Argent BioPharma

Pharma and biotech

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Valuation report

We value Argent at an un-risked net present value (NPV) of US$1.1bn. Adjusting for the company's specified probabilities of success (PoS) for its three clinical programmes gives a risk-adjusted NPV (rNPV) of US$327m or US$6.7 per share. The highest contribution is from CannEpil (NPV of US$508m, PoS 35%), a Phase II, medical-grade cannabinoid being developed for drug-resistant epilepsy. CimetrA, a plant-derived formulation with preclinical and clinical activity as an anti-inflammatory agent, is the other key contributor. We expect initial therapeutic targets to be acute lung injury and ARDS (NPV of US$239m, PoS 50%). CogniCann, a Phase I asset (cannabinoid) in development for symptoms of dementia, contributes US$416m to the NPV, with a 15% risk adjustment. IND filings with the FDA are expected in 2025, with trial launch led by CannEpil. We project a 2030 launch for CannEpil, 2031 for CimetrA and 2033 for CogniCann.

Broad portfolio targeting unmet needs

Argent's pipeline targets a broad range of indications, with a focus on central nervous system (CNS) conditions and immunology. Leading the way is CannEpil (drug-resistant epilepsy), followed by CimetrA (anti-inflammatory conditions) and CogniCann (CNS disorders). CannEpil and CimetrA are available under special access schemes in markets including the UK, US and EU, generating early revenue streams as well as real-world evidence, which should support regulatory discussions. Argent is also differentiated from the typical small biopharma with its two EU-GMP R&D and manufacturing sites in Slovenia and Malta supporting in-house drug development. These could potentially be monetised via contract manufacturing services.

Valuation: US$327m or US$6.7 per share

While Argent's assets have generated clinical data in Australia and Israel, the company is now focused on the US and European markets, given the larger commercial potential. Argent plans to file Investigational New Drug (IND) submissions with the FDA in 2025 for CannEpil and CimetrA and we estimate clinical activity to commence thereafter. We value the company using an rNPV approach for its three clinical assets, assigning PoS from Argent's management to our NPVs. We value Argent at an un-risked NPV of US$1.1bn (accounting for the three programmes and its manufacturing facilities, early access revenues, overheads and net debt). Based on the company-defined PoS estimates, our rNPV valuation is US$327m or US$6.7/share.

Historical financials

Year end	Revenue (A$m)	PBT (A$m)	EPS (c)	DPS (c)	P/E (x)	Yield (%)
06/20	2.1	(18.8)	(1.40)	N/A	N/A	N/A
06/21	3.0	(15.9)	(0.83)	N/A	N/A	N/A
06/22	4.7	(20.8)	(0.79)	N/A	N/A	N/A
06/23	3.4	(21.1)	(0.71)	N/A	N/A	N/A

Source: Company filings

Price	A$0.47
Market cap	A$23m

Share price graph

Share details

Codes	RGT.AX (to delist soon), RGT.L
Listings	ASX, LSE, OTCQB Venture Market
Shares in issue	48.41m

Business description

Argent BioPharma is a revenue-generating, clinical-stage biopharma company, focused on developing treatments for neurological and immunological conditions. Its pipeline includes three clinical-stage assets (Phase I and II) and two preclinical asset, led by CannEpil (drug-resistant epilepsy) and CimetrA (acute lung injury), both available under special access schemes in the EU, the UK and the US. Management plans to file IND applications for the two assets with the FDA by end 2025.

Bull

- Revenue generating, with sales recognised through early access schemes.
- Targeting areas of significant unmet need and commercial potential.
- Growing exposure to key markets of EU, UK and US with two products on the market (under special access) with IND filings planned by end 2025.

Bear

- Portfolio in the early stages of clinical development, with long lead times to approval under traditional regulatory pathways.
- Short cash runway with the need to raise significant capital to advance its development pipeline to the market.
- Potentially more stringent regulatory oversight for some of the assets.

