PITT STREET RESEARCH

Paradigm Biopharmaceuticals

Phase III in 2025

Share Price: A$0.43

ASX: PAR

Sector: Biotechnology

23 January 2024

Paradigm Biopharmaceuticals is about to enter a Phase III clinical trial with Zilosul. Zilosul is an injectable form of pentosan polysulfate sodium (PPS) – an anti-inflammatory drug that has shown strong potential against osteoarthritis.

All ready to go

In 2024, Paradigm has determined the optimal dose for the trial and had its trial protocol rubber stamped by the FDA. The company intends on commencing the enrolment of patients in Q1 of 2025. To this end, Paradigm has raised $16m through an institutional placement, taking its cash balance to $26.9m. Interim analysis is expected in 1H26. And this trial could be the pivotal trial before regulatory approval. Zilosul could be bought to market within less than 4 years from today.

Even prior to regulatory approval, we see upside in the company that could result from potential licensing deals for Zilosul and clinical progress against other indications the company is targeting, particularly Mucopolysaccharidosis (MPS).

Why Zilosul is needed

Zilosul is needed because of the growing presence of osteoarthritis. As we outline in this report, there are over 32m people in the USA and over 2m people in Australia suffering from osteoarthritis. Although there are drugs available for sufferers, they require frequent administration and/or suffer reduced effectiveness over time. Many of them can be opioid-based and cause side-effects not just harmful to individual patients but to society as a whole. Zilosul offers hope to people suffering from osteoarthritis for a better solution.

Updated valuation range of A$0.87-1.19 per share

We valued PAR at $227.9m in our base case and $318.2m in our bull case in our initiation report ($0.76 per share and $1.06 per share respectively). We update our valuation to $341.2m in our base case and $467.9m in our bull case, amounting A$0.87 per and A$1.19 per share respectively. This is done by reducing our discount rate from 14.9% to 12.3% in light of the developments since our initiation note (particularly the accelerated clinical timeline) but also updating the number of shares on issue following the capital raising. We believe PAR can re-rate if the trial is a success and the company can bring Zilosul to market. Please see p.8 for more details on our valuation and p.10 for the key risks.

Market cap. (A$ m)	167.4
# shares outstanding (m)	389.3
# shares fully diluted (m)	391.9
Market cap ful. dil. (A$ m)	168.5
Free float	99.97%
52-week high/low (A$)	0.58/0.18
Avg. 12M daily volume ('1000)	1,065.7
Website	paradigmbiopharma.com

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)

Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$)	0.87-1.19
WACC	12.3%
Assumed terminal growth rate	2%

Source: Pitt Street Research

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Re-Introduction to Paradigm Biopharmaceuticals (ASX:PAR)

Paradigm Biopharmaceuticals is developing Zilosul, a repurposed injectable form of pentosan polysulfate sodium (PPS).

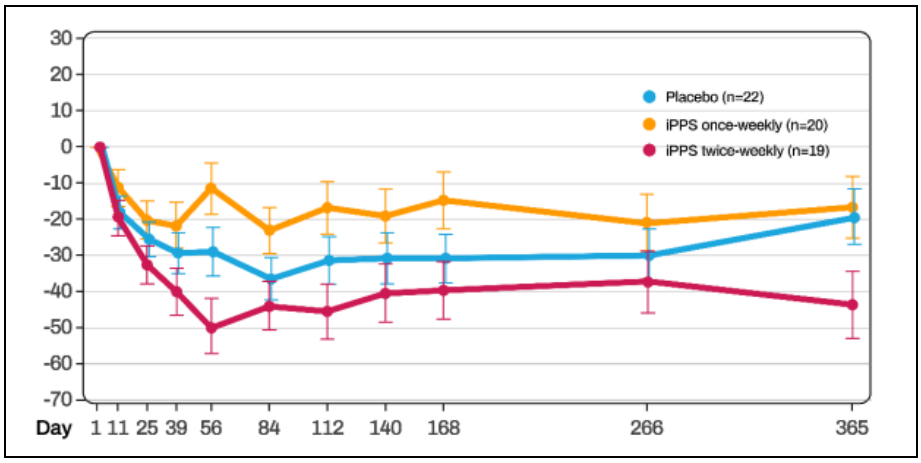
Paradigm Biopharmaceuticals is developing Zilosul, a repurposed injectable form of pentosan polysulfate sodium (PPS), to address unmet medical needs. The indication Zilosul is most advanced against is osteoarthritis, a condition that has an addressable population of over 72m in identified key markets[1]. PPS works by blocking or inhibiting cartilage-degrading enzymes. These include ADAMTS-4, ADAMTS-5a MMP-13 and MMP-3b. In so doing, PPS prevents further cartilage damage, reduces signs and symptoms of osteoarthritis and increases blood flow.

