Biotech Daily

Friday April 17, 2020

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Oncosil Medical

By Tim BOREHAM

ASX code: OSL

Share price: 11 cents

Market cap: $68.3 million

Shares on issue: 620,548,312

Chief executive officer: Daniel Kenny

Board: Dr Chris Roberts (chair), Daniel Kenny, Dr Roger Aston, Dr Martin Cross, Mike Bassett

Financials (December half 2019): revenue $325.00 (up 64.1%), loss of $3.4 million (previously $5.15 million deficit), cash of $6.8 million (down 12%)

Identifiable major shareholders*: Webinvest (Otto Buttula) 3.79%, Mr Kenny 3.76%, Dr Aston 2.0%, Dr Roberts 1.63%, Bannaby Investments (Keith Kerridge) 1.51%

***** Regal Funds Management held 5.49% on February 14, but ceased to be a substantial shareholder on February 19. Lumyna Investments held 7.35% and ceased to be a substantial shareholder on April 3.

Oncosil chief Daniel Kenny readily acknowledges the "me too" nature of the targeted radiation oncology play, which is seeking to emulate the success of Sirtex Medical which was taken over by Chinese interests for $1.9 billion after a spirited takeover tussle.

“We are standing on the shoulders of giants,” he says.

After almost a decade (or two**) of promises, Oncosil this month achieved what it expected to secure back in 2013: European approval of its eponymous treatment for pancreatic cancer.

Approval was meant to be a dead cert - or so the company thought - but in March last year the British Standards Institute (the “notified body” or proxy regulator) declared the evidence showed “insufficient clinical benefit at this time”.

But on April 1 this year, Oncosil reported the body was convinced of “significant clinical benefit” after the company re-presented the data.

Mr Kenny says while the original application essentially was unchanged, the company did a better job at explaining the clinical data and relevant literature.

“We basically just joined the dots and a CE mark came out of it,” he says. “It took a long time to come but we got there in the end.”

In mid-March the US Food and Drug Administration granted the company breakthrough device designation (BDD), in relation to unresectable (inoperable) locally advanced pancreatic cancers.

This followed the FDA’s granting of investigational device exemption (IDE) status in 2016.

The CE mark couldn’t come soon enough, given the dire prospects for pancreatic cancer patients.

Surgery is not possible in 85 percent of cases and only five percent will survive beyond five years. About 85,000 new cases in Europe are detected annually, with a further 46,000 new cases in the US.

“The prognosis in pancreatic cancer is exceedingly poor, it is a huge area of unmet need,” Mr Kenny says.

“But that didn’t sway the BSI. You had to show the survival benefits to justify approval.”

In economic terms, Oncosil believes it’s a $1 billion a year market.

Oncosil through the ages

A novel form of brachytherapy for pancreatic and liver cancers, Oncosil’s treatment involves irradiating tumors from the inside by injecting micro-particles with the radioactive isotope phosphorous-32.

The procedure involves the radiation in liquid form being injected via an endoscope directly into the tumor. While the procedure takes merely half an hour, the localized radiation is emitted for three months.

“Brachytherapy is now a widely accepted treatment for cancer,” Mr Kenny says. “It’s always been around but in a simplistic sense, such as putting seeds into prostates. In many ways the Sirtex therapy was the breakthrough.”

****** The Oncosil technology was invented in part by current board member Biotech man about town Dr Roger Aston and owned by Psivida, which he co-founded.

Formerly Neurodiscovery, in 2013, Oncosil assumed its current guise by acquiring the British outfit Enigma Therapeutics, which had in turn acquired the technology originally called Brachysil from Psivida.

A series of board rejigs from 2014 saw the departure of chairman Martin Rogers, with existing board member Dr Aston becoming chairman. He in turn was replaced by Dr Chris Roberts, who ran Cochlear for decades.

But Dr Roberts chaired Sirtex up to 2004, so has a keen interest in radiotherapy as well as hearing implants.

A front line treatment for a deadly cancer

Unlike Sirtex’s ‘salvage’ therapy, Oncosil’s studies focused on the device in the ‘first line’ setting in combination with existing chemotherapy.

(Sirtex spent millions of dollars on trials to expand the use of its SIR-Spheres from palliative and salvage to first-line use).

Carried out across sites in Australia, Britain and Belgium, Oncosil’s Panco study enrolled 50 patients, of which 42 received the eponymous treatment plus the standard of care chemo.

Oncopac, a US trial with sister protocols enrolled a further nine patients.

In essence, the results showed a doubling of median overall survival for non-resectable cases - those that can’t be operated on - from eight months to 16 months.

The average tumor reduction was 40 percent, with a maximum shrinkage of 90 percent.

