Biotech Daily

Friday November 29, 2024

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Oncosil Medical

By TIM BOREHAM

ASX code: OSL

Share price: 0.8 cents; **Shares on issue:** 4,474,080,162; **Market cap:** $37.8 million

Chief executive officer: Nigel Lange

Board: Douglas Cubbin (chair), Mr Lange, Dr Gabriel Liberatore

Financials (September quarter 2024): customer receipts $63,000, net cash outflows $3.2 million, cash balance $4 million (ahead of circa $8 million capital raising).

Identifiable major shareholders:* Pengana Capital 11.97%, Sarah Cameron 5.55%, Bannaby Investments 2.88%, My Consulting Pty Ltd 2.4%, Alua Capital 2.03%, Structure Investments (Rogers family) 1.835, Peter Hall 1%
***** Except for Pengana Capital, these numbers are ahead of the capital raising.

The targeted radiation oncology outfit has the common shortcoming of falling way behind its clinical and commercialization targets. For instance, the company promised European Union approval in 2013 and finally won this assent in April 2020.

"The company has been around for a long time, but it hasn't accomplished as much as it should have," says CEO Nigel Lange, a Berlin-based Canadian who has lived in Germany for 21 years.

"We didn't have the right skills in certain areas and I needed to define where the deficiencies were."

The eponymous Oncosil device delivers a targeted radiation treatment for local unresectable (inoperable) pancreatic cancer and, so far, has been used on more than 200 patients.

Currently the device is approved for sale in more than 30 countries including the European Union, Britain, Turkey and Israel, with initial commercial treatments undertaken in Spain, Italy, Israel, Greece and Turkey.

Crucially, the company is also working on an abbreviated method of US entry.

“We are now on the cusp of moving this thing in the right direction,” Mr Lange says.

Mr Lange worked at Sirtex, which commercialized a targeted liver cancer treatment before being taken over in 2018 for $1.9 billion, after a spirited takeover battle.

Mr Lange launched both Sirtex’s US and then European operations and was interim CEO months for seven months after CEO Gilman Wong was embroiled in an insider trading scandal.

Oh, and before Sirtex, he launched a rival liver cancer product called Therasphere.

The story to date

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 was into electrophysiological assays - or something like that - before acquiring the current technology via the cash-scrip purchase of the UK Enigma Therapeutics in early 2013.

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

In 2014 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 up until 2012.

Dr Aston and Dr Roberts left the building in 2021, while prominent fund manager Peter Hall could not accept a board seat this year for personal reasons.

Mr Lange joined Oncosil in 2020 (in the depths of Covid) to run Europe, when Dr Roberts tapped him on the shoulder for the top job.

Don’t spare the scalpel

The Oncosil device is currently approved for unresectable locally-advanced pancreatic cancer, in combination with chemotherapy (mainly gemcitabine based).

The idea is not to cure the cancer but reduce the tumors to the point where they are operable.

“Surgery is always the gold standard,” Mr Lange says.

The company estimates 10 to 15 patients of 100 can go to surgery, while 30 to 35 percent are locally advanced unresectable pancreatic cancer. The remainder have already metastasized and have few treatment options available.

Prior to receiving Oncosil, patients undergo induction Gemcitabine chemotherapy for one month. Two to three days after completion, the patient undergoes their Oncosil treatment and about three days later they resume normal chemotherapy.

Data from Oncosil’s earlier 42-patient Panco study showed the treatment ‘down-staged’ 24 percent of the subjects to the point where their tumors could be operated.

This compared with around 10 percent of patients subject to chemotherapy, or chemotherapy plus external beam radiation or stereotactic body radiation therapies.

These treatments require frequent visits to hospital, while Oncosil is a one-time treatment delivering nearly twice the radiation.

Don’t TRIPP up on choice of chemo

In addition to deploying gemcitabine chemotherapy, the company’s current study uses the chemotherapy Folfirinox which is a cocktail of multiple chemotherapy agents.

Dubbed TRIPP FFX, the study is being run in Italy by the University of Verona’s dedicated pancreatic centre.

Folfirinox is the favored chemotherapy regimen in Europe, because every component of the ‘cocktail’ is fully generic - that is, cheaper - and the results are better.

As of mid-November, the trial was 59 percent recruited with study completion expected by September next year.

The company’s second trial relates to how the device is administered.

Currently the procedures are done under endoscopic ultrasound guidance, which requires general anaesthesia.

Based at Amsterdam’s Medical Centre (AMC), an investigator-initiated trial called Pancosil is evaluating percutaneous administration of the device for feasibility and safety.

This means application via the abdomen, which can be performed in a much shorter period of time under CT (computed tomography) guidance.

“The patients are under conscious sedation, with the procedure lasting 15 to 20 minutes rather than an hour and a half for the endoscopic ultrasound-guided procedures,” Mr Lange says.

The trial is 70 percent recruited (14 of the targeted 20 patients) and as of June this year, five had been treated.

