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Dr Boreham's Crucible: Oncosil Medical

By TIM BOREHAM

ASX Code: OSL

Market cap: $56 million

Share price: 12 cents

Shares on issue: 468.5 million

Chief executive officer: Daniel Kenny

Board: Dr Chris Roberts (chairman), Dr Roger Aston, Daniel Kenny, Dr Martin Cross

Financials (March 2017 quarter): revenue nil, operating cash outflow ($2.1 million, nine months year-to-date $13.9 million), cash $9.44 million (previously $11.55 million), estimated current quarter cash outflow $2.3 million.

Major shareholders: Regal Funds Management 9.7%, Webinvest 6.4%, management and directors 14%.

Oncosil chief Daniel Kenny is upfront about the company's reputational problems which have dragged the shares down from their high watermark of 24 cents in January last year.

He insists Oncosil, which is developing an implantable radiotherapy medical device for pancreatic and liver cancer, has changed its spots after a board cleanout.

“Old management over-promised and under-delivered,” says Mr Kenny, who joined in early 2015.

A subsequent board rejig saw the departure of chairman Martin Rogers and the arrival of Dr Chris Roberts, who had just stepped down from his long-standing role as head of Cochlear.

Dr Roberts this week was anointed chairman, and given his long interest in radiation pharmacy, we’ll assume he wasn’t motivated by the modest stipend for being the company’s titular head.

Four of Oncosil’s executives are ex-Sirtex and that doesn’t include Dr Roberts, who used to chair the targeted liver cancer radiotherapy house up to 2004.

A mini Sirtex?

For better or for worse, Oncosil has been presented as a mini-me version of the $900 million market cap Sirtex, which diligent Biotech Daily readers will know has been in it deeper than a Werribee canard.

While both companies target liver cancer, Oncosil’s focus is on the $US1 billion market for pancreatic cancer, the sixth most common cancer and a bugger to treat.
The treatment involves the carrier particles containing the soft radiation being suspended in fluid and injected directly, through an endoscope, into the tumor. The procedure takes half an hour under anaesthetic, with the localized radiation emitted for around three months.

Across Oncosil’s target markets, 90,000 patients are diagnosed with pancreatic cancer each year, and it has one of the worst mortality rates of all cancers. Prognosis is poor even with treatment, with a median survival period only eight months.

Liver cancer is Oncosil’s slow burn indication. If it is ever approved, it will not compete with Sirtex, because Oncosil is better suited to small tumors. It’s more likely to compete with external radiation ablation therapy.

Regulatory progress:

The company promised Conformité Européenne (CE) mark in 2013 but the timeline proved ambitious, to say the least.

Finally, in October 2015, the regulator approved the application for the pancreatic cancer indication – on the proviso the company provides supplemental data from 20 advanced pancreatic cancer patients to support the existing safety and clinical data.

“The market has failed to appreciate what a significant achievement it is,” Mr Kenny says. “It is hard to get approval for a class three radioactive device.”

An application for US investigational device exemption (IDE) was granted in July last year, which like Mussolini's trains, was bang on schedule.

IDE status allows Oncosil to carry out a clinical study and – lo and behold – contract partner Monash Health a week ago treated the first patient for the 300-patient global trial, which seeks to establish Oncosil as a first-line therapy for patients diagnosed with locally advanced pancreatic cancer.

The Oncopac-1 trial will randomize patients to either Oncosil's Brachysil bio-silicon radiation treatment with Folfirinox chemotherapy; or Brachysil with gemcitabine and nab-paclitaxel (known as Abraxane) chemotherapy; or chemotherapy treatment alone.

Mr Kenny says some investors also misunderstood the European authorities demand for the 20-patient data as an onerous burden. "It does not involve a new trial but a subset of data from the existing trial in place for the FDA IDE," he says.

Trial progress:

To date, Oncosil has completed four studies, two for liver cancer and two for pancreatic cancer.

Most significant was a phase IIa safety study of 17 patients with locally advanced pancreatic cancer, treated with Oncosil and gemcitabine.

The results showed a reduction in tumor volume in 13 of the 16 patients - an 81 percent 'pass' rate - with a median progression-free survival of 121 days and overall survival of 309 days.

Management expects to have the additional data by the end of September, with CE mark expected by the end of 2017 and sales in the UK, EU and Australia in 2018.

Oncosil expects to lodge a pre-market approval submission to the US Food and Drug Administration in 2020.

Chief financial officer Tom Milicevic estimates a full FDA trial at $US18-20 million, which will be funded … somehow.

Dr Boreham's diagnosis:

With a $56 million market cap, Oncosil has traded in a share price range of eight cents to 23 cents over the last 12 months.

Oncosil's March quarter statement showed a cash burn of $2.1 million, with $2.3 million expected to be expended in the current quarter.

Oncosil sits on cash of $9.4 million, having raised $10 million in a placement to Regal Funds Management in February last year.

The company has no plans to go to the well again, but if someone were to offer a fistful of dollars it would be impolite to refuse.

The global trial is being supported by drug company Specialised Therapeutics, which is kindly providing a free supply of Celgene's Abraxane.

At $30,000 to $40,000 a pop for the eight to 10 local patients, that's better than a kick in the pancreas.

The misunderstood Oncosil has suffered from a bout of West Coast-itis, a virulent investor malaise reflecting the company's origins as a back-door listing through the tortured Perth-based Neurodiscovery, which caused shareholder agony by failing to commercialize drugs for neuropathic and dental pain.

However Oncosil's operations have always been Sydney-based and management would struggle to tell the difference between Freo and Rotto.

With the esteemed Doc Roberts on board, here's hoping for happier times for the company's 2,800 patient shareholders.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But like all tortured geniuses, he is profoundly misunderstood.