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Edison profile page

An innovative approach to drug development

Company overview

Argent BioPharma is a clinical-stage biopharmaceutical company focused on the development of innovative plant-derived therapies for diseases with high unmet need. The company completed a rebranding to Argent BioPharma in April 2024, supported by a substantial capital injection, reflecting its identity as a pure drug development company within the biopharmaceutical sector, with the plan to target the US and European markets. As part of this process, Argent has emphasised its focus on developing novel pharmaceutical products through a polypharmacology approach to drug discovery, acknowledging the complexities of the human body and striving to move away from historical workflows in the sector, which in some cases centred on 'one-molecule, one-target' approaches. Instead, Argent's management team believes that by targeting multiple receptors with single treatments, it has the capabilities to produce more efficacious therapies at lower doses.

A broad product pipeline

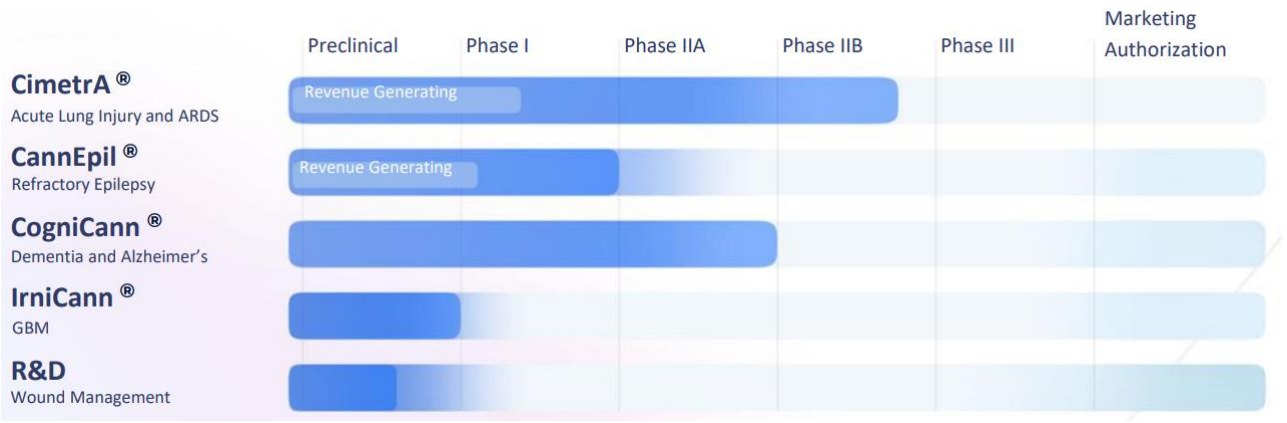
Argent's core focus is on conditions that lack effective treatment options. As such, its current pipeline spans a range of targeted indications (Exhibit 1). Leading the way are CannEpil and CimetrA, both of which are currently prescribed and sold through early access schemes in markets such as the UK, US and EU, generating early revenue streams as well as real-world evidence, which should aid future discussions with regulatory authorities.

CannEpil is being developed as a potential treatment for refractory epilepsy, aiming to reduce the number of seizures experienced by patients in cases where no other therapies have worked. The real-world evidence generated through early access schemes suggests that there have been no adverse events associated with CannEpil, reflecting the patient benefit in a real-world setting.

CimetrA was initially developed with the intention of preventing cytokine storms and as a symptomatic treatment for COVID-19, but is now targeting acute lung injury (ALI) and acute respiratory distress syndrome (ARDS), with potential to expand to other indications characterised by severe inflammation and immune dysregulation.

CogniCann, Argent's third asset, is being developed with the intention of improving quality of life in patients with dementia and Alzheimer's disease (AD) and, while it has previously been evaluated in Phase II, the programme is currently on hold while management assesses commercial and regulatory pathways under special access schemes.

Exhibit 1: Argent BioPharma's R&D pipeline



Source: Company presentation (September 2024)

IrniCann, currently in the preclinical stage of development, aims to target patients with glioblastoma multiforme (GBM), a highly aggressive, fast-growing form of cancer on the brain or spinal cord. While there is no known definitive cause of the disease, it is associated with an accumulation of genetic mutations, which can lead normal cells to develop into cancerous cells, which in turn grow into tumours. Treatments are limited to relatively aggressive options, such as surgery, followed by chemotherapy and radiotherapy, though due to the diffuse nature of GBM, it is very challenging to completely eliminate the disease. As such, survival rates are relatively low, with only c 25% of patients surviving more than one year and c 5% of patients surviving more than five years.

