Biotech Daily

Friday July 24, 2026

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Oncosil Medical

By TIM BOREHAM

ASX code: OSL

Share price: $1.205; **Shares on issue:** 30,888,898*; **Market cap:** $37.2 million

* following the June 2025 400-to-1 consolidation

Chief executive officer: Nigel Lange

Board: Dr Thomas Duthy (chair), Mr Lange, Lelde Smits

Financials (March quarter 2026): customer receipts $568,000, net cash outflows $982,000, cash balance $9.3 million, quarters of available funding 9.5

Identifiable major shareholders: Pengana Capital 20.2%, Regal Partners 10.4%, Australian Ethical Investment 8.4%

The developer of a targeted radiation device for pancreatic cancer, Oncosil is emerging as an overnight life sciences success story that has taken decades to evolve.

The path to success – which still is not assured – has not been exactly linear.

Oncosil highlights the chasm between gaining regulatory approval and achieving commercial sales.

European regulators approved Oncosil's eponymous device in April 2020 – and updated Medical Device Regulation (MDR) certification in January last year.

(Memo to marketing people: give the device a different name.)

The company's revenue has been modest to date, but this should change on multiple fronts.

In June, the company said its key trial, Tripp-FX showed Oncosil to be safe and effective when combined with the common pancreatic cancer chemotherapy drug regime, Folfirinox (5-fluorouracil, leucovorin, irinotecan and oxaliplatin).

The European gatekeepers approved Oncosil for use with the chemo infusion gemcitabine.

Oncosil plans to submit for a label expansion to include Folfirinox, thus "removing a key barrier in the patient treatment pathway".

Meanwhile, Oncosil eyes a fast-track pathway to the US, via a mechanism called the humanitarian device exemption (HDE, see below).

If that's not enough, Oncosil also is working on a device variant to deliver percutaneously – through the skin - thus further expanding its market (also see below).

About Oncosil (the company and the device)

A novel brachytherapy for pancreatic and liver cancers, Oncosil's treatment involves irradiating tumors with a targeted intra-tumoral injection of liquid phosphorous-32.

This is done under endoscopic ultrasound guidance, in combination with chemotherapy. While the procedure takes merely half an hour, the localized radiation is emitted for three months.

Oncosil evolved from the listed Neurodiscovery, which acquired the Oncosil tech via the cash-scrip purchase of the UK Enigma Therapeutics, in 2013.

Previously known as Brachysil, the therapy was invented by Dr Roger Aston and owned by the listed Psivida (now Eyepoint), which Dr Aston co-founded.

In 2014 Oncosil chair Martin Rogers departed, with Dr Aston assuming that role.

He in turn was replaced by Dr Chris Roberts, former head of Cochlear but also the chair of Sirtex until 2012. (Sirtex developed and commercialized a targeted liver cancer therapy called Sir-Spheres, and in 2018 was sold to China's Grand Pharma for $1.9 billion).

Dr Aston and Dr Roberts departed in 2021, but not before the latter tapped European head Mr Lange for the top job.

A Berlin-based Canadian who has lived in Germany for more than two decades, Mr Lange also worked at Sirtex.

In fact, he was the Sirtex interim CEO while Gilman Wong was embroiled in an insider trading scandal.

Before Sirtex, he launched a rival liver cancer product called Therasphere.

To date, Oncosil has been used on about 400 patients and is approved in 34 countries including Britain, Turkey, Israel … and Australia.

On Monday, Oncosil said the Saudi Food and Drug Authority had approved the device, thus enabling the company to sell in the Middle East's biggest healthcare market.

What's more, the oil-rich kingdom is a referral hub for other Gulf Cooperation Council nations – if patients can avoid the missiles.

The Saudi rollout is via partner Abdulla Fouad Group.

Key trial doesn't Tripp up

Oncosil is approved for use with gemcitabine, which is for 'compromised' patients such as older ones.

Folfirinox is a powerful cocktail of four chemotherapy drugs and is more effective (but patients need to be able to tolerate the side effects).

Oncosil's clinical trial Tripp-FFX combined Oncosil with Folfirinox.

The open-label, randomized study enrolled 88 patients at 15 sites in Europe and Australia.

All patients had unresectable locally advanced pancreatic cancer.

The trial had two co-primary endpoints: safety and tolerability, and a meaningful improvement in the local disease control rate (LDCR) at 16 weeks. (LDCR is the percentage of patients whose cancer stops growing or shrinks at the site of treatment.)

In short, the randomized, but non-comparative trial hit its 75 percent target.

The toxicities of the combo drug were "limited and manageable".

The Folfirinox-only control arm served as a benchmark against historical data, including from a previous study called Panco and a registry known as Osprey.

Gut German prospects

With 84 million people and 22,500 new pancreatic cancer diagnoses annually, Germany is Oncosil's most important European market and a circa $260-million-a-year opportunity.

Oncosil is subject to a trial, to be run by the Federal Joint Committee or Gemeinsamer Bundesausschuss, which we will abbreviate as G-BA.

Oncosil expects the study to kick off this year.

G-BA is for smaller medical technology companies that require more data to achieve reimbursement.

“You can have really good technology, but unless it is reimbursed, no one uses it,” Mr Lange says.

Ah! True.

The randomized study aims for 280 patients, across 40 sites.

These include the country’s key pancreatic cancer centres such as the University of Heidelberg, which carried out 708 complex pancreatic surgeries in 2025.

