Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Clarity Pharmaceuticals

By TIM BOREHAM

ASX code: CU6

Share price: $1.475; **Shares on issue:** 256,132,546; **Market cap:** $377.8 million

Financials (December half 2020): revenue $1.38 million (up 14%), net loss $4.85 million (previous $3.29 million deficit), cash post raising $104m

Chief executive officer: Dr Colin Biggin

Board: Dr Alan Taylor (executive chair), Dr Chris Roberts, Dr Thomas Ramdahl, Dr Gillies O'Bryan-Tear, Rosanne Robinson, Rob Thomas

Identifiable major shareholders*: TM Ventures Pty Ltd 7.3%**, Dr Chris Roberts 7%, Dr Alan Taylor 5.5%, Charles Morgan 4.8%, Genesiscare Ventures 4%

* China Grand will hold approximately 8.5 percent of the company if it exercises its 25,543,912 options

** An entity associated with Clarity chief scientific officer Dr Matt Harris

In the spirit of the recently-concluded Olympics and ongoing Paralympics, congratulations to the backers of the radiopharmaceuticals group for a record-breaking performance after listing this week.

In raising $92 million, Clarity was the biggest biotech initial public offer (IPO) in ASX history - and being underwritten it was never in doubt.

Clarity pips the $50 million raised by imaging and diagnostics peer Telix Pharmaceuticals, when it listed in November 2017.

The record biotech IPO was that of bio-resorbable stent outfit Reva Medical, which raised $85 million in late 2010, but delisted in mid-2019.

No doubt many investors will view Clarity as the mini-me version of Telix, now valued at almost $2 billion.

While their tech differs, both companies are deploying isotopes in an innovative manner for detecting and treating tumors.

“Radiopharmaceuticals are hot, in more ways than one,” says executive chair Dr Alan Taylor.

Some clarity on Clarity

Clarity’s reason for being is simple enough: “to achieve superior imaging and highly precise and accurate therapy”.

Clarity’s intellectual property revolves around two radioisotopes: copper-64 and copper-67. The former is for improved PET (positron emission tomography) scanning and the latter is for, like, actual therapy.

Not to be confused with icy-poles or isobars, isotopes are derivatives of an element on the periodic table that share the same number of protons but have a different number of neutrons.

At the heart of the technology is a stable functional ‘cage’ called a chelator, which prevents the leakage of copper into the body. The cage is linked to a targeting molecule, which finds and binds specific receptor cancer cells.

Dr Taylor notes cancer treatments traditionally have revolved around surgery, radiotherapy and chemotherapy

“With better understanding of the biology of tumors we have been able to target tumors with ‘warheads’: either drug conjugation, radiotherapy or immunotherapy,” he says.

These disciplines can be interlinked.

In a two-fold process, copper-64 is used to image the patient. If enough of the agent accurately hits the tumor, the patient is then eligible for copper-67 therapy if the copper doesn’t leak to the liver (where it is metabolized).

“There’s a lot of product that gets to the tumor and stays there,” Dr Taylor says. “Then we zap the tumor and [the copper] is excreted through the kidneys.”

Background briefing

Clarity's tech derived from the University of Melbourne and the Australian National University (ANU), with a little help from the Australian Nuclear Science and Technology Organisation (ANSTO).

Dr Taylor trained at the Garvan Institute in Sydney but then was lured into investment banking, where he was involved in large life science IPOs as head of Inteq Ltd. In 2013, he moved on to focus on commercializing "good Australian science".

Clarity was formed in 2010, based on the chelator development work of two luminaries: the late Dr Alan Sargeson at Australian National University and Prof Paul Donnelly at Melbourne Uni's Bio21 Institute of Molecular Science and Technology.

"When I joined Clarity it had no more than a couple of patents pending, with no employees and no money," Dr Taylor says.

Now with about 20 employees, Clarity is Sydney based with subsidiaries in Belgium and the US.

CEO Colin Biggin was the tenth employee of Norwegian radiotherapy pioneer Algeta ASA and was central to commercializing the company's commercial product for metastatic prostate cancer, Xofigo (radium-223 dichloride).

Clarity board member Dr Thomas Ramdahl was Algeta's first CEO and was there when Bayer AG acquired the company for $US2.9 billion in 2014. Fellow director Dr Gillies O'Bryan was Algeta's chief medical officer.

Rosanne Robinson was ANSTO's business development chief. Rounding out the Clarity board table are former Cochlear chief Dr Chris Roberts and former Citibank Australia chief Rob Thomas (who is also chairman of Starpharma and a Biotron director).

It's SAR good for many things

Clarity is based around its SAR (stereotactic ablative radiotherapy) platform, with its work revolving around six diagnostics and therapies covering breast cancer, prostate cancer and neuroblastoma in children.

The neuroblastoma program, Sartate, was subject to phase I trials in 2015 and is the most advanced. A trial at Melbourne's Peter MacCallum Cancer Centre compared copper-64 against a gallium-based product, the standard of care for such tumors.

With a half-life of only one hour, gallium poses logistics and imaging issues. Because copper-64 has a half-life of 12.7 hours, it can measure effects over time.

In the US, Clarity has been granted investigational new drug status for two indications and also has two rare paediatric disease designations for diagnosing and treating kids' neuroblastoma.