A strategic collaboration with SINTEF for chronic wound management (RGAI03MW01) was announced in August 2024. Argent plans to leverage its nano-formulation capabilities to address the ongoing medical challenge of effective wound care management, for which associated challenges include severe symptoms, infections, impenetrable biofilms and deteriorating tissue health. The project with SINTEF is intended to identify and select novel anti-microbial active ingredients, improve local tissue health while offering symptomatic relief, and optimise nano-formulations to enhance medical benefits. An important component of this collaboration will focus on the design of nano-formulations for selected agents, intended to be identified in initial screens. Ultimately, it is hoped that such nano-formulations will lead to improved drug delivery, increased penetration through biofilms and sustained release of active ingredients, thereby addressing challenges posed by antibiotic resistance and tissue health deterioration. We note that Argent will retain ownership of all project results.

As IrniCann and the chronic wound management programme are in the early stages of development, they are not included in our current valuation for Argent; the remainder of this report will focus on CannEpil, CimetrA and CogniCann.

Supported by in-house manufacturing capabilities

Beyond its development pipeline, Argent is well-equipped with its manufacturing facilities, making it a vertically integrated biopharmaceutical company. These include two EU-GMP R&D and manufacturing sites, in Slovenia and the latest in Malta, which should support in-house drug development efforts. The facilities have the capacity to manufacture more than 20,000 units per day (more than 6,000,000 units a year), which management anticipates should be able to support the clinical and commercial requirements of its pipeline products, such as CannEpil and CimetrA. We also note that they may present an opportunity for future revenue streams, monetising the facilities through contract manufacturing services. The feasibility of this will likely come to fruition as the company scales its internal operations.

CannEpil: Targeting drug-resistant epilepsy

CannEpil is one of Argent's primary revenue-generating assets, an oil-based product currently available in the UK under special access (introduced in 2023) and covered by insurance in Ireland (since 2019) for patients with refractory epilepsy (also referred to as drug-resistant epilepsy). Epilepsy is one of the most prevalent neurological disorders and, while many patients are able to manage the condition with available symptomatic treatments, it is estimated that approximately one-third of patients do not achieve satisfactory responses and are termed drug-resistant.

CannEpil is an enhanced iteration of a compounded isolated cannabinoid formulation. Management aims to build on historical research that suggests cannabis-based medicinal products can be an effective treatment option for some epilepsy patients. Notably, in 2018 the FDA approved GW Pharmaceuticals/Jazz Pharmaceuticals' Epidiolex, a highly purified, plant-derived CBD formulation, for the treatment of epilepsy (c $845m in sales in 2023). While Epidiolex contains CBD only, management believes that CannEpil's compounded CBD-THC formulation could offer a competitive

edge due to potential synergies between the two active ingredients, such as improved control with lower doses.

Argent is taking a strict pharmaceutical approach with the development of CannEpil to circumvent some of the challenges seen with cannabinoid-based products, such as lack of rigorous standardisation. As such, it is ensuring that all production adheres to good manufacturing practice (GMP), utilising its GMP-certified facilities to produce a stable, effective and quality product.

Backed by real-world evidence

Early-stage research, conducted through Australia's and Ireland's special access scheme programmes, has generated data to support the application of CannEpil as a potential treatment for refractory epilepsy. Management has communicated that the key findings from this research were that CannEpil was prescribed at 28–35% lower doses compared to the CBD-only drug with which it was compared, with possible lower required volumes of the oil-based product holding potential to support patient compliance, and potentially suggestive of therapeutic potency. The retention rate or continued prescription use for CannEpil was also observed to be higher than that of the CBD-only counterpart, potentially indicating an improved safety profile alongside enhanced efficacy. As a case study, Argent has presented the outcome for 'patient M', who accessed CannEpil through the I AM Billy Foundation. The real-world data exemplified the potential of CannEpil in managing refractory epilepsy, showing a notable reduction in seizures and improved quality of life after 1.5 years of treatment. In addition to controlling seizures, patient M also experienced enhanced cognitive function, motor skills, speech and sleep patterns, reflecting the perceived benefit.

