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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Chimeric Therapeutics

By TIM BOREHAM

ASX code: CHM

Share price: 0.9 cents

Shares on issue: 975,140,820 (555,009,027 more pending shareholder approval)

Market cap: $8.8 million

CEO: Dr Rebecca McQualter (chief operating officer)

Board: Paul Hopper (executive chair), Phillip Hains (chief financial officer, company secretary), Eric Sullivan, Dr Lesley Russell

Financials (year to June 30, 2024): revenue nil, loss of $12.55 million (previous deficit $26.07 million), cash balance $3.05 million (up 29%) ahead of this month's $5 million capital raising

Identifiable major holders: Paul Hopper (10.5%), Lind Global Fund 3.33%, Christine Brown 2.2%, Michael E Barish (2.2%)

A little over six months into her appointment, Chimeric's youthful chief operating officer - and in effect CEO - Dr Rebecca McQualter has two major items on her change agenda.

Number one: promote the immune oncology outfit to the investment community so it is better known and understood.

"My job is to get Chimeric out and about in Australia," she says.

Number two: re-domicile the company's clinical trial from the US to Australia, where they can be carried out more cost effectively.

"The problem for us is we raise in Australian dollars and spend in American dollars, it is a 40 percent hit with the foreign exchange," she says. "My job is to bring as much as we can home, whilst maintaining our US sites."

Her third and most urgent imperative - getting money through the door - can be ticked off with the company last week unveiling a $5 million capital raising after a three-week trading halt.

While the company hoped for more, it's game on …

About Chimeric

Chimeric's Car-T (chimeric antigen receptor T-cell) therapies involve genetically engineering t-cells to improve the immune system's ability to fight cancers.

"We are taking peoples' blood cells, engineering them and putting them back in to make them better cancer fighters," Dr McQualter says.

Founded by renowned biotech entrepreneur Paul Hopper, Chimeric listed in January 2021 after raising $35 million at 20 cents.

The company's initial focus was on its CLTX Car-T program, acquired from the City of Hope Hospital in Los Angeles.

CLTX derives from the synthesized venom of the deathstalker scorpion and we emphasize 'synthesized': they don't have to chase the blighters across the Sahara desert to milk them.

This legacy program focused on patients with glioblastoma, a hard-to-treat brain cancer.

Acquired from the University of Pennsylvania, a separate program called CDH-17 is now Chimeric's key priority.

True to its name, the program targets CDH-17, an antigen expressed on tumors and aims to treat gastric, pancreatic and colorectal cancers.

Dr McQualter says the program is scalable and addresses a high unmet need, especially with more young people being diagnosed with colorectal cancer.

A third program focuses on so-called 'natural killer' NK cells, with acute myeloid leukaemia and colorectal cancer programs under way at the MD Anderson Cancer Center in Houston, Texas and Cleveland Ohio's Case Western Reserve University.

The allogeneic (off-the-shelf) therapy involves a healthy donor providing the material, from which the cells are produced.

Changing of the guard

Dr McQualter replaced the previous Toronto-based CEO Jennifer Chow in May this year.

In Dr McQualter's frank assessment, the company was not doing enough to promote itself.

"Typically, North American companies don't put out any news unless they have something really big to talk about," she says. "I also think there was some complacency. That's … finished now and we have some work to do."

A Neil Perry dinner sealed the deal

With a Doctor of Philosophy in cell therapy and regenerative medicine from Melbourne's Monash University, Dr McQualter held senior roles at Amgen and Glaxosmithkline and most recently as Novartis's head of strategic access.

Dr McQualter says she had hoped to monetize her own cell-therapy patent stemming from her doctorate. But Mr Hopper convinced her to join over a dinner at celebrity chef Neil Perry's 'Margaret' noshery in Sydney's Double Bay.

At Novartis, she was instrumental in establishing a health data partnership with Telstra Health - an agonizingly long process. Unbeknown to most Australians, Telstra Health owns half of the nation's patient health data as it conducts the back-end systems for the national bowel and cervical screening programs.

She was also involved in a partnership with Wesfarmers Health and Roche, rolling out mobile health check stations that have since been adopted by the Shane Warne Legacy Foundation and in Priceline shops.

"We found that roughly 80 percent of the people tested had a cardiac risk factor and the majority thought they were healthy," Dr McQualter says.

We're coming home

One motive for Chimeric's patriotism is that the US programs were eligible for the Australian government's research and development tax incentive under the 'overseas finding' rules. 'Overseas finding' status means a company may receive the incentive for programs conducted offshore, but not surprisingly the taxman has tightened the arrangement and Chimeric's US programs no longer will be eligible.

Another motive for coming home is to enable local shareholders to participate in the trials, should they have the misfortune to need to.

Dr McQualter hopes the company can move quickly to bring the CDH-17 program here.

"We just have to work out whether the manufacturing is here or overseas."

On August 9, the company said it would collaborate with Cell Therapies Pty Ltd - a commercial business co-located with Melbourne's venerable Peter MacCallum Cancer Centre - to explore making the Car-Ts locally.