More importantly, the tumors of 24 percent of patients in the Panco study shrunk to the extent that they were operable, which increases survivability even if the procedure does not actually take place.

“If you are able to downstage (the tumor) to surgery with curative intent, median survival in this cohort increases to three years,” Mr Kenny says.

Technically, the resection rate was more like 33 percent, but because of co-morbidities some patients were advised against the arduous surgery which takes up to 12 hours.

If the tumor is resected, the patient's chances of five-year survival leap from five per cent to 20 percent or more.

"Half the cohort is still alive even though the study started in early 2017," Mr Kenny says.

"We will continue to follow those patients to see what their outcomes are likely to be."

On your (CE) mark …

The company is now preparing for a launch in Europe on a staged basis, with applications due to be launched in other geographies that honor the CE mark.

In essence we're talking about the world minus the US, Japan and China.

Mr Kenny says Covid-19 has impacted preparations for the European launch, in that training has been bought online and access to hospitals is limited.

The company also intended to kick off in all the Western European markets but will now focus on Britain, Germany and Belgium.

The Covid-19 plagued France, Italy and Spain will have to wait.

But amid the virus pandemic, cancer therapy continues "and has to continue."

The company was aiming to launch with the hoopla of the ESMO World Congress on Gastrointestinal Cancer in Barcelona in July, which is odds-on to become an online event.

"Our best guess for launch now is October," he says.

It takes some gall …

While Oncosil's main focus is on pancreatic cancer, the company is also targeting bile (gall) duct cancer which is known formally by its Latin name as cholangio-carcinoma.

In December 2018, the US FDA granted the company humanitarian use designation (HUD) for the intra-hepatic and distal forms of the cancer.

Our success in pancreas showed we could treat other tumors," Mr Kenny says. "The FDA agreed that success could be reasonably expected with distal cholangio-carcinoma."

Mr Kenny said at a meeting with FDA reps last June, the company was encouraged to go the next step and file for a humanitarian device exemption (HDE) for distal cholangio-carcinoma.

Oncosil plans to do so next month, which means that allowing for a 75-day decision period the company could be selling in the US in 2021.

While there are only 1,500 to 1,600 cases in the US annually, distal cholangio-carcinoma is still an $US80 million ($127 million) market.

Meanwhile, Oncosil continues to work with the FDA on what it would take its breakthrough device designation for pancreatic cancer into pre-market approval.

The breakthrough designation allows for a faster and less costly route to market, with an emphasis on post-marketing rather than pre-marketing clinical data.

“We will share the specifics with the market over the next couple of months,” Mr Kenny says.

Finances and performance

A glass half-full man, Mr Kenny notes that the low-key launch will lower costs and extend Oncosil’s cash resources - $6.8 million at last count - well into 2021.

An “immediate” capital raising is not required, although this would change at the pointy end of a US approval process.

He estimates the EU market (and other countries covered by CE mark) to be worth $1 billion to $1.5 billion.

“We are targeting 10 percent market penetration within five years,” he says.

“That means $100 [million] to $150 million of sales in five years - but don’t take that as guidance.”

Mr Kenny expects reimbursement will be widely available, both from government and private insurance.

“Private payers will pay for doubling of median survival or downsizing from unresectable to resectable.”

He adds while a strategic partner would be ideal, “it is not an absolute requirement”.

Oncosil shares peaked at 24 cents in January 2016 and plumbed to a low of 4.9 cents after the March 2019 British bombshell (down 69 percent on the day).

The shares barely blipped after news of the CE mark approval hit on April Fool’s Day, this year. Then again, global markets were in serious meltdown.

Broker Bell Potter adjudges the stock to be worth 38 cents, while Wilsons’ biotech watchers reckon 43 cents is a fair price.

Dr Boreham's diagnosis

Mr Kenny describes pancreatic cancer as a "graveyard for pharmaceutical development" with the survival rate lingering around an unimpressive five percent.

Only two pancreatic cancer drugs have been approved in the past two decades: Gemzar (gemcitabine) in the late 1990s and Abraxane (palitaxel) in 2013. These have only increased median survival by two months to 8.5 months.

Of course, Oncosil doesn't exactly cure the cancer either, but as with so many oncology drugs it buys time for the patient and - hopefully - quality of life.

"It's a unique and compelling technology designated as breakthrough in the US and Europe, but first we have to get out there to talk to the doctors and train the sites," Mr Kenny says.

"In the mean-time little old Oncosil has been able to show some significant clinical milestones."

"Little old Oncosil" has had its detractors; or perhaps it's more a case of some investors tiring of the story.

With the European marketing approval granted and the hope of US approval, Oncosil itself may become another broad-shouldered giant.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. If he stood on the shoulders of a giant he would probably fall off and break a limb.