Paradigm has an exclusive 25-year supply agreement with German manufacturer bene parmaChem for PPS, multiple method of use patents that are continually being refined and expanded and extensive evidence of PPS' efficacy against osteoarthritis and other conditions.

The progress made to this pivotal point

The company has been listed in mid-2015 and has been building up to this pivotal moment ever since. Initially, it targeted Bone Marrow Edema (BME), a condition where fluid builds up in the bone marrow following acute knee injuries but pivoted to Osteoarthritis after one particular clinical trial in BME (conducted in 2018) specifically in people with osteoarthritis where a reduction in pain was observed. A further Phase II trial (PARA_OA_008) began in 2021 to observe PPS' impact on osteoarthritis generally, and the trial was a success (Figures 1-4). The primary endpoint – a change in one or more synovial fluid biomarkers associated with osteoarthritis disease progression – was achieved at Day 56 and at Day 168. The other endpoint was also achieved, which was structural changes in the knee as determined by MRI. Other subjective data measures were positive as well including reductions in pain. 73% saw a 30% or greater improvement in pain, whilst 60% saw 50% or greater. There was also an improvement in the thickness and volume of cartilages. There were no serious adverse events, or adverse events of special interest. Clearly PPS is not just another short-term pain relief.

Figure 1: Pain perception in the PARA_OA_008 trial (y axis is WOMAC scores)



Source: Company

[1] This includes the US, EU5, Canada and Australia altogether and was estimated by the Institute for Health and Metrics Evaluation at the University of Washington.

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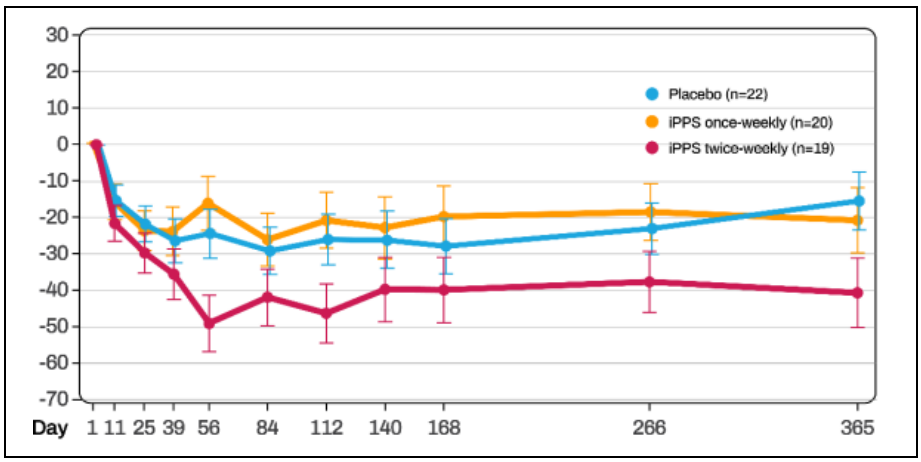
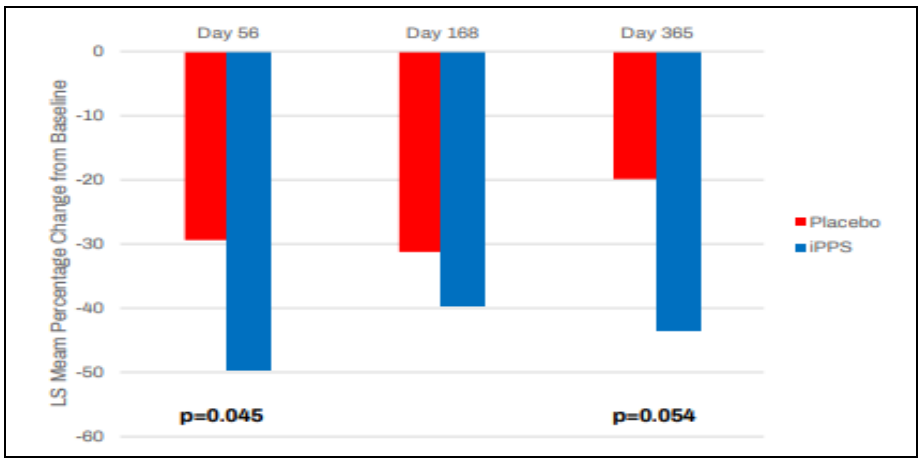
Figure 2: Function perception in the PARA_OA_008 trial (y axis is WOMAC scores)



