Biotech Daily

Thursday October 31, 2024

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.25 percent on Thursday October 31, 2024, with the ASX200 down 20.4 points to 8,160.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Starpharma was the best, up 0.5 cents or 5.6 percent to 9.4 cents, with 2.8 million shares traded. Compumedics, Genetic Signatures and Paradigm climbed five percent or more; 4D Medical, Alcidion, Aroa and Avita were up more than three percent; Proteomics rose 2.1 percent; Impedimed was up 1.85 percent; with Neuren up by 0.6 percent.

Medadvisor led the falls, down 11.5 cents or 32.9 percent to 23.5 cents, with 23.8 million shares traded. Curvebeam lost 14.55 percent; Resonance shed 11.1 percent; Imugene and Prescient were down more than eight percent; Micro-X fell 7.35 percent; Cyclopharm slipped 6.6 percent; both Actinogen and Universal Biosensors fell four percent; Cynata, Emvision and Nova Eye shed two percent or more; Clinuvel, Dimerix, Mesoblast, Pro Medicus and Resmed were down more than one percent; with Clarity, Cochlear, CSL, Nanosonics, Opthea, SDI and Telix down by less than one percent.

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 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, pending 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 will issue about 625 million shares to investors to support the proposed CDH-17 phase I/II trial.

At 0.8 cents a share the raising is a steep 42.9 percent discount to the prevailing price on September 30 (just ahead of a trading halt). Investors also receive unlisted one options for each share, exercisable at 0.8 cents within 12 months.

Mr Hopper has put up his hand for $1 million of scrip.

The placement's second tranche - including the issue of shares to Mr Hopper - is subject to shareholder approval at an extraordinary general meeting in December.

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

AUSBIOTECH, COCHLEAR, CSL

By Jamie Miller

Cochlear chief executive officer Dig Howitt and CSL chief financial officer Joy Linton say there are not enough incentives to keep commercialization in Australia.

The second day of the Ausbiotech 2024 conference included a panel discussion with Mr Howitt and Ms Linton led by Ausbiotech chief executive officer Rebekah Cassidy that discussed supporting "commercialized research, enhanced manufacturing capability and new partnerships".

In the session, titled 'Developing and commercializing companies onshore – executive perspectives from Australia's long-standing anchors' Ms Linton said programs like the Federal Government's Research and Development Tax Incentive were "traditionally very strong" but asked how it translated "into commercial success?".

"The reality is, incentives in [Australia] are not that attractive relative to other places," Ms Linton said.

Mr Howitt agreed, saying that beyond research and development there were "no incentives to continue to manufacture and commercialize in Australia".

"Other countries, I think, are doing a better job of … thinking about what other policies and incentives and regulatory environment will encourage companies [to commercialize there]," Mr Howitt said.

Mr Howitt said that prior to the Covid-19 pandemic both Cochlear and CSL had advocated for a patent box.

"It's well known that Australia has one of the highest corporate tax rates in the world … [and] a patent box is a targeted way of lowering corporate tax for companies that do [research and development] and commercialize in a country," Mr Howitt said.

The two executives argued for an "inter-company transfer visa" to bring talent back to Australia.

"Other countries have it, why don't we?" asked Mr Howitt.

Ms Linton said it was "much easier to have an Australia go and work in another part of the world, than it is to have our skills in Germany, Switzerland or the US come and work in Australia," Ms Linton said.

"We would argue that is to the detriment of Australia," Ms Linton said.

Mr Howitt said that complicated healthcare therapies "rely on global knowledge, global research and development [and] global supply chains".

Ms Linton agreed, said "the [Covid-19] pandemic was terrible for Australia, because it isolated us from the world in a way that I'm still not sure we've fully recovered from".

"We have to stay outward-focused, we have to know what's going on [in the rest of the world] and staying connected," Ms Linton said.

Mr Howitt said it wasn't all negative and "there's good reason for us to have high ambitions".

"We have an excellent education [system] … we've got access to capital … we just need to not over-regulate, [and] we need to stay globally competitive and outward looking," Ms Linton concluded.

Ausbiotech said it conducted its Agribiotech and Biosecurity summit throughout the day, with various sessions on the role of biotechnology in agriculture as well as an innovation showcase.

The organization said it would hold its annual general meeting, and other sessions in the afternoon including presentations on antibody-drug conjugates, Australia's role in early clinical trials, investing in early-stage university spin-outs and artificial intelligence.

The Ausbiotech 2024 Conference closes tomorrow.

