Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Opthea

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ASX code: OPT

Share price: 1.4 cents

Shares on issue: 1,367,978,173

Market cap: $19.2 million

Executive chair: Dr Jeremy Levin

Board: Dr Levin, Kathy Connell, Lawrence Gozlan

Financials (March quarter 2026): revenue nil, cash outflows $1.5 million, cash and equivalents $31.2 million

Identifiable major shareholders: Regal Funds 11.1%, Ocelot SPV 7%, JAF Capital 5%

When Opthea scoured for an alternative raison d'etre after the spectacular failure of OPT-302 in its two-phase III eye disease trials last year, the slimmed-down board faced three clear choices.

The first was to wind up the company and distribute the cash. But executive chair Dr Jeremy Levin said that gambit would have seen shareholders receive "a few cents per share".

Secondly, Opthea could have merged with or backdoor listed another entity – and plenty of spruikers were offering all sorts of "nonsense" proposals.

Especially from the resources sector, just sayin'.

Thirdly, the board could have "determined if anything in the company still merited investment".

Wisely Opthea has decided to build on the third option and something it knows: the vascular endothelial growth factor (VGEF) inhibitors at the core of the unsuccessful OPT-302 wet aged-related macular degeneration (wet AMD) trials.

Opthea has turned to applying the tech to an entirely new indication the rare lung disease lymph-angioleio-myomatosis.

We wouldn't want to face this one in a spelling bee, so let's call it LAM.

Reflecting this transition, the company plans to change its name to Ceryvyn Therapeutics, subject to shareholder approval.

We're back!

On Wednesday last week, Opthea shares resumed trading on the ASX for the first time since March 19, 2025 – when the stock was suspended ahead of the March 24 trial bombshell.

(Without going over old ground, Opthea's VEGF inhibitor OPT-302 proved to be no more effective than placebo, despite highly promising previous results. To its credit, the company didn't offer any false hopes and promptly canned the program). Today, Dr Levin told investors the problem was an "unexpectedly strong control group performance", rather than a problem with OPT-302. Indeed - pesky placebos have torpedoed many a trial

As expected, Opthea shares lost most their value. They plunged from the 60 cents 'frozen' price – representing a market capitalization of $820 million – to less than two cents.

Dr Levin said the board promised a relisting, "but it has taken a long time to get our ducks in a row with the ASX".

The key troublesome canard was an August 2022 debt funding agreement with Abingworth and its life sciences arm, Carlisle.

Dubbed a structured financing royalty deal, the compact looked a masterstroke at the time. It limited creditors' upside to four times their invested amount - initially $US120 million, later raised to $US170 million – so what could go wrong?

The trouble is, the terms of the deal worked equally as adversely post-trial failure. In fact, the company could have been in hock for up to a stonking $US680 million.

At the time of the OPT-302 wet AMD failure, Opthea held $US100 million of cash.

Joyously - or as providently as one can get in such a situation - the talks ended with Carlisle agreeing to take a significant proportion of the debt as equity.

The company also agreed to pay the creditor $US20 million of cash.

Send these guys to the Iran-Israel-US negotiating table!

“That [refinancing] took an extraordinarily long time, only because it was extremely complex,” Dr Levin says.

Alternative pursuits

The process also was elongated because Opthea explored numerous alternative avenues. In order to re-list, the company needed to convince the ASX it had a legitimate alternative business and wasn't just a cash box.

As it happened, the creditors were sold on the potential of the LAM program, unveiled last December. With a new reason for being, Opthea assured its survival.

A genetic condition, LAM affects between three and eight in every million women. That makes for a US patient population of 517 to 1,379 and a world incidence of 12,390 to 33,040, thus falling into the US Food and Drug Administration’s official ‘rare disease’ category of fewer than 200,000 people in the US.

On average, patients are diagnosed aged 35.

The company chose LAM because it is caused by the overproduction of agents called VEGF-C and VEGF-D. OPT-302 is a VEGF inhibitor.

LAM creates cysts in the lung, trapping air, destroying tissue and causing air leaks.

“It’s a bugger of a disease,” Dr Levin says. “[Patients] lungs deteriorate completely. They fall apart”.

When formally designated as such, rare disease developers can enjoy benefits such as expedited approval and generous reimbursement.

A biotech veteran – in differing guises

A so-called ‘trap inhibitor’, OPT-302 is a fusion protein that blocks the activity of VEGF-C and VEGF-D.

Opthea was developing OPT-302 as a wet AMD combination therapy, with the existing drugs Lucentis (ranibizumab) and Eylea (aflibercept).

These drugs only block VEGF-A. Without getting too far into Cat in the Hat territory, this shows the science of this one is not a case of ABC … or D.

Opthea's corporate history goes back to the days of Circadian Technologies, which toyed with melatonin for jet lag.

Founded by the late biotech doyen Leon Serry, Circadian incubated companies including the Victoria state-founded Amrad, (later renamed Zenyth and sold to CSL).

Other companies in its portfolio were Metabolic (which became Calzada before morphing into Polynovo), Antisense (now Percheron) and Optiscan.

Circadian acquired the VEGF eye portfolio from the University of Helsinki in 2008. The company changed its name to Opthea in December 2015.

