



# Biotech Daily

Friday February 12, 2021

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market fell 0.63 percent on Friday February 12, 2021, with the ASX200 down 43.4 points to 6,806.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell and nine traded unchanged.

Starpharma was the best, up 32 cents or 15.7 percent to \$2.36, with 4.2 million shares traded. Both Antisense and Impedimed improved 7.1 percent; Cynata and Dimerix climbed more than five percent; Optiscan was up four percent; Alterity and Neuren rose more than two percent; Telix and Volpara were up more than one percent; with Cochlear, CSL, Nanosonics, Next Science and Proteomics up by less than one percent.

Avita led the falls, down 78 cents or 11.1 percent to \$6.23, with 1.7 million shares traded. Actinogen, Oncosil and Resonance fell more than four percent; Compumedics, Immutep and Orthocell shed more than two percent; Amplia, Clinuvel, Cyclopharm, Kazia, Paradigm and Universal Biosensors were down one percent or more; with Medical Developments, Mesoblast, Opthea, Polynovo, Pro Medicus and Resmed down by less than one percent.

## DR BOREHAM'S CRUCIBLE: CHIMERIC THERAPEUTICS

**By TIM BOREHAM**

**ASX code:** CHM

**Market cap:** \$95.9 million

**Share price:** 29 cents

**Shares on issue:** 330,526,401

**Executive chairman:** Paul Hopper

**Board:** Mr Hopper, Leslie Chong, Dr Lesley Russell, Cindy Elkins

**Financials (February 2, 2020 to June 30, 2020\*):** revenue nil, operating expenses \$64,000, cash on hand \$38.5 million\*\*

\* Latest available figures

\*\* Post listing

**Identifiable major holders:** Paul Hopper 24.9%, Accbell Nominees 3.6%, City of Hope 3.5%, Dr Christine Brown 3.48%, Dr Michael Barish 3.48%

'Deathstalker Scorpion' sounds like a title for a boy's own war movie adapted from an Alistair Maclean novel, rather than a potential immune therapy-based cancer treatment.

We're talking about a real arachnid, *Leiurus quinquestriatus*, which secretes chlorotoxins that bind to unique targets in the body.

The recently listed Chimeric is right onto the therapeutic potential, having launched a clinical program to treat glioblastoma (brain cancer) with a peptide derived from the venom.

As they say in the Special Air Services: who dares wins ... and what doesn't kill you makes you stronger.

At around \$9,000 per gram, this toxin is one of the most expensive substances on the planet. But for Chimeric's purposes, the toxin - which has been used for years as an imaging agent - is synthesized.

"A poor sod doesn't have to go out to the desert and milk scorpions," says Chimeric's executive chair Paul Hopper.

## **About Chimeric**

Pronounced 'ky-meric', Chimeric is an exponent of emerging CAR-T therapies, which involve jiggling about with the body's T-cells to whomp tumors.

Chimeric shares soared on their January 18 ASX debut, which partly reflects the popularity of this emerging field.

The other reason is the Hopper Factor. One of Aussie biotech's foremost entrepreneurs, Mr Hopper has founded - or been involved in - no fewer than 14 drug companies, mainly in oncology (see below).

Chimeric is based on its CLTX CAR-T technology, acquired from the City of Hope Hospital in Los Angeles.

CLTX refers to chlorotoxin, while CAR-T is short for chimeric antigen receptor T-Cell (and not a T-model Ford).

Mr Hopper says he tried to winkle the technology from City of Hope six years ago, but was outbid by another pesky company.

In the end, his close links with the institution's research scientists paid off and its technology transfer office agreed to hive off the assets.

So far, the US Food and Drug Administration has approved three CAR-T drugs for blood cancers (leukaemia and lymphoma): Kymriah, Tecartus and Yescarta.

So far, there's nothing for solid cancers, but with no fewer than 50 glioblastoma or glioma trials underway.

Chimeric claims to be the only exponent incorporating a peptide toxin into a CAR-T cell therapy and entering human clinical trials.

The CLTX peptide also shows promise as a radiotherapy delivery conjugate and imaging agent in fluorescent-guided surgery.

## **Wheels within wheels**

Chimeric's underlying intellectual property was devised by City of Hope researchers Prof Christine Brown and Dr Michael Barish.