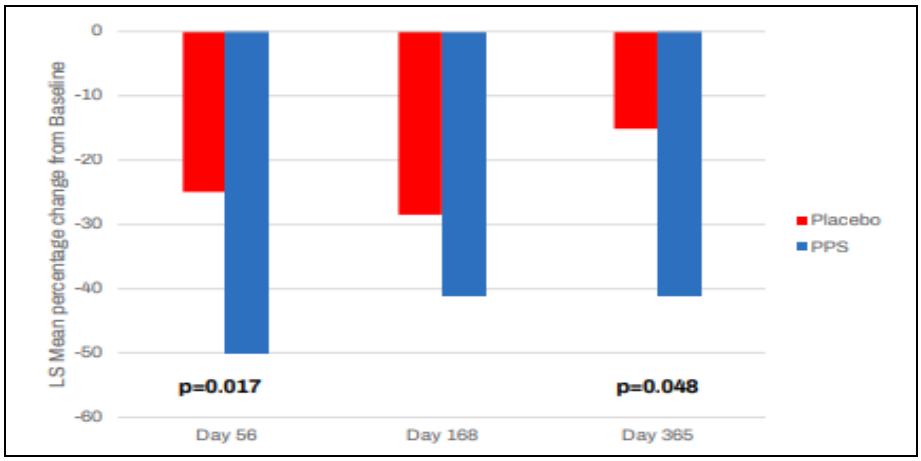
Source: Company

Figure 3: Change in WOMAC pain at days 56, 168 and 365 from baseline



Source: Company

Figure 4: Change in WOMAC function at days 56, 168 and 365 from baseline



Source: Company

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PARA_OA_012 (Phase III)

Paradigm is in the midst of a Phase 3 trial - PARA_OA_012. The company has completed the first stage of the trial: a dose selection for the second stage of the trial. In the second stage, dosage will be administered, as determined in the first stage – 2mg/kg twice weekly.

The company will start enrolling patients in Q1 2025.

The Second Stage is set to commence in Q1 2025. This is all but certain after the 30-day FDA review period passed and no substantive questions or concerns were raised that would have prevented the trial going ahead. There have been some structural changes to secondary endpoints to enhance their importance in regulatory submissions and potential label claims, but none to cause delays to the trial.

The trial will see 466 patients with half receiving the pre-determined dosage of PPS and the other half of patients receiving the chosen regimen and 233 receiving placebo. The treatment duration will be 6 weeks, with the study duration being 64 weeks. Patients will visit twice weekly during treatment and then be followed up every 4-6 weeks for the rest of the study.

The primary endpoint of the trial is a change from baseline in pain. This will be assessed by a weekly ADP (Average Daily Pain) score on the numeric scale (NRS) 11-point (0-10) scale. Secondary endpoints include pain and functional assessments at multiple timepoints up to Day 404, the Patient Global Impression of Change (PGIC) and structural changes as measured by MRI and X-Ray.

Paradigm has just completed a $16m placement to institutional and sophisticated investors in order to fund the trial set up (the site initiation and patient recruitment), ramp up of the company's inventory and manufacturing and for general working capital. The deal, which was completed at 40c per share - a slight premium to the 30-day VWAP prior to the raise; takes its cash balance to $26.9m.

What will happen after Phase III?

Results from the trial are expected in the first half of CY25.

Subject to the next phase of the Phase 3 proceeding, the new study PARA_OA_012 expects first results in 1H26 subject to recruitment rate), given initial results will be derived at the 56-day mark. Recruitment is planned to begin in Australia in Q1 of 2025, with US recruitment commencing in Q2. The company plans to submit to the FDA following the conclusion of the pivotal and confirmatory trial completion which will be approximately 1 year after the final patient is enrolled. Thereafter, the FDA could take up to 9 months to give an answer. Assuming this schedule is met, this could see it commercialised in the first half of CY28.