AUSBIOTECH

By Jamie Miller

Ausbiotech says an increase in female leadership could “harness diverse perspectives that drive innovation and enhance problem-solving capabilities”.
A panel discussion, titled ‘The lack of female leadership in Australian biotech: how do we change the tide?’ said there was evidence that companies with a more diverse board performed better than companies without.
Panelists included Cell Therapies director Michelle Burke, Medicines Australia chair and former Ausbiotech chief executive officer Dr Anna Lavelle, Australian National Digital Health Initiative (AND Health) managing-director Bronwyn Le Grice, Chimeric chief operating officer Dr Rebecca McQualter and Omnigon Care Solutions chief executive officer Gavin Fox-Smith.
Ms Burke said her research showed that 30 percent of private companies had female chief executive officers, but that the majority were contract services businesses or member-based organizations with no boards.
Ms Burke said about a third of private and public unlisted boards had no female non-executive directors, with a third including one female director and the remaining companies having two or more directors who were women.
Ms Burke said that she estimated between 11 percent and 16 percent of all Australian biotechnology companies had a chief executive officer who was a woman.
Ms Burke said there were “very experienced women, not necessarily in the public listed space, but it is still there … [and] we just need to work a bit harder to make sure we have that balanced slate”.
AND Health’s Ms Le Grice said there were “so many qualified women who may not have a particular title … who are very, very well versed, and probably far more capable … to step in and take control … and really make some really great decisions to push the company to the next level”.
Mr Fox-Smith said that “50 percent of the population are women, slightly more in Australia” and that among board directors, “big and small … is getting a diverse group outside of the core group that seems to give directorships to each other”.
Chimeric’s Ms McQualter said biotechnology was “an evidence-based industry”, and while products needed to have evidence “our board and management do not”.

ORTHOCELL

Orthocell says it has raised $17 million at 60 cents a share in its non-underwritten placement to fund the US commercialization of Remplir nerve repair product.
Last week, Orthocell said that it had “firm commitments” to raise $17 million in a non-underwritten institutional placement at 60 cents a share (BD: Oct 25, 2024).
Today, the company said the placement “received very strong support from existing and new leading Australian and international institutional investors, high net worths and family offices”.
Orthocell said its chair John Van Der Wielen had subscribed for $100,000, subject to shareholder approval.
The company said that it had about $35 million in cash and no debt.
Orthocell said that funds would be used for the “further scale-up of manufacturing infrastructure; automation projects to enhance manufacturing cost efficiency; sales force and marketing resources to oversee distribution; and working capital.
Orthocell was unchanged at 62 cents with 1.3 million shares traded.

RENERVE

Renerve says it hopes to raise up-to $7 million at 20 cents a share to list on the ASX under the code RNV to commercialize its collagen-based peripheral nerve repair products.
Renerve said it hoped to raise a minimum of $5 million and up to $7 million in the non-underwritten initial public offer, would have an indicative market capitalization of up-to $28.4 million and hoped to begin trading on the ASX on November 22, 2024.
The company said it had four products for use in peripheral nerve repair post-surgery, including its US Food and Drug Administration-approved, resorbable, pliable, semi-permeable Nervalign Nerve Cuff for nerve repairs and nerve grafts.
According to its website, Renerve's products were "developed using 'Ecoo' technology, a non-toxic solvent production method … ensuring the products are terminally sterilized with no residual chemicals".
The website said the 'Ecoo' technology maintained natural cross-linking of extra-cellular matrix, promoted cell attachment, resulted in low immunogenic risk and allowed for deep micro-structural penetration.
Renerve said it was established by a neurosurgeon working with researchers and the Commonwealth Scientific and Industrial Research Organisation's polymer science group.
The company said that Nervalign Nerve Cuff received FDA-approval in July 2022 and was launched in October 2022.
Renerve said it was developing three other products including a Nervalign nerve conduit for repairing injured peripheral nerves, a nerve guide matrix as an alternative to donor nerves and a bionic nerve to repair "long nerve gaps".
Renerve said the funds would be used for studies of its Nervalign nerve conduit, post-market study for its approved nerve cuff product other programs and working capital.
The company said its chair was former Avexa (now Tali Digital) chair Stephen Cooper and its managing-director was former Avexa chief executive officer Dr Julian Chick.
Renerve said director Dr Michael Panaccio was a former Impedimed and Dorsavi director, with former Admedus, Adalta and Avexa chief scientist Dr David Rhodes an executive director and chief scientific officer and David Lilja as chief financial officer and company secretary; Alpine Capital was the lead manager to the offer and the prospectus was at: https://renerve.com.au/wp-content/uploads/2024/10/ReNerve-Prospectus-2024.pdf.

