



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Paradigm Biopharmaceuticals

ASX code: PAR

Share price: 24.5 cents (in suspension)

Shares on issue: 626,433,356

Market cap: \$153.5 million

Executive chair: Paul Rennie

Board: Mr Rennie, Amos Meltzer, Matthew Fry

Financials (year to June 30, 2026): revenue nil, other income \$8.1 million (up 14%), loss of \$56.3 million (previous deficit \$37.5 million), cash \$15.37 million (down 9%)

Identifiable major holders: Paul Rennie and related entities 3.32%, Mark van der Steeg 2.86%, Kzee Super Fund 1.98%, Evan Philip Clucas/Leanne Jane Weston 1.73%

Paradigm Biopharma has not quite been sealed in a corporate casket and interred. But Wednesday's appointment of voluntary administrators means it has one foot in the grave.

Can the knee osteoarthritis drug developer stage a Lazarus-like comeback with a tweaked clinical program and corporate purpose?

After all, the voluntary process is intended to enable thoughtful decision-making without pressure from nervous creditors.

Formally, the decision-making is in the hands of FTI Consulting's insolvency practitioners Christopher Pattinson and Hayden White, who assume responsibility for running the company and placating borrowers.

Their appointment follows last week's revelation that the company's pivotal phase III knee osteoarthritis trial had flopped. Strictly speaking, the study did not pass an interim 'futility' analysis and was discontinued.

Paradigm said the board had "formed the view that the company requires time to resolve the mismatch between current liabilities payable in the short term and the inherent long-term value of the intellectual property portfolio".

The company hopes for a deed of company arrangement (DOCA) to restructure its balance sheet and "assess a viable path" for the business.

"There is no certainty that a DOCA will be approved or implemented, or what the outcome will be for shareholders and creditors."

Futile pursuits

'Futility' is an emotive word often associated with war, cleaning a teenager's bedroom or arguing with a chatbot.

Now it's become all too synonymous with clinical trial setbacks and Paradigm became the latest victim with its study, Para-OA-012.

An independent data safety monitoring board (DSMB) deemed there to be no purpose in continuing the 538-patient study, which tested Paradigm's knee pain remedy with an anti-inflammatory mechanism of action.

In other words, the company failed the 'futility' test as determined by the DSMB.

Paradigm's legion of 'true believer' investors had keenly awaited the results – not to mention millions of knee osteoarthritis sufferers dependent on opioids.

While the voluntary administrators continue the post-mortem, the company's shares are cocooned in a share suspension.

PPS: Possible Pain Solution

It's all academic now, but the study road-tested Zilosul, Paradigm's name for injected pentosan polysulfate sodium (PPS), for mild to severe knee osteoarthritis.

Osteoarthritis affects around 530 million people globally, 32 million in the US. Knee OA accounts for 365 million of the worldwide tally.

PPS is an anti-inflammatory, heparin-like compound made from beechwood (hemicellulose).

In the past, the drug has been used to treat a bladder condition and deep vein thrombosis. PPS has been used on dogs and horses, without any safety concerns. Currently, osteoarthritis commonly is treated with non-steroidal anti-inflammatory drugs or opioid-based painkillers, which are either ineffectual or undesirable.

Paradigm has an exclusive 25-year exclusive supply deal with Germany's Bene Pharmachem, the world's only approved PPS maker.

Bene Pharmachem can do what it likes on the animal side, but Paradigm retains the rights to human applications.

Zilosul might be in the (very) slow lane now, but it had fast-track designation with the US Food and Drug Administration (FDA).

Paradigm over time

Paradigm was founded by Paul Rennie and Graeme Kaufman and listed on the ASX on August 18, 2015, having raised \$8 million at 35 cents apiece.

Mr Rennie was Mesoblast's head of product development. Mr Kaufman was CSL's chief financial officer through the plasma behemoth's privatization and was Mesoblast's vice president.

In November 2021, Mr Rennie ceded his chief executive role and continued as chair. But in November 2022 he returned to the CEO role.

In June last year, Paradigm acquired the private Proteobioactives Pty Ltd, an early-stage oral candidate for minor to mild osteoarthritis. The purchase price was up to \$16.5 million, but only \$500,000 in cash up-front. The remainder depends on milestones.

Paradigm aimed to test PPS with Proteobioactive's COX-2 inhibitor, called Coxib. The idea was to improve drug 'bioavailability' - a shortcoming of many oral drugs.

Perhaps there's some residual value in this program?

Paradigm has exclusive rights to develop the combo for both knee osteoarthritis and the veterinary market (dogs and horses).

Where's the evidence?

Most of the sector's phase III trial flops have been a surprise, but in Paradigm's case investors were comforted by the results of no fewer than three phase II trials and screeds of 'world real' evidence.

The latter refers to about 700 patients - mainly footballers - who underwent the treatment via trials or expanded access schemes.

The first patient was dosed in 2016.

The three-phase II trials were Para-OA-005, Para-OA-008 and Para-OA-002. Para 005 achieved a primary endpoint of reduction in pain and improved function among its 121 subjects.

With 61 patients, Para-OA-008 measured the change in the synovial fluid biomarkers associated with pain, inflammation and osteoarthritis. disease, relative to placebo. In October 2023, Paradigm reported “clinically meaningful outcomes” at 365 days compared to placebo.