Outlook

Argent is currently working to complete preclinical studies across H224 and H125, and plans to file an IND application for CannEpil in 2025. This could be supported by real-world evidence (which has an increasing prevalence in drug development), which could provide useful insights into safety and efficacy from those using it in the UK and Ireland, potential facilitating future discussions with regulators. Argent is also planning to incorporate additional intellectual property (IP) protection and potential commercial safeguards, ensuring the drug's long-term viability and value proposition. Ultimately, the company's aim is to pursue an Orphan Drug Designation (ODD) from the FDA, with the goal of tapping into the drug-resistant/refractory epilepsy market, which is projected to be worth c $6bn by 2034.

CimetrA: For complex inflammatory conditions

CimetrA is an oral spray product with a multi-targeted approach holding potential to elicit broad effects on inflammation, compared to single-target approaches, positioning it as a candidate for complex inflammatory indications. The initial indications being targeted are ALI and ARDS. It comprises two active ingredients, curcumin and Boswellia serrata, plant-derived compounds backed by research that suggests they may exhibit beneficial anti-inflammatory properties and modulate immune responses. We note that while, historically, CimetrA was a three-component formulation (comprising artemisinin, curcumin and Boswellia serrata) that completed various clinical studies (see here for further details), we focus on the research conducted since its re-formulation in 2021/22 to the present two-component formulation of curcumin and Boswellia serrata.

Established mechanism(s) of action

Management attests that CimetrA's potential efficacy stems from its multipronged mechanism of action:

- Inhibition of IL-32: in vitro preclinical research has shown the inhibitory properties of CimetrA on the expression of IL-32 mRNA, preventing the production of IL-32 proteins and, accordingly, supressing inflammation and inflammatory cytokines. IL-32 is well-understood as being associated with NF-κB and p38 MAP kinase inflammatory pathways, which in turn are responsible for producing further inflammatory cytokines such as TNF-α and IL-6. Inhibition of IL-32 therefore represents a sensible strategy to prevent such conditions. While there are currently no FDA-approved drugs that specifically inhibit IL-32, there are a multitude of approved drugs that inhibit the associated cytokines. For example, AbbVie's Humira, Amgen's Enbrel and J&J's Simponi are all FDA-approved treatments for various inflammatory conditions.
- Heme-oxygenase-1 (HO-1) activation: CimetrA has demonstrated an ability to increase intracellular HO-1, an enzyme responsible for breaking down metabolites and providing protection against oxidative stress, and hence inflammation.
- As discussed above, CimetrA modulates the production of various cytokines, such as IL-1α, IL-1β, IL-6, TNF-α, and IFN-γ, all of which are implicated in inflammatory responses.

Further preclinical research, completed in August 2023, assessed the safety and toxicology profile of CimetrA in large animals. The formulation was found to be safe, adding to the data package to support a future IND application to the FDA (see below).

Outlook

While CimetrA does generate some revenues for Argent as an over-the-counter unlicensed drug product in the US, the company is working on further preclinical studies, including ex vivo testing and in vivo testing with a complex animal model, aiming to assess the potential activity of CimetrA across various indications (which we believe will focus on ALI and ARDS), which it hopes to launch by end-2024. We understand that management plans to file an IND application for CimetrA by end-2025.

CogniCann: Symptomatic relief for dementia patients

CogniCann is an oral spray designed to treat symptoms associated with dementia and AD. It is estimated that more than 55 million people suffer from these conditions worldwide, and often face a multitude of challenging symptoms relating to changes in mood and behaviour. These usually become worse over time and can lead patients to become increasingly aggressive. While there are many different forms of dementia (with AD being the most common, accounting for 60–70% of cases), CogniCann's compounded THC-CBD formulation is intended to improve behaviour and cognition in the full population.