TELIX PHARMACEUTICALS

Telix says with Subtle Medical Inc it will use artificial intelligence (A.I.) to improve its positron emission tomography (PET) imaging with Illuccix for prostate cancer.
In an email to investors, not published on the ASX, Telix said that San Fransico's Subtle PET product was a US Food and Drug Administration-cleared artificial intelligence algorithm that improved the efficiency of imaging by reducing the imaging time.
The company said Subtle Medical's software allowed "for faster PET scanning, with up-to 75 precent time savings without compromising image quality".
Telix did not disclose the commercial terms of the agreement.
The company said the partnership covered North America and the EU, excluding France and Belgium, would be launched in the US with Illuccix for imaging prostate cancer, and aimed to expand to other Telix PET-tracers, subject to regulatory approval.
Telix Precision chief executive officer Kevin Richardson said the company believed "that the combination of Illuccix and Subtle PET will further strengthen Telix's A.I. toolkit and also Illuccix's reputation as the best-in-class [prostate specific membrane antigen]-PET imaging agent for accuracy, reliability, quality, and operational excellence in the US".
Telix fell 17 cents or 0.8 percent to $20.93 with 1.0 million shares traded.

FIREBRICK PHARMA

Firebrick says it will pay Innorini Pte Ltd $6,900 a month to market and sell its anti-microbial Nasodine nasal spray in Singapore from November 1, 2024.
Earlier this year, Firebrick said it had Singapore's Health Sciences Authority approval to market its antiseptic Nasodine nasal spray for "'nasal hygiene' without any therapeutic claims", which would sell for about $28 per 25ml bottle (BD: Jun 13, 2024).
At that time, the company said Nasodine was "classified as a topical antiseptic and does not require approval or licencing by Singapore's Health Sciences Authority before sale" but it did need prior approval to advertise the product to Singapore consumers.
Today, Firebrick said Innorini would sample and promote Nasodine to general practitioners and hospital-based doctors and pharmacists in Singapore, as well as selling Nasodine to patients at clinics and hospitals.
The company said it would be paid about $12.50 from Innorini for each product sold and would provide the promotional materials and samples to the distributor "at no cost".
Firebrick said there was no commitment for any minimum quantity and the contract had an initial term of one year with an option to renew for subsequent one-year terms.
Firebrick fell 0.1 cents or 1.75 percent to 5.6 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has filed the revised protocol for its phase III trial of polysulfate sodium for osteo-arthritis to the US Food and Drug Administration.
Last month, Paradigm said the FDA had provided a "clear pathway" for a phase III trial of its polysulfate sodium treatment for osteo-arthritis (BD: Sep 18, 2024).
Today, the company said the FDA's 30-day review began yesterday, and it expected the review to allow pre-screening and enrolment of the trial "to commence shortly afterward".
Paradigm executive chair Paul Rennie said the submission and acceptance of the phase III protocol by the FDA was "a critical milestone for Paradigm, bringing us one step closer to delivering a meaningful treatment for knee osteo-arthritis".
Paradigm was up one cent or five percent to 21 cents with 6.6 million shares traded.

EMYRIA

Emyria says it has licenced University of Western Australia serotonin-releasing agents for the potential treatment of mental health disorders and neurological diseases.
Emyria said the compounds, called MX-100 and MX-200 were "inspired" by 3,4-methylene-dioxy-meth-amphetatime (MDMA, or 'ecstasy') and were being prepared for advanced screening targeting post-traumatic stress disorder and Parkinson's disease.
The company said it signed an exclusive worldwide licence for the compounds, which were developed through its research partnership with the University of Western Australia.
In 2021, Emyria said it would work with the University of Western Australia on MDMA compounds for neurological disorders and pay the University a minimum of $491,000 over 12 months to work on the MDMA-like compounds or analogues (BD: Aug 5, 2021).
Today, the company said initial studies showed that the half-life of the compounds could be reduced "allowing shorter therapeutic windows suited to psychotherapy", with a longer half-life required extended therapy sessions, increasing costs and complexity of delivery.
The company said a $499,411 grant from the Western Australia Government would "fast-track pre-clinical testing of both compounds with key results expected by early 2025".
Emyria was up 0.1 cents or 3.3 percent to 3.1 cents.

OPYL

Opyl says its annual general meeting will vote to change its name to ‘Trialkey Limited’, with its ASX ticker code to become ‘TRK’.

Opyl did not give a reason for the change of company name.

The company said it would issue director and interim chief executive officer Saurabh Jain 12,000,000 shares and 6,000,000 options and executive director Damon Rasheed 9,000,000 shares and 4,000,000 options, in lieu of their total fixed remuneration.

Opyl said it would issue director Antanas Guoga 1,125,000 shares in lieu of his previous six months of salary, as well as 4,108,000 shares, 800,000 attaching options and 2,054,000 free attaching options as repayment for a short-term loan.

The company said the meeting would adopt the remuneration report, elect Mr Jain as a director, approve the 10 percent placement capacity, approve the issue of securities to Hartness Consulting, Hammond Consulting, Irwin Biotech Nominees, Rip Opportunities and Copeak as well as renew the employee incentive plan.

The meeting will be held at 6 Middlemiss Street, Milson’s Point, Sydney, on November 29, 2024 at 10am (AEDT).

Opyl fell 0.1 cents or 5.9 percent to 1.6 cents.