The company also aspires to obtain TGA approval, although its efforts to obtain approval through fast-tracked pathway (a provisional determination application) has been unsuccessful and it will need to seek approval through the conventional pathway. Although the TGA acknowledged there was sufficient evidence to support progression with the company's clinical endeavours, the regulator could not provide a Fast-Track because minor or mild osteoarthritis is not seriously debilitating – the degree necessary to support fast-tracked approval.

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The need for Osteoarthritis treatments

Osteoarthritis is the most prevalent type of joint disease in general, impacting up to 16% of people in the developed world.

As we noted above, PPS provides hope for patients of osteoarthritis. Osteoarthritis is the most prevalent type of joint disease in general, impacting up to 16% of people in the developed world with over 72 million people in the US, EU5[2], Canada and Australia[3]. It is anticipated that the amount of people affected by osteoarthritis in these markets will grow to 250m over the course of the 2020s, up from 150m at the start of the decade.

Osteoarthritis impacts the tissue known as cartilage in the joints. Cartilage acts as a kind of shield between the bones and provides a smooth surface for joint motion. People suffering from osteoarthritis have their cartilage breaking down which can cause pain, swelling and problems moving the joint. Bits of the cartilage or even the bone may chip off and float around, causing even further damage. In the worst instances, joint replacement may be required.

People suffering from osteoarthritis experience joint pain and struggle to exercise or do everyday ordinary activities. 76% of all osteoarthritis occurs in the knees and/or hips. Furthermore, it is not just middle aged and elderly people that suffer from it. Younger adults, and even children, can be susceptible especially in long-term situations where they are vulnerable to injuring or overusing their joints such as in professional sports, the military or other physically demanding jobs.

Although there are existing treatments (Figure 6 and Figure 7), there is high dissatisfaction with current treatments from patients because:

1) Many require frequent administration and/or suffer reduced effectiveness over time,
2) A significant proportion of treatments are opioid or steroid based, and
3) All of these just relieve symptoms as opposed to treating the underlying pathology of the disease.

Paradigm's market opportunity for osteoarthritis

The USA and Australia are all but certain to be the first two markets for Zilosul.

Paradigm's two key markets are the USA and Australia. These jurisdictions are by no means the only opportunities but are all but certain to be the first two given these are where the company has applied for regulatory approval. There are varying estimates for how to value the total market and Paradigm has derived its own (Figure 5). It has estimated its opportunity as US$27bn, of which US$6.2bn is in the US and US$10.8bn is in China.

[2] France, Germany, Italy, Spain and the United Kingdom (even post-Brexit).
[3] In Australia, 3 million people are estimated to suffer from osteoarthritis.

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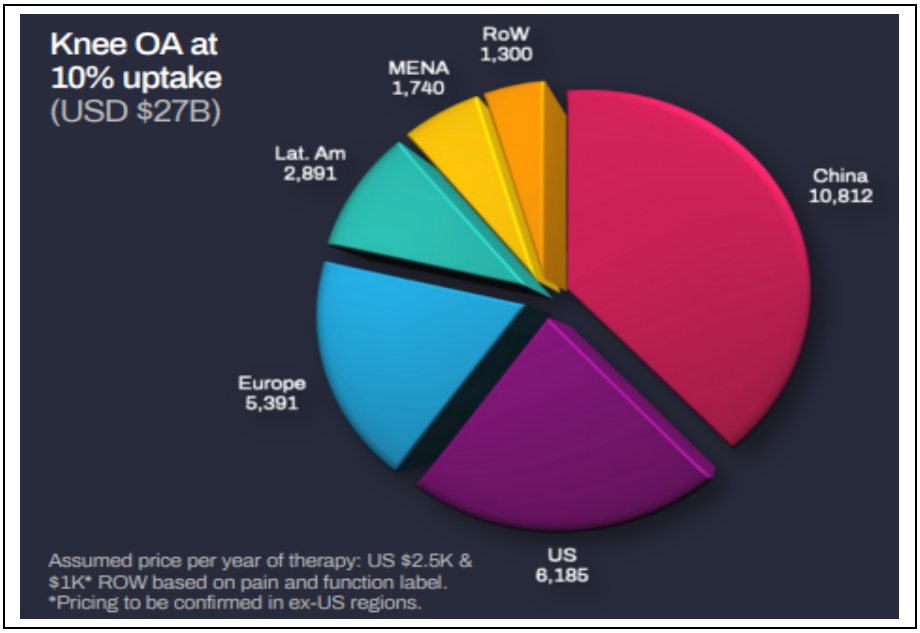
Figure 5: Pain perception in the PARA_OA_008 trial (y axis is WOMAC scores)