The former chairs Chimeric's scientific advisory board.

There's an interesting nexus with fellow ASX-listed immuno-oncology play Imugene which Mr Hopper founded: Imugene chief Leslie Chong is one of Chimeric's three directors.

Chimeric's talent pool is rounded out by chief operating officer Jennifer Chow, who held senior marketing and commercial roles at US CAR-T specialist Kite Pharmaceuticals.

Chief medical officer Dr Syed Rizvi was an executive at the Nasdaq-listed Legend Biotech.

Mr Hopper said it was “extraordinarily lucky” that this talent was available.

“They are the crème de la crème of the CAR-T space. It’s a high-powered team for a little Aussie biotech.”

In early February the company then announced that a former Juno Pharmaceuticals heavyweight, Cindy Elkins would join the board.

### **A cancer treatment with bite**

CAR-T treatments involve taking T-cells from a patient and ‘reprogramming’ them.

“T-cells are one of the main soldiers of the immune system,” Mr Hopper says. “If they see anything nasty, they clean it up and get rid of it.

“Unfortunately, they don’t always work when they see cancer.”

Formally known as a 36 amino acid peptide, the scorpion toxin recognizes a cancer marker called membrane-bound matrix metalloprotease-2 (MMP2).

Like a guided missile, the payload seeks the MMP2 target as the ‘bull’s eye’ and targets it on a search-and-destroy mission.

The ‘civilians’ - the healthy cells - are unharmed.

### **(City of) Hope for successful trial**

Aside from the unmet medical need, Mr Hopper says Chimeric chose glioblastoma because of “pretty stunning” pre-clinical in-vitro and in-vivo data.

A phase I trial is unfolding at the City of Hope.

The trial guardians have started recruiting the first of 18 patients in the open-label, dose-escalation trial, which is expected to go for 18 to 24 months.

First data is expected by December this year.

Strictly speaking, it’s just a safety trial but as Mr Hopper notes: “Anyone who runs a phase I study has a look to see if the drug is sending a signal.”

Should the trail be deemed a success, the company will move to a 50 to 75 patient trial, which could be pivotal for the drug and the company.

## **Hopper to it**

The Chimeric play is consistent with Mr Hopper's modus operandi of gathering backers to obtain intellectual property through tight networks, then hiving off the entity he holds to an already listed or newly-listed company for a tidy sum.

"I have never had a lot of trouble raising money," he says.

While he's the maestro of conjuring-up the cash, Mr Hopper is also hands-on, generally staying on as a director and sometimes as CEO or executive chair. The endgame is to sell the assets well before a drug is approved (or not, as may well be the case).

Mr Hopper has founded - or seeded the technology into - ASX-listed biotechs including Patrys, Kazia (formerly Novogen) and Prescient Therapeutics. He kicked-off melanoma outfit Polynoma LLC, acquired by the Hong Kong based CK Life Sciences, as well as Glioblast (acquired by Novogen).

He founded Bioscience Oncology, which was based on tech from the City of Hope. Scopus Biopharma bought the company in June last year and listed on the Nasdaq in December.

Mr Hopper is executive chair of Imugene, having vended in a mob called Vaxinia which acquired a chimeric pox virus patent from ... drum roll ... the City of Hope.

And do we need to mention that he chaired immuno-oncology play Viralytics, famously sold to Merck for \$504 million in 2017?

While Mr Hopper delves mainly into cancer therapeutics, he is also chair of Suda Pharmaceuticals, which is reformulating drugs into oral sprays, but last year failed to back-door a cancer technology into the company.

Is that enough? No, actually: he is executive chair of the US private company C19 Therapeutics - as in Covid-19 - a non-vaccine play based on tech from the Virginia Commonwealth University.

The scary thing is this list of Mr Hopper's past and present interests is not exhaustive.

## **Finances and performance**

Chimeric sought - and banked - \$35 million in its initial public offer, but returned the cheques to investors, who a further seeking another \$60 million.

Given the unrequited demand, we shouldn't be surprised the 20 cents shares spurted as high as 41 cents. With the usual stags taking first-day profits, the stock has retreated, but there's still a 50 percent gain on the table.

With a 25 percent stake worth \$25 million, Mr Hopper is by far the biggest shareholder and has this one tied up like pussy's bow.