Phase II study highlights potential

While there are currently no active trials running for CogniCann, it completed a Phase II trial in June 2022, conducted in Australia. This was a randomised, double-blind, cross-over, placebo-controlled study (n=22), designed to evaluate the safety and efficacy of CogniCann and to ascertain the dose response. Eligible patients undertook a six-week course of treatment with CogniCann, before crossing over to a six-week course of placebo, with a two-week 'washout' period in between. The endpoint measures included: change in Neuropsychiatric Inventory Questionnaire – Nursing Homes (NPI-NH) in the treatment group compared to placebo; change in aggressive behaviour in the treatment group compared to placebo; and change in Cohen-Mansfield Agitation Inventory (CMAI) in the treatment group compared to placebo. From a safety perspective, it was found that outcomes were comparable between the treatment and placebo groups. In terms of efficacy, NPI-NH scores showed that the placebo group experienced a greater deterioration in their condition, while the CogniCann group had a more stable neuropsychiatric profile. Further, CMAI aggression subscale scores demonstrated that the treatment group improved by 13%, versus 4% for the placebo group.

For the CMAI scale itself (a more elaborate 29-item scale to assess the frequency of manifestations of agitated behaviours), the results showed that the treatment group improved by 17%, versus 8% for the placebo group, highlighting the potential of CogniCann to reduce aggression and agitation, and hence improve the quality of life for dementia patients as well as those close to them.

Outlook

It was initially planned that the trial would aim to enrol 50 patients in total, but recruitment was disrupted due to the COVID-19 pandemic. Nevertheless, the results from this study are intended to support the design of the next phase of clinical trials, including the selected endpoints and patient sample size. As discussed above, while there are currently no active clinical trials running for this programme, Argent management is assessing potential commercial and regulatory pathways under special access schemes. We also expect to company to file a US IND application, following the submissions for CannEpil and CimetrA, potentially in 2026.

Valuation: US$327m or US$6.7 per share

With Argent being a clinical-stage biopharma company with several assets in the clinic and significant lead times to potential commercialisation, we use a risk-adjusted net present value (rNPV) to value the company, projecting cash flows to the end of market exclusivity for each asset, with a 50% year-on-year decline in sales assumed thereafter. While the company currently has five programmes in its portfolio, our valuation is derived from the three most advanced clinical-stage assets (CannEpil, CimetrA and CogniCann), which we have valued individually based on our assessment of market potential and other assumptions (discussed in more detail below). We note that while the calculated un-risked NPV is based on Edison's independent assessment of the potential market valuation of these assets, the assigned risk adjustment for the assets has been taken from Argent's internal estimates of success probabilities. To reflect the inherent risk associated with the biopharma business and potential variability in risk adjustments, we also present a sensitivity table, highlighting the possible valuation ranges based on different PoS and discount rates (Edison's standard discount rate for clinical-stage companies is 12.5%).

CannEpil

We value CannEpil at an un-risked adjusted NPV of US$508m. Applying the company's internal 35% PoS for the asset gives an rNPV of US$178m. We model the target market for CannEpil to be epilepsy patients (both adult and paediatric) with drug-resistant epilepsy (one-third of all adult patients and 20–25% of paediatric patients). Furthermore, based on management guidance, we refine our estimates for the target population further by considering only those patients affected by generalised seizures (30% of all epilepsy patients). We estimate the target population (US and Europe) for CannEpil to be 900,000 adult patients and close to 100,000 paediatric patients. We assume a year-on-year growth rate in patient population of c 4%, given the high incidence rates (c 150,000 people are diagnosed with epilepsy per year in the US). Argent plans to file an IND application with the FDA in 2025, and we model the Phase II trial to commence from 2025, projecting market approval and commercial launch in 2030.