Source: Company

For the **USA**, the CDC has estimated that 32.5 million people suffer from osteoarthritis[4]. This is approximately 60% of the total people who suffer from arthritis generally, which is 53.2 million people or 21.2% of all adults[5]. 10% of osteoarthritis sufferers – the market openly dissatisfied with current treatments according to the company – would be 3.25m.

For **Australia**, we estimate 2.1 million based on 60% of the Australian Bureau of Statistics' modelling that 3.7 million Australians suffer from arthritis[6]. There was no separate data for osteoarthritis, but we calculated the Australian market as being ~60% of the former figure which is 2.1 million.

China may be another opportunity for Zilosul in the future.

China may be another opportunity down the track. This is not included in our final valuation at this in point because market entry will be after Australia and the USA. Nonetheless, it could be a lucrative market not just because of the population generally but the population with osteoarthritis. In 2019, there were 10,681,311 cases of osteoarthritis according to the Global Burden of Disease Study conducted by the Institute of Health Metrics and Evaluation (IHME), an increase of 133% compared with 1990[7].

[4] https://www.cdc.gov/arthritis/types/osteoarthritis.htm
[5] https://www.cdc.gov/arthritis/types/osteoarthritis.htm
[6] https://www.abs.gov.au/statistics/health/health-conditions-and-risks/arthritis/latest-release
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10876716/

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Our New Valuation of Paradigm Biopharmaceuticals

We update our valuation of PAR to $341.4m in our base case and $467.9m in our bull case, equating to $0.87 per share and $1.09 per share respectively.

In our initiation report, we valued PAR at $227.9m in our base case and $318.2m in our bull case. These equated to A$0.76 per share in our base case and A$1.06 per share in our bull case, based on the 299.8m shares outstanding at the time. In light of the company's firm decision to move to Phase III, the bolstering of its cash position as well as shareholder dilution, we update our valuation to $341.2m in our base case and $467.9m in our bull case. These amount to $0.87 per share and $1.19 per share based upon 391.9m diluted shares on issue[8] (Figure 7). We have reduced our discount rate to 12.25%, utilising a 4% risk free rate of return, a 5.5% equity premium and 1.5x beta. We also adjusted our market entry assumptions by a year to FY28 (the 12 months commencing 1 July 2027) in light of the FDA's clarification and PAR enrolling patients in the coming weeks.

The key assumptions driving our DCF valuation are otherwise unchanged. These are outlined below and summarised in Figure 6.

To briefly re-summarise:

- We modelled the Australian and USA markets based on the population estimates on the previous page
- We assume the company opts for the licensing route and takes a 12% royalty on all sales. We assume a total of A$110.7m of milestone payments, with $10.7m upfront upon execution on the deal during the second half of CY24. We assume $20m upon success of the trial, $20m on regulator submission, $30m on regulatory approval in the USA, $5m on regulatory approval in Australia, $10m upon commencement of sales and $5m on the first anniversary of sales.
- We modelled Paradigm's starting point of 10% of the total market and measure market penetration as a percentage of that 10%. We assume low penetration to start with, gradually growing to reach 10% in the US by CY33 and 30% in Australia by CY33. These equate to 396,173 patients in the USA and 77,126 patients in Australia which are 1% and 3% of the total addressable markets by that year respectively – which are 39.6m patients in the USA and 2.6m in Australia.
- We have used Paradigm's assumptions of US$2,500 per treatment in the US and US$1,000 in the Rest of the World (including Australia). We assume A$1 is US$0.67 which translates to A$1.50 per US$1.00. From this starting point, we assume 2% growth per annum.
- Once Zilosul is commercialised, we assumed R&D as 45% of revenues and 3% cost inflation for general & administrative and other commercial expenses increase by 3% per annum. This means the company will reach bottom line profitability in FY26 of $13.3m, then just under $7m for FY27 and FY28 as milestone payments moderate and sales slowly increase. In those years, the net margin is 20%, thereafter growing to reach 35% by FY33.
- We used a 30% corporate tax rate.