"I grew up with the Melbourne biotech scene so it is easy to lean on my relationships and say 'help me'," Dr McQualter says.

Given the NK programs are funded by the two aforementioned US universities, they will stay in the US but the pre-clinical work will be carried out here.

Nashville patient 'doing really well'

Chimeric currently has four trials underway in the US.

The phase I/II CDH-17 trial is being carried out at Nashville's Sarah Cannon Cancer Centre and is in recruitment and early dosing stage.

"We dosed our first patient [a man in Nashville, Tennessee], who is doing really well and we are just about to dose our second patient," Dr McQualter says. "This trial is getting a lot of attention. We will keep our US sites, but just add Australian sites."

On October 24, Chimeric said it had dosed the first eight patients with relapsed or refractory acute myeloid leukaemia (AML) in the MD Anderson NK trial - dubbed Advent-AML - with no dose-limiting toxicities.

The therapy combined the company's CHM-CORE-NK (CHM0201) with the standard-of-care azacitidine and venetoclax.

Another 20 patients with newly-diagnosed AML are yet to be enrolled. For whatever reasons, these patients are not eligible for intensive chemotherapy or allogenic stem cells transplants.

In May, a separate investigator-led phase IIb NK study started enrolling at Case Western.

This one, combines CHM-CORE NK (CHM0201) with the agent vactosertib (a receptor inhibitor designed to disrupt cancer signaling pathways).

On October 7, the company said the only patient treated to date in the phase Ib stanza of the trial had showed a complete response at 28 days.

In November last year, Chimeric shares soared 35 percent after the company unveiled positive pre-clinical NK data.

The in-vitro models in ovarian cancer showed that cell killing was increased up to about 260 per cent in comparison with first-generation CHM0201 cells, while in pancreatic cancer the efficacy rose by up to 300 percent.

Ve haf come for your blood

In early September, Chimeric struck an alliance with a US ‘blood bank’ to access ‘fresher’ blood cells for its proposed immune therapies. The underlying problem is that cells used for autologous therapies - that is, the patient’s own cells - tend to be degraded because of chemotherapy and other factors related the patient’s illness.

Autologous therapies also present ‘just-in-time’ logistics issues.

Chimeric’s collaboration is with the Los Angeles-based Achieve Clinics, which cryo-preserves product collected from apheresis: the process of dividing blood into its components of red and white blood cells, platelets and plasma.

Achieve Clinics enables a zero-cost option to patient to undergo “proactive apheresis” earlier in their disease, with these cells available for later in the treatment.

Finances and performance

Announced on October 21, the $5 million placement is by way of issuing just under 625 million shares to sophisticated and professional investors.

The raising was struck at 0.8 cents apiece, a steep 42.9% discount to the prevailing price on September 30 (just ahead of a trading halt).

Investors also receive unlisted options on a one-for-one basis, exercisable at 0.8 cents within 12 months of issue.

Chairman Hopper can’t be accused of being a non-believer, having put up his hand for $1 million of scrip.

The raising is in two tranches of approximately 69.9 million shares and 555 million shares The second tranche - including the issue of shares to Mr Hopper - is subject to shareholder approval at an extraordinary general meeting in December.

The funds will be used to support the proposed CDH-17 phase I/II trial

Late last year, the company raised $4.5 million in a rights issue at 2.8 cents per share.

In August last year, Chimeric pocketed a $US3 million ($4.4 million) introduction fee from ASX-listed immune oncology peer Imugene (also chaired by Mr Hopper and relating to the latter’s deal with Precision Biosciences)

Chimeric’s full-year results showed a $12.55 million loss, an improvement on the previous year’s $26.07 million deficit but a tad steep nonetheless.

Over the last 12 months Chimeric shares have ranged between a high of 4.0 cents in early January and mid-April this year, to their current record lows. The shares tumbled 21 percent on the day of the placement announcement and peaked at 35 cents in July 2021.

Dr Boreham's diagnosis:

Dr McQualter notes that the FDA has approved seven Car-T drugs for blood cancers, but none thus far for solid cancers.

"Blood cancer is the low-hanging fruit," she says.

"I wouldn't say [tackling blood cancers] is easy, but it is more obvious because it's circulating so you can go to battle there and then. Solid tumors create a [protective] micro-environment but we hope our next-generation Car-Ts will punch right through it."

While autologous Car-T cell therapies are expensive because of the handling involved, allogenic NK cells are like a bachelor's dinner in that they can be made in big batches economically and stored in a freezer.

"We are learning a lot from the Car-Ts and how we could make it allogeneic," Dr McQualter says. "But the patients are under enough stress as it is without introducing someone else's cells into their body."

A part-time chanteuse, Dr McQualter reckons the place will be singing again in no time - but the history of drug discovery shows there will be plenty of bum notes along the way.

Should the company progress to commercialization she is well armed, having been involved in two drug launches at Amgen Oncology.

"One went very well and one went very poorly, so I had some great lessons from both of them," Dr McQualter says.

"I'm glad I've done it twice and know what to expect."

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He learns from his failures - eventually