Under an investigational new drug (IND) protocol in the US, Clarity is running a phase I/II dose-escalation study for children's neuroblastomas at five sites.

SAR-Bombesin is relevant for numerous cancers, but a trial at St Vincent's Sydney zeroed in on breast cancer (targeting the commonly-expressed gastrin-releasing peptide receptor).

"We are getting very important data right from day one with our imaging," Dr Taylor says.

Separately, Clarity has begun its 'Propeller' trial of copper-64 (64-Cu) SAR-bis-PSMA for prostate cancer at Perth's Genesiscare and Sydney's Nepean Hospital.

The 30-patient, phase I, PET imaging trial of patients with confirmed prostate cancer is blinded review, dose-ranging, non-randomized study prior to radical prostatectomy.

Clarity describes the pre-clinical data as "compelling", with both higher tumor uptake and greater tumor retention compared to current rival products.

Clarity is also running a US prostate cancer trial called Secure and just ahead of listing this week the company announced it had enrolled its first patient.

Eyes on the supplies

Radioactive isotopes don't just grow on trees, so procuring adequate supply is the key to commercialization. Copper-64 can be mass produced on cyclotrons (particle accelerators).

"I have two within walking distance from me in Redfern [part of the inner Sydney university precinct] which means the isotopes can be produced and distributed overnight to anywhere where there's a PET camera," Dr Taylor says.

Copper-67 isotopes are produced on linear accelerators, which are found in most hospitals (Rhodotrons are a new powerful version). The competing and commonly used isotope lutetium-177 needs to be produced in a nuclear reactor, which unlike 7-Elevens are not exactly on every corner.

Clarity has entered an agreement with the Wisconsin-based Northstar Radioisotopes for supply of copper-67 isotopes.

Finances and performance

It's too early to opine on Clarity's finances or performance, but suffice to say the $92 million banked should go some way to road-testing the isotopes - with a few bob left over for icy-poles.

Given the company already had $17 million in the bank, its war chest exceeds $100 million, with circa $44 million from China Grand options potentially yet to come (see below).

Pre IPO, Clarity raised $40 million to $50 million from investors, with a further $10 million or so from government grants. On listing, the shares ran out of the blocks to a day's high of $1.71, a 22 percent premium.

Ain't it (China) Grand

A quirk of Clarity's register is that its biggest would-be holder is just that - prospective.

China Grand Pharmaceuticals has an enduring interest in the Australian radio-pharmaceuticals sector, having prevailed in the three-way tussle for targeted radiation innovator Sirtex Medical. The eventual price tag was $1.9 billion.

China Grand last year struck a $450 million partnering deal with Telix.

China Grand holds about 25.5 million Clarity options, equal to 8.5 percent if converted to shares. But there are two conditions to China Grand exercising its options. One is that Clarity lists (tick) and the other is that they sign a distribution deal for greater China.

China Grand has six months exclusive negotiating rights. If the deal is done, China Grand exercises the options at $1.75 apiece - a 25 percent premium on the listing price. This would inject a further $44.6 million into the company.

Dr Taylor says: "Our products are ideal for the China, given the size of the market and the opportunity to mass produce isotopes."

The Gibb brothers would be proud

The Bee Gees might have started a joke that got the whole world crying.

In the case of Dr Chris Behrenbruch at Telix, he started an ASX trend that has kept biotech investors smiling to date.

There's more to come.

Backed by biotech entrepreneur Paul Hopper, a private mob called Radiopharm Theranostics***** plans to raise $50 million and list on the ASX in November.

The company is based on combined technologies licenced from Imperial College London, New York's Sloan Kettering Memorial Hospital and the Technical University of Munich.

More broadly, investor interest has been piqued by two transactions involving Novartis over the last three years.

Firstly, the Swiss drug giant acquired Endocyte for $US2.1 billion and then snapped up Advanced Accelerator Applications (AAA) for $US3.9 billion.

AAA has a therapy for neuro-endocrine tumors, while Endocyte is in phase III stage of developing a prostate cancer treatment, PSMA-617. Both are lutetium based.

Dr Boreham's diagnosis:

Dr Taylor is pleased with Clarity's pneumatic share price, but he's not going to be gazing at the ASX screen all day.

"The day-to-day share price fluctuations are a little bit less relevant for us than our clinical plans over the next couple of years," he says.

"We're incredibly excited about the five clinical trials we are running right now and the drive into the US."

We concur that opportunities abound in a sector that's well developed in the US and Europe, but has had surprisingly little innovation.

For Clarity, it's a case of remaining focused on the aforementioned key oncology targets and the highly potential market for niche childhood cancers such as neuroendocrine tumors.

"Because we have a platform technology, we are not limited to the products we focus on," Dr Taylor says. "We could produce 20 or 40 products, but focus is the key for us."

He adds: "Clarity is very much an Australian story and we are keen to keep it in Australia for as long as we can."

Great to see that one doesn't have to drape the flag around oneself at Cronulla beach to be a true patriotic flag waver …

***** "Theranostics" is a gruesome made-up word for the combination of diagnosis and therapeutics. The term is usually banned in this publication, but as it's part of an official company moniker we need to make a grudging exception in this case.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's convinced that while you don't need to be a rocket scientist to understand nuclear medicine it sure would help.