In October 2020, Opthea listed on the US Nasdaq exchange, raising $US128 million.

Several other capital raisings ensued - notable a monster $150 million placement and rights issue in mid-2024 - before the manure hit the propellor.

The resulting shake-out saw the departure of 80 percent of Opthea's staff and half the board.

CEO Dr Frederic Guerard and chief financial officer Tom Reilly left the building in September.

Founder, chief innovation officer and former managing-director Dr Megan Baldwin called time in July.

The company delisted from the Nasdaq in November.

Today, all the staff are consultants and the company has three directors.

The company operates out of the collective facility of Bio101, in Melbourne's leafy Hawthorn East.

A prominent physician and biotechnologist, Dr Levin was CEO of the Nasdaq-listed Teva Therapeutics and the Israel-based Teva Pharmaceuticals. Before that, he held senior roles at Bristol Myers Squibb.

Open the gates

Dr Levin describes a "stage gated" development program for LAM.

Firstly, the company needs to change the formulation from one that's injected into the eye, to a respiratory product.

It then needs to demonstrate “clear” toxicology and prove the agent can get into the lungs of animals.

After that, the company needs to prove this benefit in humans: the ultimate imperative.

If any of the ‘gates’ don't open, the company will call off the quest at that point.

The company envisages a short initial trial with a small number of patients, as befitting a rare disease.

Last December, Opthea indicated an 18-month trial to proof-of-concept stage.

“We are on track,” Dr Levin says.

“We will be extremely clear about what we have and don't have.”

He adds that work on a respiratory version is “well advanced”.

Opthea will work closely with around 70 specialist clinics globally, to hone study feasibility and endpoints. The company also will foster patient engagement and “broader community alignment” … of course.

Dr Levin says Opthea also can use advanced tools such as magnetic resonance imaging, which measures not just lung shape but aspects such as tissue damage and oxygen levels.

Combo treatment?

Currently, the main treatment for LAM is a Novartis cancer drug called Sirolimus.

Dr Levin says this drug works alright and most patients can expect normal life expectancy. But some women can't tolerate it and require frequent hospitalization because of breathlessness and fluid in the lungs.

As an immune-suppressive drug, Sirolimus creates complications and stabilizes the disease, rather than reversing it.

Side effects include high blood pressure and cholesterol, nausea, diarrhoea and mouth sores. So, it sounds worse by the moment.

Opthea’s own “heavy lifting “research discovered that OPT-302/Sirolimus resulted in cell “normalization”.

As with the wet AMD trials, Dr Levin says a LAM drug could be used in combination with the standard-of-care.

In fact, ethically it would be difficult to take patients off their existing treatment.

Finances and performance:

Given Opthea has returned to its pre-clinical days, this section could well be dubbed: 'Nothing to see here. Move on'.

The starting point is a decent wad of residual cash of $31 million, as of March 31.

Courtesy of the cost-cutting blitz, the company burnt only $1.5 million in the March stanza. Research and development costs totaled $200,000, with $1.1 million of administration expenses.

Personnel costs were nil – one doesn't see that too often - but the directors received a collective $200,000.

"Our goal is to ensure that we have plenty of capital by the time we achieve a [proof of concept] result without raising any more cash," Dr Levin says.

The relisting means legacy shareholders who bought on the ophthalmology story can exit – and crystallize a loss for tax purposes.

Last year, Regal Funds Management was listed as the company's biggest holder with a 26.0 percent stake.

After re-listing the fund had whittled down to a circa 11.1 percent holding, which is understandable given the valuation bath it endured.

Opthea shares closed at 2.5 cents on relisting day and fell to a low of 1.2 cents the next day.

The stock peaked at $3.03 in the innocent pre-Covid times of October 2019.

What's in a name?

Shareholders will convene on July 3 to rename the company Ceryvyn Therapeutics, thus symbolically expunging the body corporate's unfortunate recent past.

As is the norm with life science monikers, the name doesn't actually mean anything.

It sounds Welsh – redolent of leeks and lusty group singing.

Dr Levin says the company is not on the LAM from its recent past, but the title reflects the business no longer being into ophthalmology.

Ceryvyn also is a soft, feminine sounding name - reflecting the female nature of the disorder.

Just pronounce it while you are sobwr … or sober.

Dr Boreham's diagnosis:

A glass-half-full man, Dr Levin says last year's trial taught the company some "very interesting things, scientifically speaking".

But when it comes to LAM's potential, investors are saying 'baa humbug': the company's $17 million market cap is well below the company's cash backing.

We guess the reaction isn't surprising, given Opthea burnt up to $800 million on the wet AMD program.

Looking at Opthea's resurrection through a more dispassionate lens, the company seems reasonably well placed to ensure this spending won't go to waste altogether.

Crucially, the company has a $120 million stockpile of drug material.

"We have manufactured all the drug we need," Dr Levin says.

More broadly, Opthea can use its knowledge of what worked - and what didn't – with the eye trials.

"Because of what Opthea has done in the past, we have a unique body of information," he says.

"We have the science, we have the product and we have the unmet need."

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has learnt from the past but mainly to make the same mistake again in a different manner.