But looking over his shoulder are heavyweight shareholders including IFM Investors, Thorney Investments, Regal Funds Management and Andrew Banks (co-founder of recruiter Morgan & Banks but better known as an investor on the Shark Tank reality TV show).

### **Dr Boreham's diagnosis:**

Chimeric is girded by the reality that fewer than five percent of glioblastoma patients survive for more than five years.

(US political wonks will know that the condition killed Joe Biden's son Beau, one-time Republican candidate John McCain and McCain's old adversary Edward Kennedy).

Mr Hopper says the company will know pretty quickly whether the drug works, because it is going into glioblastoma patients who have already had cancers cut-out (only for them to recur).

"They are not in great shape and when they recur, glioblastoma is pretty aggressive," he says. "We have a lot of [development] options because there's not a lot out there."

Mr Hopper says Chimeric has "all sorts of ideas" about wider clinical trials to show the milk of the scorpion's wider applications.

"We will do studies with other cancers," he says. "We haven't determined the indications but they may be melanoma or lung."

If the Hopper Playbook is dutifully adhered to, expect the company (or the technology) to be sold well before it needs to stump up big dollars for phase III trials.

Chimeric's prospectus includes a report from Acuity Technology Management, which opines a CAR-T developer at Chimeric's stage of progress should be worth \$US80 million (\$AUD130 million) to "well in excess of \$US1 billion".

CAR-T related mega-deals include the aforementioned Kite being acquired by Gilead for \$US11 billion and Legend's mid-2020 Nasdaq-listing following a \$US450 million raising that could have easily garnered \$US1 billion.

Meanwhile Mr Hopper keeps on top of his capacious portfolio by working 12 hours days and half the weekend, usually from his regional New South Wales property.

But it's not all about dollars and the next deal.

"I don't really see it as work," he says. "I work with some of the most brilliant people on earth, it's inspirational. They are looking into the origins of life and curing cancer."

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He always thought the most expensive substance on the planet was contained in inkjet printer cartridges.***

## GLAXOSMITHKLINE

Glaxosmithkline says it will provide \$6.9 million to fund more than 14 Australian research teams investigating respiratory medicine, vaccines and oncology.

Glaxosmithkline said the funding would be available under its 2020-'21 investigator-sponsored studies program.

The company said the program partnered with researchers from nine institutions including the Gold Coast, Queensland-based Griffith University, the University of Melbourne, the University of Newcastle and Sydney's Woolcock Institute of Medical Research.

Glaxosmithkline medical director Dr Andrew Weekes said that "the program funds researcher-initiated studies that have the potential to impact medical science and address unmet patient needs, especially in areas like respiratory diseases".

"Australian academic research in respiratory disease has repeatedly challenged global thinking at the level of the cell, the person and the community ... [which has] led to better diagnostic tools, more management paradigms and therapeutics," Dr Weekes said.

"Australian researchers competed globally for the program funding and ultimately represented eight percent of the funded respiratory projects," Dr Weekes said.

## CSL

CSL says it will begin the final stages of manufacturing for the Astrazeneca vaccine "next week" with the first vaccine doses scheduled for release by April 2021.

CSL said the release of the vaccines to prevent severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) was subject to Therapeutics Goods Administration approval. Last year, the Federal Government said it would provide \$1.7 billion to CSL to supply 84.5 million vaccine doses, including 33.5 million doses of the University of Oxford and Astrazeneca AZD1222 candidate (BD: Sep 7, Oct 8, 2020).

Today, CSL said the first stages of manufacturing had been underway at its Broadmeadows, Melbourne facility, with the final stages to be undertaken at its subsidiary Seqirus's facility in Parkville, Melbourne, which would "continue to run 24 hours a day, seven days a week, with expected release of two million doses at the end of March, and then one million doses per week thereafter".

CSL chief scientific officer Dr Andrew Nash said that the manufacturing "milestone would not have happened without around-the-clock work from our skilled team across both CSL Behring and Seqirus, with ongoing support from Astrazeneca".

The company said that Astrazeneca would manage the TGA application for registration on the Australian Register of Therapeutic Goods and the Federal Government would be responsible for all rollout and implementation in Australia.

CSL was up six cents or 0.02 percent to \$276.76 with 472,622 shares traded.