For our base case scenario, we assume peak market penetration to be 7.5% in adults and 10% in children (higher unmet need), expecting this to be reached by the end of market exclusivity periods (five years in the US and eight years in Europe). We estimate a list price of US$22,750 in the US, with a gross/net discount of 50% related to payor rebates, resulting in an effective realisable price of US$11,375 per year in the US. This is based on the US$32,500 price tag attached to Epidiolex in the US, albeit with a 30% discount due to a broader target market. We assume the realisable price in Europe to be US$5,688 per year (50% of the US price) based on the standard pricing differences

between the two geographies. We estimate un-risked adjusted peak sales of US$1.27bn by 2037 for CannEpil. For reference, Epidiolex recorded US$845.5m in sales in 2023.

CimetrA

We value CimetrA at an un-risked adjusted NPV of US$239m. Applying the company's internal 50% PoS for the asset gives us an rNPV of US$119m. While CimetrA is targeting the broader anti-inflammatory space, we restrict our current valuation to the two indications initially in focus: ALI and ARDS. Both indications have an annual incidence of around 200,000, resulting in a target population of c 800,000 across the US and Europe, with an annual assumed growth rate of c 2%. Argent plans to file an IND application with the FDA by end-2025, and we model the US Phase II trial to commence in 2026, with approval and launch projected by 2031.

Given there are currently no approved drugs specifically targeting these indications, we assume a healthy 20% peak penetration rate for CimetrA in our base case scenario. For the pricing, while there is no precedence as the indications have no approved drugs, we assume a list price of US$5,000 in the US given the seriousness of the indications and high hospitalisation associated expenses. Similar to CannEpil, we assume a gross/net discount of 50% in the US for a realisable treatment price of US$2,500 per patient. The realisable price in Europe is assumed to be US$1,250 per patient. We estimate un-risked adjusted peak sales of US$570m by 2039 for CimetrA.

CogniCann

We value CogniCann at an un-risked adjusted NPV of US$416m. Applying the company's internal 15% PoS for the asset gives us an rNPV of US$62m. CogniCann is focused on proving symptomatic relief and improving quality of life in dementia patients, targeting aggression/agitation, sleep quality etc. Since AD constitutes c 70% of all dementia cases, we have used it as a proxy for the eligible patient population. We assume the drug to cater to AD patients with moderate to severe disease (c 50% of all AD patients), projecting 75% of patients seeking treatment and compliance rates of 70% (significant discontinuation rates due to the nature of the disease). Given the high prevalence rate, we estimate the target patient population to be 4.3 million patients across the US and Europe, with a 2.5% year-on-year growth rate. We estimate a Phase I clinical trial to commence in 2026, with market launch projected in 2033.

For our base case scenario, we assume the peak penetration rate to be a conservative 5% of the target population. We estimate a list price for the drug to be c US$9,500 in the US, applying a 50% discount to the c US$19,000 price tag attached with Rexulti, the only antipsychotic currently approved for agitation associated with dementia due to AD. Again, assuming a gross/net discount of 50% gives us a realisable price of c $4,750 per patient in the US. We assume a realisable price of US$2,375 in Europe. We estimate un-risked adjusted peak sales of c US$1.1bn to be achieved by 2038.

Valuation

This gives us an implied NPV of US$1,163m and an rNPV of US$360m for the three clinical programmes. Incorporating other valuation adjustments related to the company's manufacturing facilities (we include the carrying value of property, plant and equipment as a proxy), early access schemes and overheads gives us an overall NPV of US$1.1bn. This translates to an rNPV of US$327m or US$6.7 per share. We note that we currently do not ascribe any value to the company's preclinical programmes (IrniCann and RGAI03MW01), which could contribute to further upside as these assets enter the clinic. We also highlight that our valuation for CimetrA is based on the two indications for which there are current ongoing activities, although management has communicated its plans to expand to additional complex inflammatory conditions, which could add further upside, should the plans come to fruition.

A breakdown of our rNPV valuation for Argent is presented in Exhibit 2 below.

Exhibit 2: Argent's rNPV valuation

Program	Indication	Probability of success	Launch year	Peak sales (US$m)	NPV (US$m)	rNPV (US$m)
CannEpil	Drug-resistant epilepsy	35%	2030	1,265	508	178
CimetrA	ALI, ARDS	50%	2031	570	239	119
CogniCann	Dementia in AD	15%	2033	1,069	416	62
Early access sales		50%			5	3
Malta & Slovenia manufacturing facilities		100%			4	4
Overhead/admin expenses		50%			(68)	(34)
Net cash/(debt) at end-June 2024						(5.5)
Total equity value					1,099	**327**
Shares outstanding						48.4
Equity value per share (US$)						**6.7**

Source: Edison Investment Research. Note: Probability of success based on the company's internal assessment.