A typical busy centre does 50 to 60 procedures a year.

“If Oncosil were to run that trial, the cost would be approximately $35 million,” Mr Lange says. The company can charge for the trial dosages, which takes the accretive value to more like $47 million.

“The beauty of this is you have clinical and commercial [imperatives] in parallel.”

The G-BA process is two years behind schedule.

FDA response imminent

This month, Oncosil lodged its humanitarian device exemption (HDE) application with the FDA, to treat distal cholangiocarcinoma (dCCA). The FDA intends to complete the review within 45 days.

HDE is designed for rare diseases affecting fewer than 8,000 Americans a year.

The permits are assessed on the basis of probable benefit outweighing risk, rather than requiring a full-blown, phase III trial.

The path to market is quicker and the process enables the company to generate real-world evidence post-approval to spur physician adoption.

The company can sell a limited number of devices.

A rare and highly aggressive cancer with limited treatment options, dCCA fits the rare disease bill. Survival is poor.

Oncosil cites a “homogeneous reimbursement landscape” - which sounds like a good thing.

Flying the Australian flag

In May, the Australian Therapeutic Goods Administration (TGA) approved Oncosil as the "first and only TGA-approved class III device targeting tumors directly within the pancreas." This is in combination with gemcitabine to treat locally advanced patients.

Australia has around 4,350 new pancreatic cancer cases a year, and it's the eighth most common cancer here.

Mr Lange dubs the approval as a "defining moment for Oncosil and an especially proud achievement as an Australian medical technology company".

Meanwhile, the company is close to completing a new $2.1 million manufacturing facility at Sydney's Macquarie Park, in partnership with Cyclotek. The parties have completed three manufacturing validation cycles, producing 50 validation doses.

"It's ticking along nicely," Mr Lange says.

While Oncosil's German facility remains its primary site, the cost of goods is less in Australia - even taking shipping to Europe into account.

Pancosil delivers

As they say at Australia Post and the birthing ward, it's all about efficient delivery.

On that note, Oncosil eyes expanding to percutaneous delivery.

Currently, the procedure is done endoscopically, using ultrasound guidance.

Because the patient needs to be anaesthetized, the procedure takes at least one and a half hours.

Percutaneously, the patient is sedated and the procedure takes 15 to 20 minutes.

The company carried out a study called Pancosil, with the results aired at last September's Cardiovascular and Interventional Radiology Society of Europe meeting.

Mr Lange says Pancosil potentially expands Oncosil's market to procedures done with interventional radiology (IR) under computed tomography (CT) guidance.

In Europe, more than 5,000 IR procedures are carried out each year – 2,000 in Germany alone.

"There's a lot of enthusiasm from the IR community," Mr Lange says.
That's because clinicians can do many more procedures in a day – and the hospitals like it because patients are sent home in one to two hours.

The Pancosil data should support a label expansion in Europe and the UK.

Let's get real (world)

The aforementioned Osprey is a 'real world' post-market study that collects data from patients treated with Oncosil across multiple European centres.

To date the registry has enrolled 83 patients, with data reported on 64 to date.

Mr Lange says the Osprey data "matches up nicely" with the company's formal clinical study experience.

"Trial design always stipulates the best patients, in the belief that this will give the best outcome," he says. "But in the real world, clinics treat 'all comers', who are not optimally selected for the best results".

The Osprey data is also consistent with a separate "real-world" study being done by the Royal Adelaide Hospital.

Ultimately, Oncosil aims to shrink the tumors to the extent they can be excised surgically.

Currently, only 15 percent of prostate cancer patients can have surgery when diagnosed.

Finances and performance

Oncosil reported March (third) quarter customer receipts of $568,000, 158 percent stronger year on year. Cash outflows of $982,000 reflected $979,000 of research and development costs.

Management expects a similar research and development run-rate before tapering from 2027.

In March, the company launched an $8 million equity raising, $6 million through a placement and $2 million in a rights offer.

Both legs were done at 69 cents per share, a 15 percent discount. Subscribers received one free option for every share, exercisable at 90 cents by June 30 next year.

As of March 31, the company held cash of $9.3 million.

Mr Lange says Spain is Oncosil's biggest market – although the nation produced more heart attack victims during its victorious World Cup match on Monday morning.

"Italy also is starting to fire," he says.

"But's it's more about getting repeat business and quarter-on-quarter growth."

Over the last 12 months Oncosil shares have flirted between $1.97 (mid-September last year) and an all-time low of 39 cents (mid-May this year). The stock peaked at $73.00 in December 2015. (Adjusted for the 400-to-1 consolidation.)

Dr Boreham's diagnosis:

Oncosil has some busy months coming up.

Potential FDA approval aside, investors can expect the G-BA trial to start and European regulatory submissions for percutaneous labelling and the Folfirinox combo entreaty.

And did we mention the launch of Oncosil in Australia?

The company also targets a US launch by July 2027.

It's certainly nice to have someone else shelling out for a fully funded, revenue-positive trial – as is the case with Germany.

Meanwhile the company expects that US HDE approval would "enhance strategic partnering and acquisition opportunities, consistent with previous transactions".

Let's not forget Sirtex was acquired for $1.9 billion, after a spirited takeover tussle.

So, dare to dream!

Oncosil's hitherto surly investors look to be doing so, with Oncosil shares more than doubling this month.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He will dare to dream, but will also settle for just a nice nap.