## IMUGENE

Imugene says it has begun dosing the second cohort in its 32-patient, phase I, dose-escalation trial of PD1-Vaxx for non-small cell lung cancer.

Last month, Imugene said it would proceed from the low dose of 10 micrograms in its first cohort to the mid-dose of 50mcg in its second cohort, after the cohort review committee unanimously agreed that PD1-Vaxx was "safe with no dose-limiting toxicities and no serious adverse reactions observed" (BD: Jan 21, 2021).

Today, the company said the first patient received the 50mcg dose of PD1-Vaxx at the Hackensack University Medical Centre in New Jersey.

Imugene was unchanged at 10 cents with 15.8 million shares traded.

## AVITA MEDICAL

Avita says revenue for the six months to December 31, 2020 was up 56.1 percent to \$US10,163,000 (\$A13,132,180) with net loss after tax up 11.5 percent to \$US15,868,000 (\$A20,503,930).

Avita said revenue from sales of its Recell system for the treatment of burns was up 66.8 percent to \$US8,413,000 and other revenue included funding from the US Biomedical Research and Development Authority (BARDA) which was down 57.1 percent to \$US1,045,000 compared to the previous corresponding period.

Avita said its diluted loss per share rose 1.4 percent to 74 US cents and it had cash and cash equivalents of \$US59,765,000 at December 31, 2020 compared to \$A124,658,000 (\$US96,455,000) at December 31, 2019.

Avita fell 78 cents or 11.1 percent to \$6.23 with 1.7 million shares traded.

## STARPHARMA

Starpharma says it had an agreement with Merck & Co Inc for a preclinical research evaluation of its dendrimer enhanced product (DEP) for antibody drug conjugates.

Starpharma said the New Jersey-based Merck & Co traded as Merck Sharp & Dohme (MSD) outside the US and the agreement would use Starpharma's DEP technology to provide enhanced characteristics to antibody drug conjugates including greater homogeneity, site specific attachment, and increased antibody ratios.

Starpharma was up 32 cents or 15.7 percent to \$2.36 with 4.2 million shares traded.

## RECCE PHARMACEUTICALS

Recce says R327 synthetic anti-infective has shown a 99.9 percent reduction of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), in-vitro.

In July, Recce said the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and Melbourne's Doherty Institute had accepted its R327 for a Sars-Cov-2 screening program (BD: Jul 8, 20, 2020).

The company said at that time both R327 and R529 were delivered to the Doherty "fee for service SarsCov-2 antiviral screening program" but only Recce-327 had been accepted. Today, the company said that tests by the CSIRO and Doherty showed that R327 reduced Sars-Cov-2 viral genome numbers at 4,000 parts per million (ppm) and the virus was "no longer detectable by viral titration".

Recce said a reverse transcription-polymerase chain reaction, a sensitive technique for viral detection and quantitation used in Covid-19 test swabs, detected a drop in viral genome copies of 99.9 percent.

The company said minimal toxicity was observed at 4,000ppm of R327 with no cytotoxicity at or below 1,333ppm and it would conduct further testing to decide whether to continue with R327 as Sars-Cov-2 inhibitor.

Recce was up nine cents or 8.7 percent to \$1.12 with 1.7 million shares traded.

## BOTANIX PHARMACEUTICALS

Botanix says it has received \$6,876,853 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Botanix said the rebate related to research and development expenditure for the year to June 30, 2020.

Botanix fell half a cent or 3.45 percent to 14 cents with 6.5 million shares traded.



### LIVING CELL TECHNOLOGIES

Living Cell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 38.9 percent from a low of 1.8 cents to a high of 2.5 cents today and noted a "significant increase" in the trading volume from February 10 to 11, 2021.

Living Cell said it was "engaged in confidential discussions with two unrelated parties" to discuss the possibility of a merger of the company with another compatible business in the biotechnology field".

The company said the talks were preliminary with no deal terms agreed and there was no certainty that it would reach any agreement with either party.

Living Cell fell 0.3 cents or 12.5 percent to 2.1 cents with eight million shares traded.

### TALI DIGITAL

Tali had requested a trading halt "pending an announcement regarding a proposed capital raising".

Trading will resume on February 16, 2021 or on an earlier announcement.

Tali last traded at 4.2 cents.

