company Overview

Argent BioPharma is a specialised biopharmaceutical company focused on developing and marketing innovative drugs that are pioneering in the field and represent the new generation of advance pharmaceutical treatments. Our operations include independent EU-GMP manufacturing plants, and a development centre staffed by an experienced team. With continuous research and development efforts, we aim to bring new and innovative therapies to market, enhancing the quality of life for patients and addressing significant gaps in medical care. Our core research focuses on the CNS and Immune System.

The company is currently listed on the London Stock Exchange, the Australian Stock Exchange, and the OTCQB. Our main operations and management are in the UK and EU, and a new investor base is from the USA. In the future, we may explore dual listing on a national exchange in the USA, such as the NASDAQ or NYSE.

Argent BioPharma has two investigational drugs with early sales in the UK, Ireland, and the USA under special access schemes, which can generate real-life data on our treatments, helping us to improve our medicines as we proceed with regulatory pathways to marketing authorisations as licensed drugs in Europe and the USA in the coming years.

Our experienced management, medical advisory teams, and multidisciplinary professionals can develop drugs in-house from the research stage to final production. We have a fully automated commercial EU-GMP pharmaceutical manufacturing site in Malta and an EU-GMP research facility in Slovenia, equipped to develop new drugs and produce them for early sales. This hub

employs researchers, a quality team, and a medical team, ensuring high standards in research and production.

In-House Research, Development, and Manufacturing

Argent produces and develops new drugs entirely in-house, without outsourcing or external services. All our existing drugs now use our internal IP, and we will move forward to establish Argent's own property in all aspects of our drug development. Our manufacturing and R&D facilities have been operating for five years, staffed by 40 highly experienced pharmaceutical and medical professionals, with the capability to take drugs from concept to receiving marketing approvals in the US FDA and EMA markets[1], operating in accordance with high standards, including EU GMP facilities, capable of supporting clinical trials, commercial production, and R&D with top-tier facilities, ensuring compliance with the highest regulatory standards.

R&D Centre in Slovenia

The R&D department operates to develop a pipeline of new original drugs. It serves as a powerful tool for the company to expand its portfolio in the long term, with the potential to bring value to shareholders and address diseases currently lacking optimal solutions. This EU-GMP centre has the capability to develop and produce products for Early Patient Access in targeted markets.

Malta Factory

Our fully automated liquid dose form EU GMP facility was commissioned in May 2023, and is strongly supported by the Maltese government through multi-million dollar grants[2]. Based on the company's current drug portfolio and potential contract manufacturing services, it has the potential to produce a future revenue stream. The company is working on providing intermediate contract manufacturing services to other pharma companies till our internal needs fulfill the capacity.

Argent's Flagship Drug Products:

- **CannEpil®** (in early sales) for the treatment of Refractory Epilepsy, in which approximately 30% of epilepsy patients do not respond to medication, and we aim to address this critical area. Currently, it is not running in clinical trials. At the same time, we started communication with the FDA under Pre-IND to define the path forward to Marketing Authorisation, with sales started in the UK under patient-name-based prescription in May 2023 and in the Irish market under a special access scheme fully reimbursed by the national health insurance as an unlicensed drug[3] since June 2021.
- **Cimetra®** (in early sales) is an innovative treatment for unmet medical needs relating to acute respiratory distress syndrome (**ARDS**) and Acute Lung Injury. It is currently running under Phase IIb studies as part of a clinical programme to target the prevention of Cytokine Storm, which is the key cause of lung failure. A US distributor has signed distribution agreements, and sales have reached over a million dollars in the US through the special access scheme of OTC unlicensed drugs[4]. CimetrA holds an NDC number as part of the early patient access scheme (NDC No: 83278-001).

[1] Refer to announcement dated 15 September 2021
[2] Refer to announcement dated 3 November 2021
[3] Refer to announcement dated 15 June 2021
[4] Refer to announcement dated 7 July 2023

- **CogniCann®** (in the clinical stage) has demonstrated improved behaviour and reduced agitation in dementia patients during Phase IIa studies[5], which has the potential to change the lives of millions of patients. Cognicann is currently not in clinical trials, but the company is assessing its commercial and regulatory pathways under special access schemes.
- **RGAI02GB01 - IrniCann®** (in the pre-clinical stage) is an innovative pre-clinical stage drug targeting Glioblastoma Multiforme (**GBM**), one of the deadliest forms of brain cancer, with the potential to transform treatment outcomes for this aggressive disease. This could bring significant relief to critically ill patients around the world.
- **RGAI03MW01 -** (in the pre-clinical stage) combined biological and chemical nano-formulations for Chronic wounds which present complex challenges, including severe symptoms and management of topical infections complicated by antibiotic resistance, impenetrable biofilms, and local tissue health deterioration.

Benefits of Early Access Programmes (EAPs) for Argent BioPharma

EAPs for our investigational medicinal products (**IMPs**) may enable faster market entry and the potential for early revenue streams. Moreover, they support ongoing research and business operations. These programmes provide valuable real-world data on therapy safety and efficacy, enhancing regulatory submissions and treatment protocols. Additionally, EAPs build trust with patients and healthcare providers, strengthen regulatory relationships, and offer a competitive advantage by addressing unmet medical needs. They foster brand recognition and loyalty, contribute to financial stability, and demonstrate the company's commitment to social responsibility.

Leveraging Real-World Data

One of the key outcomes of the EAPs is the collection of Real-World Data (**RWD**) such as safety data, adverse events, treatment protocols, dosing and efficacy. Integrating RWD into Argent BioPharma's research provides numerous advantages, from enhancing regulatory submissions to optimising clinical practices and expanding market opportunities. By leveraging RWD, Argent BioPharma aims to achieve continuous improvement of its therapies, leading to better patient outcomes.

Summary

Argent BioPharma is on a promising path with its innovative approach and comprehensive capabilities. Our R&D facilities give us control over each stage of the drug life cycle, from research to production. Focusing on unmet medical needs, we are developing potentially transformative medicines like CannEpil® and Cimetra® to address critical health challenges. Our refreshed management team will drive our strategic initiatives, aiming for revenue growth, a robust drug pipeline, successful product launches, and operational efficiency.

I strongly believe that Argent BioPharma is well-positioned for sustained growth and there is a bright future for our company and stakeholders.

Yours faithfully,

Roby Zomer

[5] Refer to announcement dated 6 June 2022

Authorised for release by the board of directors, for further information please contact:

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About Argent BioPharma

Argent BioPharma Limited (the **Company**) (ASX: RGT; LSE: RGT; OTCQB: RGTLF) an innovative multidisciplinary drug development Company within the biopharmaceutical sector. The Company focuses on multidisciplinary methods with Nanotechnology, developing multi-target therapies for comprehensive disease management, especially concerning the Central nervous system (**CNS**) and Immunology treatments.

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