These included significant pain reduction and functional improvements and durable improvements in stiffness. The results were measured by the Western Ontario and McMaster Universities Osteoarthritis Index (Womac) questionnaire.

The company also reported reduced use of pain medication, with the placebo group resorting to paracetamol (or such) five times more than the treated group. The 600-patient Para-OA-002 trial confirmed the minimum effective dose for the phase III study.

The company also was encouraged by MRI imaging of 15 patients, suggesting ‘functional’ joint improvement.

This meant the drug not only reduced pain but halted the cartilage reduction at the epicentre of the problem.

What went wrong?

Er, good question.

The 538-patient, phase III study was being carried out across 57 sites, 41 in the US, 12 locally, three in Moldova and one in Hong Kong.

The outcome follows the DSMB’s review of unblinded interim efficacy and safety data. The analysis took place when about 50 percent of participants had reached day 112 of treatment.

According to Paradigm, the problem stems from missing data, which raises the prospect of a giant snafu on the part of the company or the contract research organization.

We’re not pointing fingers because we don’t know.

“Operational challenges in the conduct of the study resulted in a significant amount of missing data, which has impacted the interim efficacy results,” Paradigm said.

“Under the statistical analysis plan, missing data is imputed and this imputation impacted the efficacy outcome”.

In other words: you can't fill in the gaps in the way unpopular polities do when they talk about the 'silent majority' of voters not expressing their preference.

Currently, the data remains blinded.

When it is unblinded, the company will review all the data including pain, function, safety and other pre-specified endpoints.

"The company continues to review the available data to obtain further information and better understand the nature and extent of that impact."

David Baker, founder of Adelaide firm Baker Young said "upwards of 30 percent" of the trial data appeared to be missing.

This "corrupted the overall read outs from approximately 50 percent of the total test participants"

He adds: "The FDA insists on a total data read out and nothing less" - which indeed is true.

Finances and performance

Among other housekeeping, management needs to assess trial wind-down costs and contractual obligations.

The decision to appoint a voluntary administrator was made in cahoots with specialist financier Obsidian Global Partners, which had extended a \$US27 million (\$A41 million) convertible note facility.

Last Thursday, the company said it would return the latest (tranche four) drawdown of \$US2 million to Obsidian, with the related two million convertible notes cancelled.

"No premium, redemption amount, fee or other additional payment is payable by the company in connection with this arrangement," Paradigm said.

Phew!

In the year to June 2026, Paradigm reported a net loss of \$56.3 million, compared with a \$37.56 million deficit previously.

As trial activity ramped up, research and development expenditure jumped to \$53.9 million, from \$17.7 million previously.

At the end of June, the company held cash of \$15.37 million, 8.6 percent lower.

During the year the company raised \$21.7 million: \$14 million in an institutional placement and \$7.74 million in a well-supported share purchase plan. This was done at 19 cents per share.

The offer included 117 million attached options exercisable at 23.75 cents apiece. Sadly, they were in the money until disaster struck.

This month, the company expects to pocket a \$7.62 million Federal Government Research and Development Tax Incentive.

The company was funded through the planned interim analysis and top-line primary endpoint readout.

Over the last year, Paradigm shares creaked between 45 cents (mid-October last year) and an all-time low of 14 cents on early June this year.

The shares peaked at \$4.17 in January 2020, just as the pandemic hit.

Now, the stock is likely to worth one big fat donut.

Dr Boreham's diagnosis:

It's probably futile to mention this as readers know already, but Paradigm joins a disheartening list of ASX drug developers with late-stage trial flops.

For the record they were Opthea (now Cervyn, eye disease), Percheron (then Antisense, Duchenne muscular dystrophy), Immutep (lung cancer) and Cynata (knee OA and graft-versus-host-disease).

Argenica and Syntara also have run into mid-stage trial whoopsies.

Like Tolstoy's unhappy families, each study ended unhappily for different reasons.

For instance, Opthea's and Percheron's control groups appeared to be unhelpfully effective.

In each case there was clear evidence of safety and efficacy from previous phase II studies.

So, something didn't translate to the bigger pivotal issues, or in each case they were victims of glitches in trial design and execution.

While Paradigm promises updates, investors and patients might never know what really went wrong.

To be honest, we get the impression that in most cases of failed trials the proponents still don't know, either.

Whether Paradigm's phase III flop proves to be a terminal roadblock remains to be seen.

Subject to the administrators' assessment and available resources, the company hopes to continue to review the study.

This process should take eight weeks.

An obvious question is why (perhaps) 30 percent of the trial data went missing.

“Over the next few weeks there will be a huge amount of investigation - it must be resolved,” David Baker said ahead of the administrator appointment.

“This is a fabulous drug”.

Management points out that it retains its intellectual property, which suggests Zilosul can be directed to other stuff in the anti-inflammatory field.

In the past, the company has mentioned heart failure, rheumatoid arthritis and respiratory distress syndrome.

Mr Baker notes the company had passed all previous FDA-compliant trials “with distinction”.

“Hopefully, Paradigm can get back on track, to deliver a well-being drug which will change the life of so many people across the globe”.

With the voluntary administrators sizing up the company through a dispassionate monetary lens, that outcome now looks, sadly, unlikely.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Does that make his life futile? Not at all!