[8] 389.3m ordinary shares, plus 2.5m options and 125,000 shares in escrow.

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Figure 6: Our key DCF assumptions

Assumptions	Base	Bull
Launch (USA)	CY27	CY27
Launch (Australia)	CY27	CY27
Estimated market size (patient numbers - US)	3,517,905	3,517,905
Estimated market size (patient numbers - AU)	228,285	228,285
Potential market penetration	3%	3%
Realised price ($US) for USA	2,500	2,500
Realised price ($US) for ROW	1,000	1,000
Peak sales (A$m)	1,914	2,292
Peak royalty revenue (US$m)	230	275
Discount rate	14.90%	14.90%
Royalty rate	12%	12%
Tax rate	30%	30%
AUD/USD	0.67	0.67
Net margin (by CY33)	35%	38%

Estimates: Pitt Street Research

Figure 7 shows our valuation summary for Paradigm, while Figure 8 depicts the sensitivity of our valuation to various WACCs and the upside potential of the stock. The midpoint of our valuation range is A$0.91 per share.

Figure 7: DCF calculation

Valuation (A$m)	Base Case	Bull case
Present Value of FCF	49.9	86.0
Present Value of Terminal Value	299.2	389.7
Enterprise Value (A$ m)	**349.1**	**475.7**
Net (debt) cash	(7.9)	(7.9)
Equity value (A$ m)	**341.2**	**467.9**
Share outstanding (Diluted)	391.9	391.9
Implied price (A$ cents)	**0.87**	**1.19**
Current price (A$ cents)	0.43	0.43
Upside (%)	102.5%	177.6%

Estimates: Pitt Street Research

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We foresee the stock being re-rated to our valuation range if the following factors eventuate:

- Successful results from the PAR_OA_012 and PAR_OA_003 clinical trials.
- Regulatory approval, in both Australia and the USA,
- Commercial partnerships, either before or after regulatory approval, including potential licensing deals or even potential M&A, and
- Progress against other indications, particularly MPS.

Risks facing Paradigm Biopharmaceuticals

We see the following major risks for Paradigm as a company and as a listed stock:

- **Timing risk.** There is the risk that the company's products may take longer than expected to move through the clinic, leading to investor inertia and potentially the need to raise more capital.
- **Regulatory risk**. There is the risk that regulators may decline to approve PAR products. Even if PAR considers the data submitted to be adequate, the regulator may beg to differ, and even if the data is supportive, regulators still may decline for other reasons, such as the potential for negative interactions with other drugs. Even prior to the final submission, a key risk is that the FDA will not find the minimum dosing regimen found to be effective (namely 2mg/kg) acceptable to use.
- **Uptake risk**. There is the risk that the company products may not be taken up by its target markets. This may be due to poor sales and marketing efforts or disillusion from target markets that the solution is any different to existing solutions out on the market.
- **Funding risk**. There is the risk the company may not be able to secure finding to bring the drug through the clinic and regulators to market. Even if secured, future capital raisings may prove dilutive to existing shareholders. Moreover, a key assumption of ours is that a licensing transaction is conducted – although it is not impossible the company could opt to commercialise the drug in its own right, this would require a lot more capital.
- **Key personnel risk**. There is the risk that the company may lose key personnel and be unable to replace them and/or their contribution to the business.

Risks related to pre-revenue Life Science companies in general.

The stocks of biotechnology and medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character.

Since most biotechnology and medical device companies listed on stocks exchanges in Australia and around the world fit this description, the 'term' speculative can reasonably be applied to the entire sector.

The fact that the intellectual property base of most biotechnology and medical device lies in science not generally regarded as accessible to the layman adds further to the riskiness with which the sector ought to be regarded.

Caveat emptor. Investors are advised to be cognisant of the abovementioned specific and general risks before buying any the stock of any biotechnology and medical device stock mentioned in this report, including Paradigm.

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Appendix I – Analysts' Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms

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