AMC is Europe’s biggest recruiter of pancreatic cancer trial patients, which helps with the recruitment efforts.

Plucking the low-hanging fruit

The company has navigated tighter European rules governing medical devices, prompted by a French medical scandal involving exploding breast implants.

With Oncosil approved Europe-wide, the company is focusing on the low-hanging fruit.

“Spain has been the first one out of the gate [with 30 patients treated to date],” Mr Lange says. “Phosphorous-32 is not a widely used isotope. Most Spanish sites have their [nuclear medicine] licence and so didn’t have to re-apply.”

Some Italian hospitals are expected to start using the device shortly and the company still is getting doses into Israel, on Israel’s carrier EL Al from Frankfurt.

“Generally, in the larger markets we employ a direct sales force, but in the smaller markets we work through another company known as a distributor where it makes little sense - from a return on investment perspective - to employ our own people,” Mr Lange says.

Last week Oncosil tied up distribution deals covering the searing expanses of Egypt and the icy Nordic climes (Sweden, Denmark, Norway, and Finland). Earlier the company struck distribution compacts in the Gulf States, Saudi Arabia and Portugal.

Entering the US through the back door (no, not via Mexico)

As always, the US market is the big prize, but the cost of entry is prohibitive.

“For locally-advanced pancreatic cancer, we would need to do a large randomized, controlled pivotal trial which would take a long time and a lot of money,” Mr Lange says. “Even to show a small difference in overall survival you need a lot of patients.”

Instead, the company plans to tap its humanitarian device exemption (HDE) status for distal cholangial carcinoma (DCCC) – better known as bile duct cancer.

HDE - which allows for reimbursement - is limited to a disease with fewer than 8,000 US patients (there are about 1,500 DCCC sufferers in the US).

DCCC tumors are especially tricky because the worm-shaped growths can form in different places, wrapped around the bile duct. This makes it harder to apply the dose evenly.

Jet-setting isotopes

Oncosil's doses accrue more frequent flyer miles than a pollie on the hustings. Fortunately, phosphorous-32 is a "forgiving" isotope with a 14-day half-life.

"If you miss a flight, it is not an issue at all," Mr Lange says. "The hospital can generally treat the patient within a nine-day window, which is a big advantage."

Currently, the microparticle material is sourced as a powder and is shipped to Germany, where it is placed in a special ampoule and then a canister.

The canister is shipped to Australia where it is placed in the Australian Nuclear Science and Technology Organisation's (ANSTO's) reactor, at Lucas Heights in western Sydney, for two weeks of 'cooking'.

The ampoules are shipped to Germany, where patient doses are produced and dispatched to hospitals.

However, the company is starting a secondary fully-automated manufacturing facility at Macquarie Park, just down the road from Lucas Heights. Mr Lange says the site will ensure production and enhance supply chain robustness should the German plant go off line.

Finances and performance

In late October Oncosil replenished its coffers with a capital raising of up to $8 million, $7 million via an institutional placement and up to $1 million from a share purchase plan (SPP). Both were struck at one cent, a 23 percent discount to the prevailing price.

The placement and share plan include one option for every share issued, exercisable at 1.5 cents up to three years from issue date.

In July, Oncosil raised $2.7 million in placement that introduced Pengana Capital as a 12 percent shareholder. In the June half year, Oncosil raised $6.8 million in a placement and rights offer. At the end of September, Oncosil held cash of $4 million, having burnt $3.2 million in that stanza.

Over the last 12 months Oncosil shares have lairized between 0.4 cents in June 2024 and 2.0 cents in late September this year. The shares peaked at 24 cents in January 2016.

Dr Boreham's diagnosis:

The 12th most common cancer in men and eleventh in women, pancreatic cancer remains the deadliest form of tumor and has eluded effective treatments.

About 500,000 new pancreatic cancer cases are detected each year, with a median survival of 8.5 months. Only 12 percent of patients will last five years,

Oncosil estimates an addressable market of 79,000 patients across its approved geographies, equating to an addressable market of $US588 million.

The company has an "aspirational target" of five to 10 percent market penetration in existing and near-term markets by 2029, implying up to 4,710 units (doses) a year.

Given its past foibles, Oncosil has carried more baggage than a travelling diva - as reflected in its lowly valuation. But the company is now in its best position to shed this historical luggage.

Investors have been promised a "catalyst rich" 2025 and 2026, including expected filings to the local Therapeutic Goods Administration in early 2025, entreaties to Argentina and Brazilian authorities and Pancosil trial top-line results due by next June.

The last word is courtesy of an Indian guru.

"Mahatma Gandhi once said that the difference between nothing and something is infinite," fundie Peter Hall said.

"Oncosil is something. It offers a treatment which has the potential to impact the lives of the hundreds of thousands of people who contract pancreatic cancer and their families and loved ones."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is a biotech non-guru who travels light.