As mentioned earlier, the risk adjustments used above are based on the company's internal estimates. Given that these are subject to variability, we also present a sensitivity table that provides the range of valuations, based on different success probabilities and discount rates (Exhibit 3).

Exhibit 3: Sensitivity of rNPV to success probabilities and discount rates

Discount rates \ Probability of success	11%	16%	21%	26%	31%	36%	41%	46%	51%
16.5%	48	82	116	150	185	219	253	287	321
15.5%	57	96	135	174	213	252	290	329	368
14.5%	68	112	156	201	245	290	334	378	423
13.5%	80	131	181	232	283	334	384	435	486
12.5%	94	152	210	268	**327**	385	443	501	559
11.5%	110	177	244	310	377	444	511	577	644
10.5%	129	206	283	359	436	513	590	666	743
9.5%	151	240	328	416	505	593	682	770	858
8.5%	177	279	381	483	585	687	789	891	993

Source: Edison Investment Research

Risks and sensitivities

Argent BioPharma is subject to the typical sensitivities and risks associated with drug research and development. Its prospects will be affected by development delays or failures, competitor successes, regulatory risks, IP risk and financing risks. We highlight the key risks and sensitivities for the company below.

Funding and dilution risks

A key sensitivity in the near term, in our view, is access to capital. Drug development is a capital-intensive exercise characterised by front-end loaded expenses and long lead times to internal cash flows. We estimate that Argent's three ongoing clinical programmes will need a total of US$80m in development costs to take them to commercialisation. The pace and success of ongoing development work would therefore hinge on the company's ability to raise timely and sufficient external capital. We note that at present Argent's cash resources are restricted (A$0.7m/US$0.5m in gross cash at the end of June 2024) and A$8.7m/US$6m of convertible debt (under the 2020 and 2022 agreements with Mercer Street Global Opportunity Fund) needs to be either refinanced or redeemed in the near term. While the company is generating initial revenues from early access schemes (A$0.9m/US$0.6m), this is likely to provide limited support given the significant overheads (A$15.6m/US$10.8m of administrative expenses in the year ending June 2024). The funding, if raised through debt issuances, could come with restrictive covenants and high servicing cost. On the other hand, equity issuances could result in significant shareholder dilution (the extent will be contingent on the issue pricing). We note that Argent had raised US$8.4m against the issue of

32.5m shares for the year ending June 2024 and a further US$2.5m post-period in July. The July raises were achieved at a c 400% premium to the trading price.

Regulatory and development risks

Two of the three clinical assets in development by Argent are medicinal-grade cannabinoids, with different combinations of CBD and THC. While the potential entourage effect of adding THC to CBD is being studied widely, THC is also characterised by its psychoactive effects and may therefore invite increased regulatory oversight from the authorities. Despite off-label usage of cannabinoids, to date the US FDA has approved only one plant-based cannabinoid as a medicinal product (Epidiolex, which is a pure CBD extract with no THC). Sativex, a cannabinoid developed by GW Pharma (acquired by Jazz Pharma in 2021) that is a 1:1 CBD THC formulation targeting moderate to severe spasticity due to multiple sclerosis, while approved in European countries, has not received approval from the US FDA, after unsuccessful Phase III trials in the country.

Intellectual property risks

Argent holds patent protection for its drugs CimetrA and CannEpil and has been working towards trademarking all products in its portfolio. However, we note that, given the plant-based origins of the products, the IP position could be challenged by other formulations developed by competitors. We therefore conservatively assume that Argent's pipeline, if commercialised, will receive the typical five-year market exclusivity in the US and eight years in Europe, following which we expect a steady sales erosion. If the company is able to secure the ODD for CannEpil, market exclusivity could increase by another two years across the geographies.

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