### INCANNEX

Incannex has requested a trading halt in relation to "the launch of a fifth research program following further pre-clinical results from IHL-675A".

Incannex has previously said that IHL-675A is a combination of cannabidiol (CBD) and hydroxychloroquine.

Trading will resume on February 16, 2021 or on an earlier announcement.

Incannex last traded at 22 cents.

### AUSCANN

Auscann says it has bought back 7,964,285 shares at 18 cents a share in unmarketable parcels worth \$500 or less, held by 7,748 investors.

Last year, Auscann said it had a buy-back facility for holders of unmarketable parcels of shares worth less than \$500, based on 15.0 cents a share (BD: Jul 17, 2020).

Today, the company said the buy-back had been suspended and delayed in relation to its acquisition of Cannpal Animal Therapeutics (BD: Nov 16, 2020).

Auscann said Euroz Hartleys Securities managed the sale of the bought-back shares.

The company said that following the buy-back, it had 15,977 remaining shareholders, reduced from 23,079 shareholders.

Auscann fell one cent or 5.4 percent to 17.5 cents with 4.3 million shares traded.

### KAZIA THERAPEUTICS

Platinum Investment Management says it has reduced its substantial shareholding Kazia from 9,878,438 shares (7.83%) to 8,532,217 shares (6.76%).

The Sydney-based Platinum said it sold shares between November 19, 2020 and February 10, 2021 with the single largest sale 404,053 shares for \$700,830 or \$1.73 a share on November 19, 2020.

Kazia fell two cents or 1.6 percent to \$1.26.

## ORTHOCELL

Orthocell chief scientific officer Prof Ming Hao Zheng and Ying Fan say they have ceased their substantial shareholding in the company.

In the substantial shareholder notice filed after the close of market on February 11, 2021, Prof Zheng said his substantial holding ceased on December 11, 2019 following Orthocell's \$13 million placement at 50 cents a share (BD: Dec 4, 2019).

Prof Zheng said that between July 11 and September 10, 2019 he acquired shares in lieu of fees at prices ranging from 41.5 cents to 48.2 cents a share and held 7,853,337 shares. Biotech Daily calculates that Prof Zheng and Ying Fan hold 4.16 percent of Orthocell. Orthocell fell 1.5 cents or 2.6 percent to 56 cents.

## ACTINOGEN MEDICAL

The San Francisco-based BVF Partners LP says its 239,927,273 shares in Actinogen have been diluted from 17.27 percent to 14.88 percent.

Yesterday, Actinogen said it had raised about \$3.55 million in a shortfall placement at 2.2 cents a share, taking the total raised to \$10.91 million (BD: Feb 11, 2020).

Actinogen fell 0.1 cents or 4.55 percent to 2.1 cents with 12.6 million shares traded.

## COCHLEAR

Cochlear says that acting chief financial officer Stu Sayers has been appointed as its chief financial officer.

Last year, Cochlear says it had appointed Mr Sayers as acting chief financial officer to replace Brent Cubis with a permanent chief financial officer expected to be appointed by June 30, 2021 (BD: Jul 13, Dec 15, 2020).

Today, the company said Mr Sayers joined the company as an executive in 2016, previously held senior roles with the ANZ bank and McKinsey Consultancy.

Cochlear said that Mr Sayers held a Bachelor of Economics from the University of Sydney and a Master of Business Administration from the Wharton Business School of the University of Pennsylvania in Philadelphia.

Cochlear was up \$1.05 or 0.5 percent to \$206.41 with 59,608 shares traded.

## BIOINTELECT

Biointelect says it has hired Mark Glover, Crissa Kyriazis, Lena Miloradovic and Dr Jack Lamshead as managers and consultants to improve strategy and commercialization. Biointelect said Mr Glover was appointed general manager and had 30 years' experience in the healthcare industry, with Serono Oceania, Allergan and Inova.

The company said Ms Kyriazis had been appointed commercial project manager and had more than 20 years' experience in healthcare organizations.

Biointelect said Ms Miloradovic joined the company as a project management consultant and was previously head of project management at CSL's Seqirus.

The company said Dr Lamshead was appointed as a senior associate with expertise in regenerative medicine, had previously worked in clinical research ethics at Melbourne's St Vincent's Hospital and held a Doctor of Philosophy from Melbourne's Monash University. Biointelect is a private company.